Polyclinic

ACCREDITATION STANDARDS MANUAL

Version 1.0, Effective January 1, 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.

STANDARDS 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 alphanumerical 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.

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SECTION 1: BASIC MANDATES

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Anesthesia Options		
1-A-1	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.	Verify the facility operates within its accredited anesthesia class (A, B, C-M (international only) or C). (See Anesthesia Class Definitions & Requirements) **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.
1-A-2	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.	**Please see the Anesthesia Class Definitions & Requirements document for Interpretive Guidance and References**
Sub-section B: Basic Mandates		
1-B-3	The facility has defined a mission statement that reflects the population it serves and the services it provides.	Verify the facility's mission statement clearly defines what it wants to achieve at the highest level for its patients/service users. **Evaluating Compliance**: Review the facility's mission statement Interview leadership and staff regarding its implementation.
1-B-4	The facility has provided a set of organizational values which guide daily operations, are familiar to all staff, and are available to the public.	Verify the facility's values clearly define how the facility provides its services. **Evaluating Compliance:** Review the facility's values Interview leadership and staff regarding its implementation.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
1-B-5	The facility must inform the public of the services.	Verify the facility has clearly communicated its available services to the public. **Evaluating Compliance**: Review public notices (e.g., website, brochures) to ensure they are consistent with services provided.
1-B-6	The facility must ensure that no marketing and advertising regarding the competence and capabilities of the organization is misleading or implies that it provides care or services that it is not capable of providing.	Verify the organization's marketing materials truthfully represent its service capabilities and competencies. **Evaluating Compliance**: Review documents with marketing/advertising content with facility leadership Confirm whether representations align with actual services and capabilities.
1-B-7	Only recognized abbreviations are allowed to be used in the clinical record.	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. **Evaluating Compliance**: 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	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: 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.	Verify the facility performs annual self-surveys, documents non-compliance, and takes corrective actions to maintain compliance with QUAD A standards. **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.
1-B-9	The facility must make its final survey results publicly available.	Verify that the facility's final survey results are accessible to the public. **Evaluating Compliance**: Confirm the method(s) of public disclosure (e.g., posted on website, certificate displayed in facility).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section C: Patient Selection		
1-C-1	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.	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. **Evaluating Compliance:** Review policies for: 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 Interview staff about scheduling protocols and incidence of routine hospital transfer Review clinical records for compliance with facility policy.
1-C-2	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 facility consistent with federal/national, state/provincial, and local regulations, if applicable.	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. **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.
1-C-3	The process for entry or admission to the facility for a procedure must be coordinated and defined in a policy.	Verify the facility has an approved patient admission and registration processes to coordinate care delivery. **Evaluating Compliance:** Review policies for defined procedures to admit the patient to services and care coordination mechanisms Review documents for consistency with policies Interview staff about process implementation and the understanding of registration workflow Observe processes in practice (when possible).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
1-C-4	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.	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 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. **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.
Sub-section D: Patients' Rights		
1-D-1	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.	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. **Evaluating Compliance:** Confirm the Bill or Rights document(s) are publicly displayed or provided to the patient (or responsible adult) in writing upon admission.
1-D-18	The patient has a right to personal privacy.	Verify that the underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, dressing), during procedures/surgeries, and when requested as appropriate. People not involved in the care of the patient should not be present without the patient's consent while the patient is being examined or treated. Video or other electronic monitoring or recording methods should not be used when the patient is being examined without the patient's consent. If a patient requires assistance during toileting and other personal hygiene activities, staff should assist, giving the utmost attention to the patient's need for privacy.

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		Privacy should also be afforded when staff visit the patient to discuss clinical care issues or conduct any examination. A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when there is an emergency and transfer to a hospital is pending. **Evaluating Compliance:** Observe: How staff provide patient privacy What safeguards are in place to protect patient privacy (e.g., privacy curtains, secured workstations, patient identifiers on white board, etc.) Interview staff on: How they provide patient privacy What staff education is provided on patient privacy
1-D-19	The patient has a right to receive care in a safe setting.	Verify that each patient is receiving care in an environment that a reasonable person would consider to be safe. The facility staff should follow current standards of practice for patient environmental safety, infection control, and security. The facility staff should also provide protection for the patient's emotional health and safety, such as respect, dignity, and comfort, as well as the patient's physical safety. **Evaluating Compliance:** Review PSDR submissions to identify any incident patterns concerning a safe environment Review infection control and QAPI documentation to determine if the facility is identifying problems, evaluating them, and taking steps to ensure a safe environment. Observe the environment Interview staff and patients to see if there are any concerns about safety.
1-D-20	The patient has a right to be free from all forms of abuse or harassment.	Verify the facility is prohibiting all forms of abuse, neglect (as a form of abuse), and harassment from staff, other patients, or visitors. The facility must have mechanisms/methods in place ensure that patients are free from all forms of abuse, neglect, or harassment. **Evaluating Compliance:** Review policies for inclusion of investigating allegations of abuse and neglect, reporting, and staff training Interview staff to determine if they know what to do if they witness abuse and what training they have had
1-D-22	The patient has a right to refuse treatment.	Verify the facility informs patients of their right to receive complete health information, participate in care decisions, and refuse care (with legally permitted exceptions). Facility policies must include key exceptions for: Minors Patients lacking mental capacity Life-threatening conditions Public health risks (e.g., infectious diseases)

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		In these cases, guardians may exercise refusal rights. **Evaluating Compliance:** Review facility policy for treatment refusal provisions and exception protocols Review the Patient Rights document(s) for inclusion of verbiage for treatment refusal and exceptions Interview staff about the refusal processes Review any clinical records involving treatment refusals and advance directives or power of attorney with guardian involvement.
1-D-23	All new staff must have training regarding the Patient Bill of Rights including concerns and complaints from family members / adult escorts and the various religious and ethnic concerns of the usual patient population and the policy and process for addressing concerns and complaints.	Verify staff providing care services have received education that supports the delivery of compassionate, person-centered care which respects patients'/service users' rights., including: Respecting patients' rights Respecting patient privacy and dignity Communication skills Shared decision making Understanding what matters & is most important in their care Understanding & respect for different beliefs, customs, and traditions Addressing patient concerns Process for addressing/resolving concerns and complaints. Education may be provided by the facility or by external providers. **Evaluating Compliance:** Review policies for procedures addressing patient concerns and complaints Review facility documents (i.e., complaint logs, Governing Body meeting minutes) for evidence of complaints and their resolution Interview staff regarding patient rights and the facility's complaint process Review personnel records for evidence of training (initial, updates).
1-D-24	Any issues judged significant related to the Patient's Bill of Rights must be brought to the attention of administration in a timely fashion.	Verify the staff understands the types of patient rights concerns that require escalation. **Evaluating Compliance:** Review policies for: Concerns that require escalation and investigation (e.g., abuse, discrimination) Timeframe for response to complainant Directive to comply with any mandated reporting (e.g., abuse) Review facility documents (i.e., logs, Governing Body meeting minutes) regarding accommodations, escalations, and reporting Interview staff regarding which issues require escalation.

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1-D-25	The facility must have the patient acknowledge that the Bill of Rights has been reviewed and understood by the patient/legal representative.	Verify the facility effectively communicates the Patient's Bill of Rights by: Providing clear explanations and Q&A opportunities Offering translated versions/interpreters for non-native speakers **Evaluating Compliance:** Observe process for how staff explains the Patient's Bill of Rights Review clinical records for signed patient acknowledgments and documentation of language assistance (if applicable)
1-D-26	The facility must provide patient privacy including gender-specific dressing and lavatory areas. This may include gender-specific dressing and lavatory areas as well as dietary provisions if provided by the facility.	Verify the facility protects patient privacy by: Securing personal information Providing gender-specific changing areas and restrooms Accommodating special needs (e.g., dietary restrictions). **Evaluating Compliance:** Review policies to confirm privacy protocols exist for: Facility design Special accommodations Interview staff regarding privacy practices Observe compliance during delivery of patient care Confirm dressing/restroom areas have gender-specific designations and proper signage.
1-D-27	The staff provide care in a manner that is respectful, professional, and consistent with the facility's mission statement.	Verify staff demonstrate professional conduct in all patient and family interactions, in accordance with the mission statement **Evaluating Compliance:** Interview patients/families about their experience at the facility Observe staff interactions with patients/families
1-D-28	The Patient's Bill of Rights is printed and available in the language of the majority (and substantial minority) of the patient population served.	Verify the facility's Patient's Bill of Rights is: Written in plain language Available in the main patient languages (e.g., Arabic. English, Spanish, etc.) Accessible via posting and/or direct distribution. **Evaluating Compliance:** Review policies for requirement of language accommodations and which languages were selected for translation Interview staff regarding the facility's distribution process and their language accommodation procedures Confirm the Patient's Bill of Rights is printed in the prominent languages of the populations served.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section E: QUAD A - Mandated Reporting		
1-E-1	Changes in facility ownership must be reported to the QUAD A Central Office within thirty (30) days of the change.	Verify QUAD A records accurately reflect current facility ownership. **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.
1-E-2	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. **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. **RHC:** Physicians, Advanced Practice Providers (NP, PA, CNM) and licensed behavior health providers (CP, CSW, MFT, MHC) must submit professional licenses. **Physical Therapy (OPT, I-PT):** SLP, OT, PT, SLPA, OTA, PTA must submit professional licenses. **Polyclinic:** Physicians, Dentist, Advanced Practice Providers (NP, PA, CNM), Physiotherapist, and Physical Therapists must submit professional licenses.	Verify QUAD A records accurately reflect the licensed providers performing procedures, treatments, or furnishing patient care services in the facility. **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.
1-E-3	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.	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. **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.
1-E-4	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	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. **Evaluating Compliance:**

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	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.	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.
1-E-5	All adverse events which occur in the facility or as a result of care provided at the facility must be communicated to the affected patient(s) and/or facility staff.	Verify the facility discloses adverse events to patients (and facility staff) to ensure patients understand any implications to their health status and to support a robust culture of safety. **Evidence of Compliance:** Review policies for a directive to disclose adverse events (e.g., medication errors, wrong site surgery) to patients and the Governing Body (GB) Interview quality coordinator regarding: Procedures for communicating adverse events to patients (or responsible adults) Request evidence of disclosures to facility staff (e.g., GB meeting minutes) (if applicable) Request clinical records from any adverse events reported in the past year to confirm the disclosure was reported to the patient (or responsible adult).
Sub-section F: Patient Safety Data Reporting (PSDR)		
1-F-1	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.	Verify the facility complies with PSDR reporting standards for random cases and adverse events and meets quarterly reporting deadlines. **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: 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	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	Verify the facility complies with the PSDR reporting standard (1-F-2) for random cases. **Evaluating Compliance:** 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

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	respective period, every three (3) months. If a surgeon/proceduralist performed fewer than three (3) cases, an exemption form must be submitted.	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	The facility is up to date with accurate PSDR reporting. Reportable adverse events must be submitted to PSDR, including, but not limited to: • 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; • Any iatrogenic dental trauma	Verify the facility complies with adverse event submissions into PSDR. **Evaluating Compliance:** 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.
1-F-15	Each adverse event submission must include: • 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.	Confirm the facility complies with adverse event submissions. **Evaluating Compliance:** 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.

SECTION 2: FACILITY LAYOUT & ENVIRONMENT

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Layout		
2-A-9	There is a separate waiting room which is adequately sized and adequately lighted.	Verify the facility maintains a waiting room appropriate to the population served and for guests. **Evaluating Compliance:** Confirm there is a separate area where patients and guests have adequate seating and light furnishings,
2-A-10	There is designated area for administrative activities.	Verify the facility maintains an area for administrative operations. **Evaluating Compliance:** Confirm there is a separate, administrative area that allows for administrative work.
2-A-11	There is at least one examination room.	Verify there is an area for patient examination. **Evaluating Compliance:** Confirm at least one (1) separate examination room.
2-A-12	This examination room is separate and distinct from the operating room.	Verify there is an area for patient examination. **Evaluating Compliance:** Confirm that a patient exam room is available outside of the Operating Suite.
Sub-section B: Facility Environment		
2-B-3	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.	Verify the facility maintains cleanliness and implements organizational cleaning and disinfection protocols. **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.
2-B-4	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.	Verify the facility is constructed with materials that allow for easy cleaning/disinfection, as recommended for high-hygiene environments, including: Use of non-porous, cleanable surface materials

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	If the floors contain seams or individual tiles, they are sealed with an impermeable sealant other than silicone.	Monolithic OR flooring (see FGI recommendations) Use of washable materials for curtains/blinds Carpet use only in non-clinical areas. **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.
2-B-6	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.	Verify the facility minimizes the potential for contamination to the environment from air pollutants and pests. **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.
2-B-7	There are no overloaded wall plugs or overloaded extensions in use, no altered grounding plugs in use, and wires are not broken, worn, or unshielded.	Verify the facility addresses electrical safety hazards, including: Using only UL-certified medical equipment with three-prong grounding Using only hospital-grade relocatable power taps or power strips (NEMA-5-15P) for multi-device needs Restricting the use of extension cords Not used instead of creating permanent wiring solutions Should not exceed current capacity. **Evaluating Compliance:** Inspect facility electrical components for: Proper grounding UL markings Non-compliant power strips Trip Hazards Extension cords use being temporary (<1 procedure/event) and not powering permanent equipment.
2-B-9	The entire facility is appropriately lighted, properly ventilated, and temperature controlled for patient and personnel comfort.	Verify the facility environment is adequately maintained for the comfort of patients and others. **Evaluating Compliance:** Interview staff regarding environmental controls, unresolved issues, and patient complaints Confirm uniform lighting in work areas, functional HVAC systems, and thermostat settings between 68-73° F (20-23° C).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
2-B-10	The entire facility provides adequate work space and sufficient space and storage for supplies and equipment.	Verify the facility layout is sufficient and organized to support safe operations, taking into consideration the services provided and the volume of cases performed. **Evaluating Compliance:** Interview staff regarding the adequacy of space for services and storage, and any workflow challenges Inspect the facility for adequate workspaces and compliant storage conditions (for equipment and supplies).
2-B-14	The lavatory facilities are sufficient to accommodate patients and staff needs.	Verify the number of bathrooms in the facility meets the needs of patients, guests, and staff. **Evaluating Compliance:** Interview staff regarding the number of lavatories versus the volume of patients and staff Confirm easy access to lavatories in clinical and non-clinical areas.
2-B-19	Smoking is prohibited in the entire facility.	Verify smoking is not allowed within the facility. **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.
Sub-section E: Storage		
2-E-1	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.	Verify the facility maintains the integrity of sterile supplies and equipment. **Evaluating Compliance:** Review policies for adoption of nationally recognized infection prevention and control guidelines Inspect sterile storage areas for evidence of: 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).
2-E-2	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.	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.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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.
2-E-3	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.	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 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) 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. **Evaluating Compliance:** 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.

SECTION 3: SAFETY

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: General Safety		
3-A-2	There is a reliable means of two-way communication to necessary personnel in other facility locations.	Verify the facility maintains a reliable source for secondary communication for emergencies. **Evaluating Compliance:** Confirm the presence of a backup, two-way communication device Require demonstration of device operation Interview staff regarding: Knowledge of emergency protocols Alternative communication methods.
Sub-section B: Facility Safety Manual		
3-B-1	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.	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. **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.
3-B-4	The facility safety manual provides employees with information about hazardous chemicals used and methods to minimize hazards to personnel.	Verify that the facility maintains Hazard Communications resources, including: Complete chemical inventory for the facility Safety Data Sheets (SDS) for all hazardous chemicals formatted using the Global Harmonized System (GHS) Providing employee training on chemical hazards and exposure minimization. **Evaluating Compliance:** Review the safety manual for the facility's hazardous chemical list and SDS access instructions Confirm SDS access (using GHS format) exists for current chemicals inventory Select one random chemical and request the SDS Interview staff regarding workplace chemical hazards and protective measures Review personnel records for evidence of training (initial hazard communication, chemical -specific instruction).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
3-B-5	There is a written exposure control plan, which is reviewed and updated at least annually.	Verify that the facility implements an Exposure Control Plan, including: Spill/slip/fall prevention Hazardous material response Communicable disease response Providing staff training (initially, with updates). **Evaluating Compliance:** Review the safety manual for prevention protocols, emergency response procedures, and annual review Interview staff regarding knowledge of hazard response steps and reporting procedures Review personnel records for evidence of training (initial, update acknowledgements).
3-B-6	There is a written chemical hazard communication program, which is reviewed and updated annually.	Verify the facility implements a Hazard Communication program, including: Documenting inventory of hazardous materials (updated annually) Proper labeling in accordance with recognized international standards Providing readily available access to Safety Data Sheets (SDS) for all hazardous chemicals. Providing chemical safety training **Evaluating Compliance:** Review the safety manual for hazardous chemical inventory, SDS index, and annual review Interview staff regarding SDS location for a randomly chosen chemical and safety protocols Confirm chemicals are properly labeled, stored, and appropriately disposed Review personnel records for evidence of training (initial, annually, when new chemicals added).
Sub-section C: Hazardous Agents		
3-C-2	All explosive and combustible materials and supplies are stored and handled in a safe manner with appropriate ventilation according to state/provincial, local or national laws and regulations.	Verify the facility safely handles explosive and combustible materials according to: Applicable fire and safety codes and worker safety regulations Safety Data Sheets (SDS) or the manufacturer's instructions for use (IFU) Government and regulatory requirements at the local, regional, or national level governing hazardous materials management and fire safety. **Evaluating Compliance:** Review policies for alignment with applicable fire and safety standards SDS or 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.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
3-C-4	Compressed gas cylinders are stored and handled in a safe manner according to local, state/provincial, or national laws and regulations.	Verify the facility safely stores and handles compressed gas cylinders according to: Fire and worker safety standards Government regulations (state/provincial/local/national) Industry standards. **<u>Evaluating Compliance:</u>** Review policies for alignment with fire and worker safety standards, regulations, and protocols 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.
3-C-5	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.	Verify the facility ensures proper labeling per: NFPA 704 standards OSHA Hazard Communication Standard 1910.1200 (as applicable) International fire and worker safety standards This includes decanting hand soap or hand sanitizer from one container to another. **<u>Evaluating Compliance:</u>** 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.
Sub-section D: Medical Hazardous Waste		
3-D-1	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.	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.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Evaluating Compliance: Review policies to confirm the waste management plan includes: Containment standards (double-bagging if contaminated) Storage/transport requirements Interview staff regarding waste handling procedures Inspect waste disposal containers, procedures, and storage areas for Proper bag/container use (no overfilling) Labeled, puncture-resistant sharps containers Ventilated storage areas.
3-D-4	Used disposable sharp items are placed in secure puncture-resistant containers that are located as close to the use area as is practical.	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: 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 ¾ capacity If reusable, containers must be FDA-approved, marked for reuse, and effectively disinfected. **Evaluating Compliance:** Review policies for alignment with OSHA 1910.1030 (Bloodborne Pathogens) and FDA standards or equivalent local/international regulation. Review documents to ensure any reusable containers meet FDA/DOT, or equivalent local/international regulation, reuse criteria Interview staff regarding one-handed sharps disposal and sharps container emptying practices Observe sharps containers in use to confirm: Fill level ≤ ¾ capacity without protruding sharps Proper mounting or stability Compliance with placement/accessibility guidelines.
Sub-section E: Fire Safety		
3-E-1	The facility is equipped with functioning heat sensors and/or smoke detectors that are tested annually.	Verify the facility maintains a fully operational fire detection system (heat/smoke alarms) to ensure safety compliance. **Evaluating Compliance:**

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review policies for Fire Safety (including maintenance protocols) Review documents for inspection records of detection systems Interview staff regarding alarm activation procedures and emergency response protocols Observe for proper placement of heat/smoke detectors and alarm system functionality.
3-E-2	The number of fire extinguishers available and their location must conform to local fire codes. Minimally, a fire extinguisher is located within 75 feet of any location in the facility. Fire extinguishers are visually inspected monthly, maintenance inspections are done annually and conform to local fire codes.	Verify the facility's fire extinguishers are: Sufficient in number (per square footage/local codes) Properly maintained per OSHA 29 CFR 1910.157 and NFPA 10 standards, or equivalent local/international regulation. Readily accessible (≤75 feet from any point) Key Requirements: Monthly visual inspection by staff: Observe for physical damage (dents/corrosion) Pressure gauge in green range Pull-pin/seal integrity Annual inspection by certified fire protection company: Full examination and tag verification Periodic (5–12 years*) internal maintenance by certified fire protection company Hydrostatic testing and component checks *Frequency varies by extinguisher type (e.g., 5 years for CO_2, 12 years for dry chemical). **Evaluating Compliance:** Review policies for alignment with OSHA and NFPA, or equivalent local/international regulation. Review documents confirming: Monthly inspection logs (last 12 months) Annual maintenance tags (current year) Internal maintenance records (per schedule) Inspect the facility to confirm extinguishers: Placed ≤ 75 feet apart and access not obstructed Have no physical damage Pressure gauges in "green" range.
Sub-section F: Exits		
3-F-3	There are sufficient emergency lights for exit routes and patient care areas in case of power failure.	Verify the facility provides emergency lighting for critical areas (patient care areas and exits). **Evaluating Compliance:** Review policies for power failure procedures that address: Emergency lighting duration Backup power sources

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Interview staff for knowledge of backup systems and emergency protocols Confirm emergency lighting in patient care zones and exit routes.
3-F-4	Hallways, stairways and elevators are sufficiently wide to allow emergency evacuation of a patient by emergency personnel and their equipment.	Verify the facility maintains unobstructed egress paths (hallways/stairways/elevators), including: Compliance with NFPA 101 Life Safety Code. or equivalent local/international regulation Compliance with local/state fire codes Ensuring minimum width requirements are met Keeping clutter out of evacuation routes. **Evaluating Compliance:** Review policies for alignment with NFPA/local regulations, or equivalent local/international regulation, and emergency evacuation procedures Interview staff regarding emergency evacuation procedures Inspect the facility to confirm: Corridor widths (≥ 44" for new healthcare) Stairwell clearance Non-obstructed pathways in evacuation routes.
Sub-section G: Personnel Safety		
3-G-1	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.	Verify the facility takes steps to protect staff from harmful exposure to Ethylene Oxide and Glutaraldehyde Exposure Information: Ethylene Oxide (EtO) – OSHA-regulated carcinogen (29 CFR 1910.1047) Glutaraldehyde – NIOSH REL 0.2 ppm (ACGIH TLV 0.05 ppm ceiling) Note: International facilities should abide by equivalent national safety organization recommendations. **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

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Observe for use of personal monitors in the workroom Review personnel records for evidence of staff training on safety procedures.
3-G-2	Personnel are properly trained in the control procedures and work practices that have been demonstrated to reduce occupational exposures to anesthetic gases.	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). **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).
3-G-3	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.).	Verify the facility maintains policies aligned with OSHA standards and implements task-specific PPE requirements. **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).
Sub-section H: Laboratory, Radiology Services, and Laser Safety		
3-H-2	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.	Verify the facility ensures laboratory services are performed safely and accurately in accordance with CLIA requirements or equivalent international/national laboratory quality standards. **Evaluating Compliance:** Review policies for directive to perform quality control testing per the manufacturer's instructions for use (IFU) Review CLIA or equivalent internationally recognized certificate for evidence that the: Type matches services provided (waived, provider-performed microscopy, moderate complexity) Laboratory Director credentials are current Review quality control logs and patient test documentation Interview staff regarding control procedures and equipment calibration (per IFU) Review personnel files for competency in laboratory tests provided.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
3-H-3	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	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 Observe procedures with radiation exposure for evidence of badge placement Review personnel records for quarterly exposure reports and employee acknowledgement.
3-H-8	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: 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

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Facility Equipment		
4-A-1	If a central source of piped oxygen is used, the system must meet all applicable local, state/provincial, and country safety codes.	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. Key Requirements: Certified verifier for central systems Category-appropriate compliance Documented corrective actions for identified issues. **Evaluating Compliance:** Review documents: Certified verifier reports from qualified technician Corrective action logs Confirm testing frequency matches IFU Inspect systems to spot-check actual vs prescribed oxygen delivery.
4-A-2	Medical equipment and supplies are available in the facility in appropriate sizes and quantities based on the patient population served.	Verify the facility maintains age-appropriate equipment/supplies for all patient populations served to ensure an adequate inventory to support safe patient care **Evaluating Compliance:** 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).
4-A-3	The Polyclinic has an oxygen cylinder.	Verify the clinic can administer supplemental oxygen when necessary to support safe patient care. **Evaluating Compliance:** Confirm at least one (1) full portable cylinder of oxygen is available with a regulator applied to confirm an adequate supply of oxygen Confirm an adequate inventory of single-use supplies necessary for oxygen delivery: Nasal cannula tubing (for supplemental oxygen delivery not in an emergency) Bag-mask ventilation device (for use in emergencies).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section B: Operating Room Equipment		
4-B-2	There is a properly functioning operating room table or chair.	Verify all OR tables and chairs function properly for safe patient positioning and are adequate to support intended procedures. **Evaluating Compliance:** Review documents preventive maintenance records Interview staff regarding routine maintenance, malfunction reporting, and weight capacity awareness Observe tables and chairs to ensure: Function of height/tilt mechanisms, locking features, and emergency release Integrity of the padding.
4-B-11	The Polyclinic has a suction machine and suction tubing supplies.	Verify the clinic can provide effective suctioning when necessary to support safe patient care. **Evaluating Compliance:** Confirm at least one (1) operational and portable suction machine is available Confirm an adequate inventory of single-use supplies necessary for suction delivery.
Sub-section C: Anesthesia Equipment		
4-C-16	If nitrous oxide alone is used, then a safe delivery system is used. A safe delivery system meets these criteria: 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	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. **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% O_2 minimum) Backup O_2 flush mechanism Confirm visual alerts/audible alarms for Hypoxic mixture (<25% O_2).
Sub-section E: Maintenance of Equipment		
4-E-1	The facility has a preventive maintenance program to ensure that all essential mechanical, electric and patient-care equipment is	Verify the facility maintains all equipment per manufacturer specifications in the instructions for use (IFU)

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
	maintained in safe operating condition and is replaced no less frequently than according to a schedule. 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.	**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.
4-E-5	The manufacturer's specifications and requirements for all equipment are kept in an organized file and followed for each piece of equipment.	Verify the facility retains manufacturer instructions for use (IFU) for all equipment and implements the specified maintenance and testing procedures. **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.
4-E-10	The facility regularly conducts appropriate testing in accordance with the manufacturer's specifications for all equipment. Records of that testing are maintained within the facility for at least three (3) years.	Verify the facility implements the specified maintenance and testing procedures as recommended by the manufacturer's instructions for use (IFU). **Evaluating Compliance:** Review documents for: Inventory log and maintenance schedules per IFU Equipment test records from past 3 years Maintenance logs Interview staff regarding testing procedures/frequency and process for incorporating new equipment Inspect ≥ 5 randomly selected pieces of equipment: Confirm inclusion in inventory log (by matching model numbers) Cross-check testing schedules and calibrations with the IFU.
4-E-11	All equipment not requiring a qualified technician inspection is on a preventative maintenance schedule with appropriate records kept for a minimum of 3 years (examples include manual wheelchair, manual stretcher, etc.).	Verify the facility performs periodic inspections on non-technical equipment (e.g., manual wheelchairs, stretchers). **Evaluating Compliance:** Review policies for preventative maintenance of non-technical equipment, to include: Maintenance schedules Staff responsibilities Inspection/service report retention (3-year minimum) Cleaning schedule

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review documents for evidence of inspection reports and service records (current, archived) Interview staff regarding process for reporting equipment issues and incorporating new equipment.

SECTION 5: IN CASE OF EMERGENCY

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Emergency Equipment		
5-A-1	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.	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. **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.
5-A-3	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.	Verify the facility maintains a functional defibrillator/AED for emergency use. **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.
5-A-5	The emergency equipment must be immediately available for the use of emergency situations.	Verify that the facility has adequate supply of emergency equipment and supplies immediately available to the operating room(s) (OR). The equipment and supplies must be in working condition. The facility's policies must address whether the equipment and supplies must be present in each OR, or in what quantity and location(s) they will be available to all ORs as needed.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		The facility must ensure that qualified staff are available who are capable of using all emergency equipment as needed. Staff must be able to operate the emergency equipment in accordance with their scope of practice. There is no requirement for all clinical staff to be trained on every piece of emergency equipment; however, whenever a patient is in the operating room, there must be staff present who are qualified to use the necessary emergency equipment. **Evaluating Compliance:** Determine whether the designated emergency equipment is immediately available to the OR(s) if needed. Interview staff to determine if they know where the emergency equipment is located.
5-A-6	The emergency equipment must be appropriate for the facility's patient population.	Verify that the facility incorporates emergency equipment, supplies, and medications that are appropriate for the potential emergencies associated with the procedures performed and the population served. The facility's policies must account for the characteristics of its patient population, including any prevalent risks or co-morbidities. The facility must also consider the types of procedures performed, the anesthesia used, and the specific risks or types of emergencies that may arise from those procedures. For example, a facility that routinely treats pediatric patients must ensure it maintains emergency equipment and supplies in sizes and configurations appropriate for pediatric use. **Evaluating Compliance:** Verify emergency equipment, supplies, and medications meet the emergency needs of the patients, taking into account the patient population and types of procedures performed and anesthesia used.
5-A-7	The emergency equipment must be maintained by appropriate personnel.	Verify that all mechanical and electrical emergency equipment is regularly inspected, tested, and maintained to ensure it is available and functional when needed. Emergency supplies and medications must be routinely monitored and replaced whenever they are used or reach their expiration date. The facility must utilize qualified personnel—or qualified contracted staff—to perform maintenance of emergency equipment. **Evaluating Compliance:** Verify that mechanical and electrical emergency equipment is regularly inspected, tested, and maintained Verify supplies and medications are current and not expired.
Sub-section C: Emergency Protocols		
5-C-1	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.	Verify the facility maintains comprehensive emergency preparedness, including: 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 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.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Evaluating Compliance: Review policies for: Evacuation procedures Roles/responsibilities Evidence of annual review Review drill documentation for required components, frequency not >365 days, retention for three (3) years 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.
5-C-2	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.	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) 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. **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.
5-C-3	There must be a written protocol for fires and fire drills. This protocol must include the provision for: fire drills; staff training upon hire and annually; drill documentation and retention of documentation for a minimum of three (3) years.	Verify the facility maintains comprehensive emergency preparedness, including: Annual review of fire response procedures Annual drills (documenting date/time, scenario, attendees, and after-action report) Staff training (at hire, annually, after protocol changes) Record retention of three (3) years 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. **Evaluating Compliance:**

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review policies for: Fire response procedures Evacuation routes Roles/responsibilities Evidence of annual review Review documentation for required components, frequency not >365 days, retention for 3 years Interview staff regarding fire response 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.
5-C-4	There must be a written protocol for returning patients to the operating room or transfer to the hospital in the event of patient emergencies.	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). **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.
5-C-7	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.	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). **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).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
5-C-11	There must be a written protocol for isolation procedures.	Verify the facility implements a comprehensive policy to minimize the risk of transmission of infections that aligns with recognized infection prevention and control guidelines, including: Annual review of policy Inclusion of Standard Precautions Inclusion of Transmission-Based Precautions (for airborne, contact, droplet diseases) Surveillance for symptoms of active infection Triage, isolation of patient, and use of appropriate barriers (e.g., mask the patient, cover wound) Staff training (initial, annual, with updates). **Evaluating Compliance:** Review policies for inclusion of required elements and evidence of annual review Interview staff regarding knowledge of transmission-based precautions and environmental cleaning Observe patient care for compliance with Standard Precautions (e.g., hand hygiene, cough etiquette, PPE use) Review personnel records for evidence of training (initial, annual, with updates).
Sub-section F: Disaster Preparedness Plan		
5-F-1	There is a written protocol for a disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the facility.	Verify the facility's readiness to respond to disasters and emergencies, including: A comprehensive preparedness plan Biennial review/testing Staff competency Key Requirements: Emergency response procedures Staff roles/responsibilities Patient care continuity Resource management. **Evaluating Compliance:** Review the emergency preparedness plan for: Required elements Contact protocols Emergency procedures Review documentation for evidence of biennial review/updates and plan testing Interview staff regarding emergency responses/roles and plan accessibility Review personnel records for evidence of training (initial, annual, updates).
5-F-2	Facilities must conduct a biennial review and test of its disaster preparedness plan.	Verify the facility's readiness to respond to disasters and emergencies, by periodically reviewing and testing the procedures laid out in their disaster preparedness plan (DPP) Key Requirements:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review the DPP at least every two (2) years Test the plan at least every two (2) years Rotating scenarios (e.g., weather events, security events) Evaluation the effectiveness of the plan for the scenario tested Making changes (as necessary) to update the plan. **Evaluating Compliance:** Review documents for evidence of: Biennial review/testing of the DPP Evaluation after testing the plan Updates to the plan (if required).

SECTION 6: MEDICATIONS

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Medications		
6-A-2	Drugs must be prepared and administered according to established policies and acceptable standards of practice.	Verify that drugs and biologicals used within the facility are administered in accordance with formally adopted facility policies, and that both the policies and the facility's actual practices conform to accepted professional practice and acceptable standards of medication administration (e.g., ISMP). The facility must maintain and implement policies and procedures designed to promote medication administration consistent with acceptable standards of practice. At a minimum, the policies and procedures should address: Medication orders Administration Manufacturer's instructions Timeliness of preparation Labeling of pre-filled syringes Infection control practices **Evaluating Compliance:** Review clinical record for medication order(s) are: Signed by a qualified provider Administered only by nurses or other qualified individuals, or under the supervision of nurses or other qualified individuals, as permitted under Federal, National or State law and the facility's policy Determine whether medications are properly labeled, stored, and have not expired Observe safe injection processes Interview staff on medication administration processes and safe injection practices.
6-A-5	Outdated medications are removed and destroyed in accordance with federal/national, state, provincial, and local pharmacy regulations.	Verify the facility's medications are safe and effective, through proper expiration date management and storage compliance **Evaluating Compliance:** Review policies for: Directive to comply with manufacturer's recommendations Procedures to monitor for expirations and storage conditions Expired medication disposal process

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review temperature logs for medication stored in refrigerators and freezers Interview staff regarding: Checking expiration dates (how often) Monitoring storage conditions Disposal process Inspect medication storage areas (e.g., cabinets, carts, refrigerators) for: 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	Medications are stored in a secured area away from patient and visitor access.	Verify the facility's medications are secured, whilst maintaining emergency readiness **Evaluating Compliance:** 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.
6-A-7	All drugs and biologicals given to patients must be approved by the physician/dentist with a signed order.	Verify the proper documentation of all medication orders to maintain patient safety and regulatory compliance **Evaluating Compliance:** Review policies for read-back verification process and requirement for prescriber to sign order promptly Interview staff regarding verbal order process Review clinical records for evidence of written, signed orders for all drugs/biologicals administered Confirm physician signatures follow verbal order documentation, especially in recovery.
6-A-8	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.	Verify the facility maintains adherence to professional standards for medication safety to prevent medication errors **Evaluating Compliance:** Review policies for safe medication storage/preparation/administration/verbal order(VO) protocols Review documents for: Confirm designated pharmaceutical supervisor (pharmacist when required by state) Tracking medication errors/adverse drug reactions Interview staff regarding safety protocols (e.g., 5 rights, high-risk meds, VO) and error reporting Observe medication preparation/administration during patient care delivery Review personnel records for training on medication safety Review clinical records for evidence of: Written, signed orders for medications administered (especially VO in PACU) Medications administered in the sterile field.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section B: Intravenous Fluids		
6-B-1	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.	Verify the immediate availability of IV fluids and administration sets for all patient populations served **Evaluating Compliance:** 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	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.	Verify the facility maintains stringent protocols to minimize the risks of infections, transfusion reactions, and circulatory overload associated with blood transfusions **Evaluating Compliance:** 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 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-3	The facility has the means for obtaining and administering blood or blood substitutes such as Dextran, if necessary.	Verify the facility has timely access to blood/blood products for transfusion when medically necessary. **Evaluating Compliance:** Review policies for written protocols regarding: Blood acquisition/transportation Emergency release of products Blood substitutes (if applicable) Massive transfusion Review documents for evidence of established relationships with blood banks and emergency suppliers Interview staff regarding emergency ordering process and turn around time Confirm availability of: O-negative blood (for emergency use) Blood typing supplies.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section D: Controlled Substances		
6-D-1	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	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, 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.	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. **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).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
6-D-3	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.) 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.	Verify the facility reduces the risk of controlled substance (CS) diversion through verified inventory counts and waste documentation by qualified personnel. **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).
Sub-section E: ACLS/PALS Algorithm		
6-E-5	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.	Verify staff readiness to perform cardiopulmonary resuscitation through defined roles, annual training, and protocol maintenance. 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. **Evaluating Compliance:** Review policies to verify CPR/Code Blue protocols include drills, staff training, drill documentation, clear role assignments and define response team Interview staff regarding emergency activation, roles during code, use of emergency equipment/medications Review facility documentation for annual drill Review personnel records for CPR training (initial, annual, updates) and competency (BLS/ACLS certification).
Sub-section F: Emergency Medications		
6-F-1	All emergency medications, as noted, must be available and in the facility at all times. Licensed personnel in the facility must know their location.	Verify emergency medications and supplies are continuously available, immediately accessible, and that staff can rapidly locate them during crises. **Evaluating Compliance:** Review policies for definitions of minimum quantities based on patient volume and acuity

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review checklists to ensure stock of the required drugs is regularly monitored Interview staff on monitoring protocols, restocking procedures, and minimum quantity requirements Inspect the stock to confirm all required emergency medications are present (not expired) Confirm quantities are sufficient and medication are appropriate for the patient population served.
6-F-2	The following medication must be available in the facility at all times: IV Antihistamines (e.g. Diphenhydramine) – Minimum 50 mg.	Verify IV Antihistamines are continuously available, in the appropriate concentration and quantity for the patient populations served. **Evaluating Compliance:** Review checklists to ensure the stock of the required drug is regularly monitored Inspect stock for: IV Antihistamines (e.g. Diphenhydramine) Minimum dose 50 mg (not expired) Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).
6-F-3	The following medication must be available in the facility at all times: Short-acting beta-blocker (e.g., esmolol or labetalol).	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. **Evaluating Compliance:** Review checklists to ensure the stock of the required drug is regularly monitored Inspect stock to verify that a short-acting beta-blocker (e.g., esmolol or labetalol) is present (not expired) Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).
6-F-6	The following medication must be available in the facility at all times: Vasopressors other than epinephrine (e.g. Ephedrine).	Verify vasopressors (other than epinephrine) are continuously available, in the appropriate concentration and quantity for the patient populations served. **Evaluating Compliance:** Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for vasopressors (e.g., ephedrine, phenylephrine, norepinephrine) (not expired) Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).
6-F-8	The following medication must be available in the facility at all times: Bronchospasm-arresting medication (inhaled beta-agonist, e.g. albuterol).	Verify bronchospasm-arresting medication (inhaled beta-agonist) is continuously available, in the appropriate concentration and quantity for the patient populations served. **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).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
6-F-9	The following medication must be available in the facility at all times: Anti-hypertensives	Verify anti-hypertensive medications are continuously available, in the appropriate concentration and quantity for the patient populations served. **Evaluating Compliance:** Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for anti-hypertensive medications (not expired) Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).
6-F-10	The following medication must be available in the facility at all times: Seizure-arresting medication (a benzodiazepine, e.g. Midazolam).	Verify seizure-arresting medications (benzodiazepines) are continuously available, in the appropriate concentration and quantity for the patient populations served. First-line seizure-arresting medications are fast-acting medications that include lorazepam, diazepam, clonazepam, and midazolam (IV or nasal spray). Phenytoin is **not** considered a first-line seizure-arresting medication; it is a second-line medication used for established status epilepticus (20 – 40 minutes). 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. 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. **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).
6-F-11	The following medication must be available in the facility at all times: Intravenous corticosteroids (e.g., dexamethasone).	Verify intravenous corticosteroids are continuously available, in the appropriate concentration and quantity for the patient populations served. **Evaluating Compliance:** Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for intravenous corticosteroids (e.g., dexamethasone) (not expired) Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).
6-F-12	Facilities administering regional or tumescent anesthesia containing bupivacaine must always have 20% lipid emulsion available.	Verify 20% lipid emulsion is continuously available for the immediate treatment of Local Anesthetic Systemic Toxicity. **Evaluating Compliance:** Determine the need for stock of 20% lipid emulsion through staff interviews or a review of clinical records

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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-13	The following medication must be available in the facility at all times: A narcotic reversal agent (e.g., naloxone, nalmefene).	Verify narcotic reversal agents (e.g., naloxone, nalmefene) are continuously available, in the appropriate quantity for the patient populations served. **Evaluating Compliance:** Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for narcotic reversal agents (e.g., naloxone, nalmefene) (not expired) Confirm quantities align with patient volume (pediatric dosing is present when applicable).

SECTION 7: INFECTION PREVENTION AND CONTROL

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Infection Prevention and Control		
7-A-10	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.	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. **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, 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 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-12	The facility staff must have knowledge of infection prevention and control techniques.	Verify the facility provides training on the infection prevention and control protocols key to supporting safe patient care and protecting staff. **Evaluating Compliance:** Review training materials for: Alignment with current, recognized infection prevention and control guidelines Adequacy to address the services provided by the facility and the risks to patients, staff, and guests (e.g., infection prevention and control surveillance, standard precautions, environmental cleaning, disinfection and sterilization)

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Interview staff regarding knowledge of procedures to prevent and control the spread of infection Review personnel files for evidence of training (initial, annual, updates).
7-A-13	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.
7-A-14	Policy and practices exist to prevent and control infections such as: proper use of antibiotics, hand hygiene, prevention of site infection, and infection event reporting.	Verify the facility implements comprehensive infection prevention and control policies and procedures. **Evaluating Compliance:** Review policies for: Evidence of annual review/updates Alignment with current infection prevention and control guidelines Adequacy to address the services provided by the facility and the risks to patients, staff, and guests (e.g., infection prevention and control surveillance, standard precautions, environmental cleaning, equipment disinfection, sterilization of patient care devices) Observe staff for compliance with the facility's policies.
7-A-15	Aseptic techniques are maintained during procedures and between cases.	Verify that facility staff maintain strict compliance with approved techniques to prevent the introduction of microorganisms and minimize the risk of infection, protecting both patients and healthcare workers. **Evaluating Compliance:** Review policies for procedures that: Align with current infection prevention and control guidelines Are adequate to address the services provided by the facility and the risks to patients, staff, and guests (e.g., infection surveillance, standard precautions, environmental cleaning, equipment disinfection, sterilization) Interview staff regarding knowledge of aseptic technique Observe staff for compliance with facility policies.
Sub-section B: Hand Hygiene		
7-B-1	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	Verify the facility minimizes infection risk through rigorous hand hygiene protocols that align with CDC/WHO guidelines, including: Surgical hand antisepsis

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
	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 current adopted guidelines and standards of practice for hand hygiene.	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 Compliance with "WHO Five Moments" (e.g., before patient contact, after environmental contact) Data analysis, feedback, and documented corrective actions HH audits results integration into the facility's QAPI program Interview staff regarding indications for HH and surgical scrub protocols (e.g., brushless technique, duration) Observe practices for adherence during patient care and procedures Inspect facility to ensure alcohol-based hand rub, surgical scrub supplies, and sinks are: Readily accessible in semi-restricted/restricted areas (not expired) Separate from instrument cleaning sinks.
Sub-section C: Instrument Processing		
7-C-1	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.	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. **Evaluating Compliance:** Review policies for: 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 Interview staff regarding ophthalmic instrument reprocessing to prevent TASS and endophthalmitis: Cleaning intraocular instruments in a designated area, separate from general surgical instruments Importance of rinsing/flushing phaco handpieces and cannulas (single-use preferred) Observe staff to ensure: 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 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., ANSI/AAMI ST79)

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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.
7-C-2	There is strict segregation of dirty surgical equipment and instruments that have been cleaned and are in the preparation and assembly area.	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. **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).
7-C-3	The instrument preparation and assembly area (clean processing area) are separated by walls or space from the instrument cleaning and decontamination area (reprocessing area).	Verify the facility prevents cross-contamination and minimizes infection risk by maintaining strict physical separation between clean and dirty processing areas. **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).
7-C-4	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. 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.	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) 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. **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 *unless* 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 For reusable devices approved for a limited number of sterilization cycles (e.g., gel implant sizers, LMAs, some liposuction cannulas):

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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.
Sub-section D: Sterilization		
7-D-1	All instruments used in patient care are sterilized where applicable.	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. **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.
7-D-2	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 applicable. Instrument reprocessing and sterilization must follow the manufacturer's instructions for use.	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. **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

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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.
7-D-3	Additional methods in use can be chemical (Chemclave©) or gas (ethylene oxide/EO) sterilizer.	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 Note: Chemical sterilizers require rigorous safety protocols due to hazardous agents; facilities should prioritize steam sterilization when feasible. **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).
7-D-4	Gas sterilizers and automated endoscope re-processors (AER) must be vented and tested for occupational exposure in accordance with the manufacturer's specifications.	Verify the safe and effective use of gas sterilizers and automated endoscope reprocessors to protect staff from occupational exposure to hazardous agents. **Evaluating Compliance:** Review policies for alignment with manufacturer instructions for use (IFU), including: 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:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Use of PPE (e.g., respirators, gloves) and engineering controls (e.g., ventilation, closed-system transfer) Adequate ventilation and monitoring
7-D-5	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: • 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.	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. **<u>Evaluating Compliance:</u>** 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.
7-D-6	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.	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. **<u>Evaluating Compliance:</u>** Review policies to ensure they require: 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).
7-D-7	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.	Verify sterilized instrument packages are clearly and accurately labeled to maintain sterility, support tracking, and enable recall if needed. **<u>Evaluating Compliance:</u>**

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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).
7-D-9	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.	Verify sterilization processes are monitored to confirm sterility assurance and comprehensive records are maintained to support traceability and recall efforts. Note: Logs must be retained per facility policy (typically ≥3 years). Electronic record systems must ensure data integrity and accessibility. **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) 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).
7-D-10	There is a written policy and procedure for the management of a positive biological indicator.	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. **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: 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: To confirm response effectiveness and compliance with policy timelines To ensure recalled instruments are reprocessed

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Affected sterilizer was not used until repaired, challenged, and cleared for use Interview staff regarding positive BI management protocols and recall process.
7-D-11	Immediate use steam sterilization (IUSS) is not done on a routine or frequent practice.	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. **Evaluating Compliance:** Review policies for directives to: 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: 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: Implants (unless documented emergency with no alternative) Prion-related contamination Non-validated cycles.
Sub-section E: High-Level Disinfection (HLD)		
7-E-1	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).	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 Note: Prioritize sterilization over HLD for rigid scopes when feasible. **Evaluating Compliance:** 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

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Device-specific IFUs (e.g., immersion time, concentration, rinse steps for HLD) Handling and storage post-processing to prevent recontamination.
7-E-2	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.	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. **Evaluating Compliance:** 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 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	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: • 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.	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. **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:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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).
7-F-3	There is a written policy for cleaning spills, especially spills that may contain blood-borne pathogens.	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). **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 Understanding of post-exposure protocols (e.g., reporting, prophylaxis) Review training records to ensure bloodborne pathogen training is documented.
7-F-4	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.	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. **Evaluating Compliance:** Review policies for blood/body fluid spill cleanup procedures that includes: 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: 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).

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
7-F-5	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.	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. **Evaluating Compliance:** Review policies for: 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: Review the written contract to ensure it: Details specific areas to be cleaned, frequencies, and methods Requires the vendor to comply with all applicable standards (e.g., CDC, OSHA, QUAD A) Includes validation of staff competence and training Confirm the contract is integrated into the facility's quality improvement (QAPI) program, with processes for: Regular audits of cleaning effectiveness (e.g., visual inspection, ATP testing) Corrective actions for non-compliance.
7-F-6	Instrument handling and reprocessing areas are cleaned and maintained.	Verify the facility's instrument handling and reprocessing areas are consistently cleaned and maintained to minimize contamination risks and support effective sterilization/disinfection processes. **Evaluating Compliance:** 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: Organized surfaces and absence of visible soil, dust, or debris Segregation of clean and dirty zones.

SECTION 8: CLINICAL RECORDS

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: General Clinical Records		
8-A-5	Clinical records must be kept secure and confidential, consistent with national patient privacy regulations.	Verify patient health information (PHI) is secured against unauthorized access, damage, or theft through physical and electronic safeguards that comply with national patient health information privacy regulations. **Evaluating Compliance:** Review policies for: PHI access, storage, and disposal (e.g., shredding, digital wiping) procedures Breach response protocols (including patient notification) Interview staff regarding security protocols and mechanism for reporting suspected breaches Perform a security assessment, including: Hard copy medical records are: 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) Electronic medical records utilize: 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-8	Clinical records for each patient must be accurate, legible, and promptly completed.	Verify clinical records are accurate, legible, complete, and promptly finalized to support safe, continuous patient care. Clinical records (hard copy or electronic) must meet legal, regulatory, and accreditation requirements. **Evaluating Compliance:** Review policies for: Timeliness requirements for documentation completion Authentication protocols (e.g., electronic signatures) Documentation requirements Interview staff regarding documentation standards and consequences of incomplete or late entries Review clinical records to ensure they include, as applicable: Patient identification (e.g., name, DOB, medical record number) Significant medical history and physical exam results Allergies and abnormal drug reactions Pre-operative diagnostic studies (if performed) Properly executed informed consent(s) Operative findings and techniques, including pathology reports for removed tissues

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Anesthesia administration records (if applicable) Discharge diagnosis Confirm all entries are: Accurate: reflect actual care provided and patient status Legible: easily readable (handwritten or electronic) Authenticated: signed and dated/timed by authorized author Prompt: completed contemporaneously or as required by policy.
8-A-9	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.	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. **Evaluating Compliance:** Review policies for mandatory retention ≥ 3 years (or longer state/national-mandated period) for active/inactive records Confirm procedures for destroying paper-based records, that include: Use of secure methods (e.g., shredding, incineration) to protect patient privacy Authorization protocols (e.g., designated personnel, oversight) Confirm procedures for EMR conversions ensure paper records are destroyed only after: Successful data migration and validation A defined, reasonable timeframe Interview staff regarding retention requirements and destruction protocols, roles in destruction or conversion.
8-A-10	Clinical records are maintained and easily accessible by the accredited facility.	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. **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.
Sub-section B: Pre-Operative Documentation		
8-B-1	Clinical records must contain patient identification.	Verify patient identity is accurately validated using multiple identifiers (e.g., full name, date of birth, unique ID) to prevent errors in care, treatment, and documentation. Photo identification alone is insufficient; corroborating details are required. **Evaluating Compliance:**

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review policies for: Requirement of at least two (2) patient identifiers (e.g., name, DOB) before providing care Prohibition of reliance solely on photo ID or verbal confirmation by patient Interview staff regarding process for patient identification before procedures & medication administration Observe staff identify patients during provision of care (e.g., during patient intake) Review clinical records to ensure: Patient identity is clearly documented using first name, middle initial (if available), and last name Additional identifiers (e.g., DOB, MRN) are consistently included in records and on wristbands (if applicable).
8-B-2	A pre-operative surgical safety checklist must be used for each patient and noted in the patient record.	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. **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.
8-B-7	The pre-operative clinical record includes significant medical history and a physical examination covering the organs and systems commensurate with the procedure(s) are recorded on all patients and placed in the clinical record prior to the surgical procedure.	Verify that the H&P, when required, is completed and placed in the patient's clinical record before the pre-surgical assessment is performed. The pre-surgical assessment must incorporate the findings of the H&P. Both the H&P (if applicable) and the pre-surgical assessment must be in the patient's clinical record prior to the start of surgery. **Evaluating Compliance:** Review clinical records to confirm: The record contains both the H&P (if required) and the pre-surgical assessment. For patients scheduled for surgery during the on-site survey, both documents are present in the clinical record before the surgical procedure begins.
8-B-8	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. The pre-surgical assessment must include documentation of any	Verify that the pre-surgical assessment is completed and documented in the clinical record before the start of surgery, and that it includes documentation of allergies to drugs and biologicals—or a statement that the patient has no known allergies. **Evaluating Compliance:** Review clinical records to confirm:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
	allergies to drugs and biologicals. This assessment must be placed in the patient's clinical record prior to the surgical procedure.	The operating physician, or another qualified practitioner acting within applicable state or national laws and standards of practice, has completed the pre-surgical assessment. The patient was examined prior to the commencement of surgery. Allergies (or "no known allergies") are clearly documented.
8-B-9	The pre-procedural operative assessment includes documentation regarding special needs such as physical impairments, disabilities, religious and/or ethnic concerns.	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. **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: 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).
8-B-10	The pre-operative clinical record includes documentation of blood pressure, pulse, respiration and temperature as taken prior to the operation.	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. **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.
8-B-11	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.	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. **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.
8-B-13	The pre-operative clinical record includes documentation of any allergies and abnormal drug reactions.	Verify patient medication allergies (and their specific reactions) or no known allergies are clearly documented in the clinical record to prevent adverse events and guide safe treatment decisions. **Evaluating Compliance:** Interview staff regarding process for obtaining/documenting allergies and actions taken when identified

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Observe staff for allergy verification during patient intake Review clinical records to verify allergies are prominently documented (e.g., front of chart, electronic health record alert) Confirm entries include allergen, reaction details, and date of last occurrence/validation (if known).
8-B-14	The pre-operative clinical record includes documentation of current medications.	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. **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).
8-B-15	The pre-operative clinical record includes documentation of medical history.	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. **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.
8-B-17	The pre-operative clinical record includes documentation of any previous operations.	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. **Evaluating Compliance:** Observe history-taking during patient intake for thoroughness.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Review clinical records to ensure the record includes a list of previous surgeries Confirm documentation is current and from appropriate sources.
8-B-18	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.	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. **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 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).
8-B-19	A written pregnancy testing policy must be in place that requires discussion and documentation of the issue with each patient, as appropriate.	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. **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).
8-B-20	The pre-operative clinical record includes evidence that treating physicians or consultants are contacted in cases when warranted by the history and physical examination.	Verify consultations with treating physicians or specialists are initiated and documented when the history and physical reveals conditions that could impact procedural safety. **Evaluating Compliance:** Interview staff regarding: Criteria for initiating consultations Procedures for communicating and documenting consultant input

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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.
8-B-22	The pre-operative clinical record includes pre-operative diagnostic studies and laboratory procedures (entered before surgery), if performed.	Verify that if pre-operative diagnostic studies were performed, they must be included in the medical record prior to the start of surgery. **Evaluating Compliance:** Review clinical record to confirm: Presence of any pre-operative ancillary testing (e.g., labs, diagnostic imaging).
8-B-27	A physician is responsible for determining the medical status of the patient and must examine the patient immediately before procedures and update the H & P.	Verify any changes in the patient's medical status (since the preoperative history and physical) are identified and documented immediately prior to the procedure. This focused assessment updates the H&P and evaluates procedure and anesthesia risks based on the patient's current condition, the planned procedure, and the anesthesia type. **Evaluating Compliance** Interview staff regarding: How to identify and document changes in patient status Review clinical records for: Preoperative assessment conducted immediately before the procedure by an appropriate staff member Evaluation of risks related to the procedure and anesthesia Confirmation the updated assessment addresses any changes in the patient's condition since original H&P,
8-B-29	An anesthesia history and physical and risk assessment (e.g. physical status anesthesia classification) are recorded in the medical/dental records.	Ensure the anesthesia history of pediatric patients is assessed prior to any procedure, confirming the patient's readiness for the planned anesthesia and addressing any special considerations for pediatric care. **Evaluating Compliance** Interview staff regarding process to ensure pediatric anesthesia assessment is performed before proceeding to the procedure area Review clinical records for: Documentation of anesthesia history Plan of care specific to minimizing risk of known anesthesia reactions (when applicable).
8-B-32	The facility must implement a policy related to patient health needs that are noted during the health assessment conducted	Verify the facility implements a comprehensive policy addressing patient health needs identified during preoperative assessments. This policy must include provisions for providing and documenting patient education

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
	preoperatively. The policy must include providing and documenting relevant patient education related to identified areas of need as applicable, such as: 1. Smoking cessation; 2. Importance of good nutrition; 3. Importance of exercise; and 4. Substance abuse resources in the medical record.	related to specific health needs, including smoking cessation, nutrition, exercise, and substance abuse resources. Education must be tailored to the patient's identified risks and documented in the medical record to support continuity of care and promote positive health outcomes. **Evaluating Compliance** Review policies for requirement of providing/documenting patient education for health needs identified Interview staff regarding procedures for providing patient education & resources for education material Review clinical records for evidence of: Specific health needs identified at preoperative assessment Appropriate education provided (with referrals when applicable).
Sub-section C: Informed Consent		
8-C-1	Properly executed informed consent forms are always obtained, from the patient or, if applicable, the patient's representative, which includes: • 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.	Verify properly executed informed consent is obtained from the patient (or representative) prior to any surgical or invasive procedure. The consent process must be thorough, transparent, and documented, covering all critical elements to ensure the patient (or representative) fully understands the procedure, its risks, benefits, alternatives, and the roles of all involved practitioners. **Evaluating Compliance:** Review policies regarding informed consent and directives to ensure: All required elements are addressed when attaining an informed consent Written consent is attained before the surgery/procedure Only authorized staff may obtain consent Patients lacking capacity (e.g., children, cognitive impairment) require consent from a legal representative Interview staff and practitioners regarding: Process for attaining consent (who may attain consent, who may witness signatures) Process for when patients lack capacity Review clinical records for evidence of properly executed informed consent, that includes: Description of the proposed surgery and anesthesia Indications for the surgery Risks and benefits Treatment alternatives Name of the surgeon/proceduralist Disclosure if other physicians will perform important tasks Disclosure if non-physician practitioners will perform important tasks & their roles (as permitted by law) Signature by the patient (or representative) before sedation or commencement of the procedure.
8-C-4	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.

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		Evaluating Compliance: Review policies regarding patient consent for marketing-related videography or photography to ensure: 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: Documentation of processes to withdraw consent Verification of consent for use in marketing-related media (when applicable).
Sub-section E: Laboratory, Pathology, X-Ray, Consultation, Treating Physician Reports, etc.		
8-E-1	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.	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. **Evaluating Compliance** 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.
8-E-5	The name of the healthcare provider appears on the reports.	Verify the name of the healthcare provider responsible for generating, interpreting, or reviewing reports is clearly documented on all clinical reports. This includes diagnostic, laboratory, consultation, and procedural reports to ensure accountability, traceability, and continuity of care. **Evaluating Compliance** Review policies for directive for healthcare provider's full name and credentials to appear on clinical reports Review clinical records to confirm all reports include the full name and credentials of the healthcare provider responsible for generating content.
8-E-6	Outside clinical laboratory procedures must be performed by a licensed and accredited facility.	Verify outside clinical laboratories used by the facility are properly licensed, accredited, and comply with all applicable regulations to guarantee safe and accurate laboratory procedures. If laboratories are located in another country, facility policy must explicitly state whether results from these laboratories will be accepted and under what conditions. **Evaluating Compliance** Review policies for use of outside clinical laboratories to confirm: Domestic Labs: Evidence of licensure, accreditation, and CLIA certification International Labs: Whether results will be accepted and verification requirements/special considerations Review documentation for all outside laboratories to validate requirements are met Interview staff regarding requirements for using outside laboratories and credentialing standards.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
8-E-9	The name of the pathologist must be on all pathology reports.	Verify the name of the licensed physician responsible for the pathological review of surgical specimens is clearly documented on all pathology reports. **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).
8-E-10	All laboratory results must be reviewed and acknowledged by the ordering health care provider.	Verify all laboratory results are reviewed and acknowledged by the ordering healthcare provider. This process confirms that results are assessed, acted upon if necessary, and integrated into the patient's care plan in a timely manner. **Evaluating Compliance:** Review policies for: Process for reviewing laboratory results, including identification of abnormal values and required actions Directive that all laboratory results must be reviewed by the ordering healthcare provider The timeframe for review and the method of acknowledgment Interview staff regarding: Laboratory review and acknowledgement process Documentation requirements Review clinical records to verify: All laboratory results are reviewed and acknowledged by ordering provider Acknowledgments include the provider's name, credentials, and date/time of review Acknowledgements in electronic health records are electronically authenticated.
8-E-11	All other reports, such as pathology reports and medical clearance reports, must be reviewed and acknowledged by the ordering healthcare provider.	Verify all reports, such as pathology and medical clearance reports, are reviewed and acknowledged by the ordering healthcare provider, who may be an internal or external provider (e.g., referring physician, consultant). This process ensures that critical diagnostic and clinical information is assessed, integrated into the patient's care plan, and acted upon when necessary. **Evaluating Compliance:** Review policies for: Directive that all medical reports must be reviewed and acknowledged by the ordering provider Procedures for both internal and external ordering providers The timeframe for review and the method of acknowledgment Documentation standards, including electronic authentication (reviewer's name, title, date/time of review) Interview staff regarding: Report review and acknowledgement process How to facilitate acknowledgment from external providers and document it appropriately Review clinical records to verify: All relevant reports are present and reviewed by the ordering healthcare provider Documentation of report transmission and acknowledgment from external providers

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Hard copy records: review is documented with initials, date, and time Electronic records: review is electronically authenticated with the required elements.
8-E-12	If tests/studies are done in the facility, the laboratory meets applicable licensure, standards, and state/provincial/national laws and regulations.	Verify all laboratory tests and studies performed within the facility comply with applicable licensure requirements, recognized standards, and state/provincial/national laws and regulations. This includes adherence to clinical laboratory standards, safety protocols, and quality assurance measures to guarantee accurate, reliable, and safe testing processes. **Evaluating Compliance:** Review policies for: Directive requiring compliance with applicable licensure, standards, and regulations for in-house lab testing References to specific standards (e.g., relevant national or provincial requirements) Procedures for regular audits, competency assessments, and quality control measures Review documents for evidence that: Lab license/certification/accreditation documents are compliant with applicable requirements Quality control records, proficiency testing results, and audit reports adherence to standards Laboratory staff credentials and training records are up-to-date and meet regulatory requirements Interview laboratory staff regarding knowledge of applicable standards, regulations, and facility policies Interview laboratory managers for knowledge of reporting requirements for incidents of non-compliance Observe staff performing testing protocols, safety measures, and quality assurance procedures .
8-E-13	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.	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. **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.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section F: Anesthesia Care Plan		
8-F-12	The anesthesia care plan is based on allergy history.	Verify the development of a safe, individualized anesthesia care plan that prevents exposures to patient reported allergens. **<u>Evaluating Compliance</u>** Review policies for: Directive for an individualized anesthesia care plan for each patient Specifying required elements of the plan (e.g., patient history, physical status, anesthesia type, risks) Documentation formats (e.g., checklists, narratives, or electronic templates) Interview provider to assess their understanding of the care plan development process Review clinical records to confirm the pre-anesthesia assessment and anesthesia care plan include the required elements: Patient's medical history and physical status (including assessment of allergens and reactions) Type of anesthesia planned Monitoring plan Contingency plans for potential complications Verify the plan is individualized to the patient's needs and is signed/authenticated by the provider.
Sub-section H: Intra-Operative Anesthetic Monitoring and Documentation		
8-H-5	The clinical record must contain evidence of oxygenation and circulation monitoring by continuous pulse oximetry. When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the care team. **Note**: This standard does not apply if **only** topical and/or local anesthetic is used without the use of an oral premedication.	Verify adequate oxygen concentration in the blood is maintained during all anesthetics through continuous monitoring via clinical observation and pulse oximetry. Pulse oximetry must be employed for all anesthetics except topical and local anesthesia without oral premedication. When used, the pulse oximeter's variable pitch pulse tone and low threshold alarm must be audible to the care team. **<u>Evaluating Compliance:</u>** Review policies for: Requirement for continuous oxygenation monitoring via pulse oximetry for all applicable anesthetics Mandate that the pulse oximeter's audible tone and low threshold alarm is active/audible to the care team Definition of exceptions (e.g., topical/local anesthesia without oral premedication) Interview staff regarding monitoring requirements and alarm management Observe practice to ensure pulse oximetry is applied and alarms are audible Confirm functional pulse oximeters with audible variable pitch tones & low threshold alarms Review clinical records (anesthesia records) for evidence of: Continuous pulse oximetry monitoring during delivery of anesthesia and post-anesthesia care Responses to any desaturation events.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section J: Post-Anesthesia Care Unit (PACU) Documentation		
8-J-10	There is a procedure/operative report completed by the surgeon/proceduralist, which includes procedure technique and findings.	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. **Evaluating Compliance:** Review policies for: 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 Interview surgeons and proceduralists about report documentation requirements and timely completion Observe the documentation process to ensure compliance Review clinical records for evidence of complete, accurate, and timely reporting, that includes: 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-8	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. The standard does not apply if **only** topical and/or local anesthetic is used without the use of an oral premedication.	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. **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 Interview staff about discharge instruction protocols, transportation policies, and "responsible adult" criteria

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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.
8-K-15	Patients receiving only local anesthesia without sedation may transport themselves.	Verify patients who receive only local anesthesia without sedation are permitted to transport themselves post-procedure, provided they meet facility-defined criteria for safe self-transportation. The facility must establish clear policies distinguishing these cases from those requiring accompaniment. **Evaluating Compliance**: Review policies for: Self-transportation allowed after local anesthesia without sedation Definition of eligibility criteria (e.g., stable vital signs, no dizziness, clear cognition) Prohibition of self-transport if sedation or systemic medications are administered Interview staff regarding self-transportation policies and assessment criteria Observe discharge process to ensure compliance with self-transportation policy Review clinical records for evidence of: Type of anesthesia administered (local only, no sedation) Assessment confirming patient stability for self-transport Patient acknowledgment of self-transportation instructions.
Sub-section L: Operative Log		
8-L-1	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. **Evaluating Compliance** 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	Standard / Regulatory Reference	Interpretive Guidance
8-L-3	An operative log must include the date of procedure.	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. **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.
8-L-4	An operative log must include the patient's name and date of birth or other identification number.	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. **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.
8-L-5	An operative log must include record of surgery(ies) and other invasive procedures to be conducted during the case.	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. **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.
8-L-6	An operative log must include the surgeon/proceduralist's name.	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. **Evaluating Compliance:** Review policies for: Operative log required elements 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.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
8-L-7	An operative log must include a record of the type of anesthesia used.	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. **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.
8-L-8	An operative log must include the name of person(s) administering anesthesia.	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. **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.
8-L-9	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).	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. **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.

SECTION 9: GOVERNING BODY

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Governing Body		
9-A-1	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.	Verify that the facility has a designated governing body that provides oversight for all facility operations. The governing body is responsible for establishing facility policies, ensuring that those policies are implemented, and monitoring compliance with them. It must also periodically review and assess the facility's policies to determine whether revisions are necessary. The governing body is responsible for: Direct oversight of the Quality Assessment and Performance Improvement (QAPI) program Ensuring the overall quality of healthcare services provided by the facility Ensuring the safety and integrity of the facility environment Developing, approving, and maintaining a comprehensive disaster preparedness plan In the case of a facility that has one (1) owner, that individual constitutes the governing body. **Evaluating Compliance:** Review governing body minutes for evidence of how the policies are implemented and monitored Review governing body/quality minutes for evidence of QAPI oversight Interview staff on how frequently the governing body meets Review administrative documents to see if the governing body has delegated operational responsibilities to a manager Review disaster policies and meeting minutes to verify governing body's role in disaster preparedness.
9-A-5	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.	Verify that the facility has a formal, documented scope of services that clearly states things such as: 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) **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.
9-A-7	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.	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. **Evaluating Compliance**

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		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.
9-A-10	The governing body/facility leadership: Sets policy on how individual staff deal with each other and external parties.	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. **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) Review GB meeting minutes for evidence of: 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 Interview staff regarding behavioral expectations, reporting mechanisms, & accountability measures Observe staff interactions for compliance with behavioral standards and professionalism.
9-A-11	The governing body/facility leadership: Sets policy on staff's role in properly dealing with patients.	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. **Evaluating Compliance** Review policies for: 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 Review GB meeting minutes for evidence of: 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 Interview staff to assess:

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		Understanding of customer service expectations and training received Awareness of feedback mechanisms Confidence in fair enforcement of standards Observe staff interactions with patients for professionalism, empathy, and adherence to service protocols.
9-A-12	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.	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. **Evaluating Compliance** Review policies for: 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 Review GB meeting minutes for evidence of: Regular review of operational/performance reports (e.g., quality metrics, financial statements) Decisions related to resource allocation, strategic planning, and risk management Actions taken to address performance gaps or operational challenges Interview senior leadership regarding the GB's engagement and accountability Verify the GB receives regular, comprehensive reports on facility performance.
9-A-14	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.	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. **Evaluating Compliance** Review policies to ensure: 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 Review GB meeting minutes for evidence of: 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 Interview senior leadership and to: Assess understanding of (and adherence to) policies and procedures Determine if staff feel supported in reporting concerns.
9-A-16	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,	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.

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	including laboratory, radiological, pathologic, and anesthesia services.	**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.
9-A-17	The governing body/facility leadership must ensure that all outside services are provided in a safe and effective manner.	Verify when the facility contracts with third parties for provision of the facility's patient care services, including the facility's environment, that the facility assures that the contract services are provided safely and effectively. Contractor services must be included in the facility's QAPI program. Such contracting does not relieve the governing body from its responsibility to oversee the delivery of these facility services. **Evaluating Compliance:** Ask facility for a complete list of current contracted services Review personnel files of contract personnel to determine required elements are present Interview staff to see how the safety and effectiveness of the contracted service is measured Review QAPI plan and quality meeting minutes.
9-A-20	The facility's policies and services are developed with the advice of a group of professional personnel that includes one or more physicians / dentists, one or more physician assistants / nurse practitioners / mid-level clinical personnel, and at least one community member who is not a member of the clinic staff.	Verify a multidisciplinary professional group (e.g., clinicians, administrators, technical staff) and at least one community representative collaborate to advise on the facility's policies and services. This inclusive approach promotes patient-centered care, community engagement, and alignment with diverse stakeholder needs. **Evaluating Compliance:** Review policies for: Requirement for multidisciplinary community input for development/review of facility policies and services Definition of composition of the advisory group (e.g., roles, expertise, community representation) Outline of the frequency of meetings and mechanisms for incorporating feedback Review GB meeting minutes for evidence of: Establishment and ongoing engagement of the multidisciplinary advisory group Inclusion of community representative(s) in discussions and decisions Integration of advisory feedback into policy and service improvements Interview advisory group members to confirm their roles and contributions Assess whether feedback from the group leads to tangible changes in policies or services.
9-A-21	The policies, procedures, and processes adopted by the governing body/facility leadership are reviewed and revised at least annually	Verify all policies, procedures, and processes are reviewed at least annually and updated as needed to reflect current standards, regulations, and best practices. This ongoing review ensures operational compliance, patient safety, and continuous improvement.

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	and in accordance with any implementation timelines adopted by the governing body/facility leadership.	**Evaluating Compliance** Review policies for: Requirement for an annual review (minimum) of all policies, procedures, and processes Directive to document each review, including dates, participants, and changes made Mandate that updates are made promptly when new regulations, standards, or best practices emerge Review GB meeting minutes for evidence of: Annual reviews of policies, procedures, and processes Discussions and approvals of updates or revisions Documentation of effective dates for revised policies Interview staff regarding awareness of the review process and their role in it Confirm staff can: Access current policies Have received training on updated policies and procedures (when applicable).
9-A-22	The governing body/facility leadership must document the content of any policies, procedures, or processes implemented in key functional areas of the facility. The governing body/facility leadership must document its approval of the policies, procedures, or processes.	Verify facility leadership is explicitly accountable for the development, documentation, approval, and maintenance of all facility policies, procedures, and processes. This includes establishing clear ownership, review cycles, and approval mechanisms to ensure consistency, compliance, and operational effectiveness. **Evaluating Compliance** Review policies for: Designated leadership roles/responsibilities for policy development, approval, and maintenance Procedures to documentation of approval (e.g., signatures, dates, version control) Requirement for regular review (e.g., annually) and updates Review GB meeting minutes for evidence of: Discussions and formal approvals of policies, procedures, or processes Designation of leadership accountability for specific policies or areas Periodic reviews/updates of existing policies Interview leadership and staff to assess understanding of policy ownership and approval processes Confirm staff access to current, approved policies and procedures.
9-A-23	The facility's leadership reviews and updates strategic objectives annually.	Verify the facility's leadership conducts an annual review and update of strategic objectives to align with evolving organizational goals, regulatory requirements, and community needs. This process supports continuous improvement, resource allocation, and long-term sustainability. **Evaluating Compliance:** Review policies for: Requirement for an annual review (minimum) of strategic objectives by leadership Process for developing, evaluating, and revising objectives (e.g., data analysis, stakeholder input, scans) Directive to document each review, including dates, participants, and changes made Review GB meeting minutes for evidence of:

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		Annual discussions and approvals of strategic objectives Analysis of performance metrics (e.g., clinical outcomes, financial stability, patient satisfaction) Adjustments to objectives based on internal/external factors (e.g., regulatory changes, market trends) Interview staff regarding their involvement in the annual strategic review process, including: Awareness of current strategic objectives and their role in achieving them Whether objectives are communicated and integrated into departmental goals.
9-A-27	The governing body/facility leadership will designate a person or committee responsible for implementation and ongoing management of the risk management program.	Verify facility leadership is explicitly accountable for the development, implementation, and oversight of a comprehensive risk management (RM) program. This program must proactively identify, assess, and mitigate risks to patient safety, operational continuity, and regulatory compliance, with clear lines of authority and responsibility. **Evaluating Compliance:** Review policies for: Designation of leadership responsible for the RM program (e.g., Governing Body, CEO, Risk Mgr) Processes for risk identification, assessment, mitigation, and reporting Requirement for regular review (e.g., quarterly) of risk data and program effectiveness Review GB meeting minutes for evidence of: Regular discussions of RM reports, trends, and incident analyses Approval of risk mitigation strategies and resource allocations Evaluation of program effectiveness and adjustments as needed Review organization chart for: Clear delineation of roles/responsibilities for RM (e.g., Risk Officer, Committee) Reporting lines accountability to leadership Interview leadership and RM staff to assess understanding of their roles and the program Interview staff to confirm: Training is provided to report risks and incidents promptly RM is integrated into organizational culture and operations.
9-A-28	The facility's risk management program must include the assessment of vulnerable patients.	Verify the facility's risk management (RM) program proactively identifies, assess, and mitigate risks to patient safety, including vulnerable patients. Patient intake should include a comprehensive evaluation of factors like age, health conditions, social determinants, and functional status to identify potential risks such as falls, neglect, or infection. **Evaluating Compliance:** Review policies for: Directive to perform prospective risk assessment upon admission Process for escalating positive findings (e.g., fall risk → colored wrist band → assisted ambulation) Mandatory reporting (e.g., abuse, neglect) Interview staff regarding: Understanding of vulnerability risks (physical/mental wellbeing, social determinants of health, safety)

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Process for accommodation (e.g., quiet environment for identified sensory sensitivities) Referrals and reporting mechanisms Observe for evidence of patient accommodation (e.g., accessible equipment, large print patient education materials, assistance with transfers).
9-A-29	All identified risks and adverse events must be logged and retained in a risk register (log) for tracking and trending over time.	Verify facility implementation of a comprehensive risk management (RM) program that includes formal identification and analysis of active risks (near misses) and adverse events to improve patient safety, meet regulatory and accreditation requirements, and reduce future occurrences. The facility must analyze this data for trends, so it may proactively address systemic issues rather than only reacting to individual incidents. **Evaluating Compliance**: Review policies for requirements to: Maintain a risk management log (written or electronic) Identify types of events to log and analyze (e.g., patient death or serious injury, events that resulted in unintended harm to the patient, near misses, patient complaints, harm from device failure or improper use) Define processes for risk identification, regular analysis (e.g., monthly, quarterly), mitigation, & reporting Review risk log for evidence that risk incidents and adverse events are documented, tracked, & trended Interview risk manager (or quality coordinator) regarding: Process for risk analysis and performance improvement Communication to governing body Implementation of risk reduction measures Interview staff for: Understanding of what constitutes a risk (near miss) or adverse event and how to report Confirmation that incidents/adverse events are analyzed and risk reduction measures are implemented.
Sub-section B: Transfer of the Patient		
9-B-3	The facility must have an effective procedure for the immediate transfer to a hospital for patients requiring emergency medical care beyond the capabilities of the facility.	Verify that the facility has an effective procedure for the immediate transfer of a patient to a local hospital when the patient experiences a medical emergency that the facility is not equipped to manage, or when the patient requires emergency care that exceeds the facility's 24-hour timeframe for care. An effective procedure for immediate emergency transfers must include: Policies and procedures that define: The circumstances that warrant an emergency transfer Who is authorized to make the transfer decision Required documentation that must accompany the patient Process ensuring the transfer is completed safely, efficiently, and with appropriate communication to the receiving hospital Provision of emergency care and initial stabilizing treatment within the facility's capabilities prior to transfer.

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		Arrangements for immediate emergency transport, such as calling 911 for EMS services. Even when EMS is used, the facility remains responsible for direct communication with the receiving hospital to ensure a safe and coordinated transfer. **Evaluating Compliance:** Review policy on emergency transfer of the patient Interview staff: How is this policy communicated to staff? Ask how a medical emergency would be handled Ask if there have been any transfers in the last 12 months Review clinical record of a transferred patient(s) for evidence that policy was followed.

SECTION 10: QUALITY ASSESSMENT/QUALITY IMPROVEMENT/RISK MANAGEMENT

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Quality Assessment/Quality Improvement/Risk Management		
10-A-2	The governing body/facility leadership must identify the specific committee or individual(s) responsible for the development, implementation, and oversight of the quality assurance and risk management program.	Verify the facility appoints the individual (or committee) responsible for its quality assurance and risk management program to ensure a formal, structured, and accountable process for improving patient care. **Evaluating Compliance:** Review policies for: Directive to appoint the staff member (or committee) in charge of the facility's quality/risk activities Oversight requirements (e.g., chart review, peer review, policy development, reporting to the GB) Review Governing Board documents/meeting minutes for written appointment and GB participation Review documents (e.g., dashboards, spreadsheets) from QAPI program to verify trends have been reviewed and staff oversight Review organizational chart for evidence of staff appointment, oversight of QAPI program, and evidence of directional reporting.
Sub-section B: Quality Improvement Program		
10-B-2	The facility has a written quality improvement program implemented which includes surveys or projects to: • Monitor and evaluate patient care • Evaluate methods to improve patient care • Identify and correct deficiencies within the facility • Alert the facility's Quality Improvement Program to identify, track, trend, evaluate and resolve problems.	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. **Evaluating Compliance** Review policies of QI program for: Goals and objectives aligned with patient safety and care standards 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.
10-B-6	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	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.

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	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.	**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.
10-B-19	The governing body/ facility leadership must ensure that the QAPI program is defined, implemented, and maintained by the facility.	Verify that the facility has an ongoing and effective QAPI program that is actively supported and directed by facility leadership. The governing body must assume responsibility for the design, implementation, and oversight of every phase of the QAPI program. The governing body must ensure that the facility's QAPI program: Is formally defined in writing and fully implemented Includes quality and patient safety indicators Specifies the indicator data to be collected, including what data will be collected, how it will be collected, and the frequency of collection Uses collected and analyzed data to drive performance improvement Evaluates the effectiveness of performance-improvement changes, and makes additional modifications when needed Clearly establishes that patient safety is a governing body priority, demonstrated not only through tracking all adverse events but also through processes that analyze causes and implement changes to prevent recurrence Has adequate resources, including qualified staff (internal or consultants), sufficient staff time, information systems, and necessary training to support the program **Evaluating Compliance:** Review QAPI for essential elements Review governing body minutes to verify discussion of QAPI elements Interview staff on how the governing body/facility leadership is involved in QAPI Interview facility leadership how it uses QAPI to improve performance Interview facility leadership on the details of the resources allocated to QAPI.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
10-B-24	The quality improvement program will demonstrate measurable improvement in patient health outcomes by focusing on high risk, high volume, and problem-prone areas.	Verify the facility's quality improvement (QI) program demonstrates measurable improvements in patient health outcomes through systematic data collection, analysis, and targeted interventions. The program must prioritize high-impact areas, track progress, and validate that changes lead to enhanced clinical results. **<u>Evaluating Compliance</u>** Review policies of QI program for: Defined metrics for health outcomes (e.g., infection rates, surgical complications, patient satisfaction) Baseline data collection and periodic reassessment to measure progress Action plans for interventions aimed at improving outcomes Methods for analyzing data and validating improvements Alignment with evidence-based practices and regulatory requirements Review QI meeting minutes for evidence of: Discussion of outcome metrics and trends Analysis of data to identify areas for improvement Implementation of interventions and monitoring of their impact Documentation of measurable improvements achieved Interview staff regarding QI goals and specific improvements in patient health outcomes Confirm staff awareness of data-driven changes and their effects on patient care.
10-B-25	The quality improvement program will improve patient safety by using quality indicators or performance measure(s) by focusing on incidence, prevalence and severity of problems identified.	Verify the facility's quality improvement (QI) program utilizes specific quality indicators and performance measures to systematically monitor, analyze, and improve patient safety. The program must demonstrate measurable enhancements in safety outcomes through data-driven interventions and continuous evaluation. **<u>Evaluating Compliance</u>** Review policies of QI program for: Defined QI indicators & performance measures for patient safety (e.g., fall rates, medication errors, SSI) Baseline data collection, targets for improvement, and methods for ongoing monitoring Action plans for addressing identified safety risks Processes for validating improvements and sustaining gains Alignment with national standards (e.g., CMS) and evidence-based practices Review QI meeting minutes for evidence of: Regular discussion of QI data and safety performance Analysis of trends, root causes of safety issues, and effectiveness of interventions Decisions regarding resource allocation or process changes to address safety gaps Documentation of improvements achieved in patient safety metrics Interview staff to assess: Understanding of key quality indicators and their relevance to patient safety Awareness of recent safety improvements and their role in achieving them Familiarity with reporting mechanisms for safety incidents and near misses.
10-B-26	The quality improvement program will implement a process to identify and reduce medical errors.	Verify the facility has a structured, proactive process to identify, analyze, and reduce medical errors through its quality improvement (QI) program. This process must prioritize patient safety by systematically addressing

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		errors, near misses, and underlying systemic issues to prevent recurrence. **<u>Evaluating Compliance</u>** Review policies of QI program for: Standardized process for reporting medical errors and near misses (e.g., incident reporting system) Methods for root cause analysis (RCA) or similar methodologies to investigate errors Action plans for implementing corrective and preventive actions (CAPA) Metrics to track error rates, trends, and the effectiveness of interventions Review of QI meeting minutes for evidence of: Discussion of reported errors, near misses, and RCA findings Development and monitoring of CAPA to address identified issues Trends in error rates and evaluation of intervention effectiveness Efforts to foster a culture of safety and continuous improvement Interview staff to assess: Understanding of the error reporting process and their role in it Awareness of recent errors, lessons learned, and implemented changes Confidence in the non-punitive nature of the reporting system.
10-B-27	The quality improvement program should include patient/service user satisfaction assessment and other performance measures.	Verify the facility's quality improvement (QI) program includes a systematic process for assessing patient satisfaction to identify opportunities for enhancing patient experiences, care delivery, and outcomes. The program must collect, analyze, and act on patient feedback to drive meaningful improvements. **<u>Evaluating Compliance</u>** Review policies of QI program for: Defined methods for collecting patient feedback Metrics and targets for patient satisfaction Processes for analyzing feedback, identifying trends, and integrating findings into QI initiatives Action plans to address areas of concern Specification for frequency of data collection/reporting Review QI minutes for evidence of: Regular discussion of patient satisfaction data and trends Analysis of feedback to identify root causes of dissatisfaction or areas for improvement Development and implementation of actions to address patient concerns Monitoring of the effectiveness of interventions over time Interview staff to assess: Understanding of patient satisfaction metrics and their importance Awareness of recent patient feedback and related QI actions Involvement in initiatives to improve patient experiences.
10-B-28	The number and scope of distinct quality improvement projects conducted annually must reflect the scope and complexity of the facility's services and operations.	Verify the facility's annual quality improvement (QI) projects are aligned with the scope, complexity, and risks of the services offered and operations. Projects should address high-priority areas such as patient safety, clinical outcomes, operational efficiency, and regulatory compliance, and should be tailored to the facility's specific

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		services and patient population. **<u>Evaluating Compliance</u>** Review policies of QI program for: Selection criteria for projects based on facility scope of services, complexity, and risk assessment (e.g., high-volume procedures, high-risk services, patient safety incidents). A documented annual QI plan with specific projects, goals, metrics, and timelines. Processes for prioritizing projects that address critical areas (e.g., infection prevention and control, medication safety, surgical outcomes, and patient satisfaction) Methods for evaluating the effectiveness of QI projects and making adjustments Requirement for annual review and approval of QI projects by leadership or the governing body Review QI meeting minutes for evidence of: Discussion & selection of QI projects based on the facility's services and operational needs Monitoring of project progress, including data collection, analysis, and interim results. Evaluation of project outcomes & decisions for continuation, expansion, or modification of initiatives Integration of QI findings into policies, procedures, and staff training Interview staff regarding: Understanding of the annual QI projects and their relevance to the facility's services Involvement in project implementation and awareness of goals and progress Knowledge of how QI projects impact patient care and operational efficiency.
10-B-29	Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.	Verify the facility's performance improvement (PI) activities systematically track and address specific, high-priority areas relevant to its scope of services, patient population, and operational risks. These activities must be data-driven, focused on measurable outcomes, and integrated into the facility's daily operations to promote continuous enhancement of care quality and patient safety. **<u>Evaluating Compliance</u>** Review policies of QI program for: Verify the QI program explicitly defines the specific areas to be tracked (e.g., surgical site infections, medication errors, patient falls, wait times, patient satisfaction) Confirm the program includes: Clear objectives and performance measures for each tracked area Data collection methods and frequency Processes for analyzing data, identifying trends, and implementing corrective actions Responsibilities for staff involved in performance tracking and improvement activities Ensure the program requires regular review and updating of tracked areas based on emerging risks or regulatory changes. Review QI meeting minutes for evidence of: Regular discussion of performance data related to the tracked areas Analysis of trends, root causes of issues, and effectiveness of interventions Decisions regarding resource allocation, policy changes, or staff training to address identified gaps Documentation of improvements achieved in the tracked areas

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Interview staff to assess: Understanding of the specific areas being tracked and their importance Awareness of current performance data, goals, and recent improvements Involvement in data collection, analysis, or improvement initiatives.
Sub-section C: Risk Management		
10-C-1	As part of an ongoing risk management program, the facility must conduct a risk assessment of its operational activities at least annually. The assessment must 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 Risk Assessment must be prioritized for risk mitigation, risk management, and QA/PI (Quality Assessment/Quality Improvement) projects.	Verify the facility conducts an annual, comprehensive risk assessment as part of its ongoing risk management program. This assessment must evaluate risks to patients and staff across critical areas, including medication management, fall hazards, infection prevention and control, equipment safety, patient risks from long-term conditions, and nutrition (if food/beverage services provided). Findings must be prioritized to drive risk mitigation strategies, management actions, and quality assessment/performance improvement (QAPI) projects. **Evaluating Compliance** Review policies of QI program for: Requirement for annual risk assessment (RA) of operational activities, with defined scope Methodologies for risk identification, analysis, and prioritization (e.g., risk matrices, scoring systems) Mandates to integrate findings into risk mitigation plans and QAPI initiatives Review of annual RA for: Evaluation of each required area with identified risks, their likelihood, impact, and prioritization levels Action plans for high-priority risks, including timelines and responsible parties Linkage to QAPI projects and ongoing monitoring of measures Risk assessment updated within the past 12 months Review QI meeting minutes and GB documents for evidence of: Discussion/approval of annual risk assessment Prioritization of risks and allocation of resources for mitigation Oversight of QAPI projects derived from assessment findings Interview leadership and risk management staff to assess: Understanding of the risk assessment process and their roles Awareness of high-priority risks and corresponding mitigation efforts Involvement in QAPI projects triggered by the assessment.
10-C-2	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 (QA/QP).	Verify the facility develops and maintains a comprehensive risk management program tailored to its size, scope of services, and patient population. This program may be integrated with the Quality Assessment/Performance Improvement (QAPI) program but must explicitly focus on identifying, analyzing, and mitigating risks to patients, staff, and the organization. The program shall proactively address clinical, operational, and environmental risks through systematic processes. **Evaluating Compliance:** Review policies of QI program for: Formal risk management program, defining scope, objectives, and integration with QAPI activities Processes for risk identification (e.g., incident reporting, audits, environmental scans)

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Methods for risk analysis & prioritization (e.g., risk matrices, severity-frequency charts) Strategies for risk mitigation (e.g., preventive actions, staff training, policy updates) Procedures for monitoring and reviewing effectiveness of risk controls Directive to review risks annually and update as needed Review Risk Management Program to ensure: Documentation of identified risks and their prioritization Action plans for high-priority risks, assigned responsibilities, and timelines Evidence of implemented mitigation measures and their outcomes Records of regular program reviews and updates Integration with QAPI activities (e.g., shared data sources, coordinated improvement projects) Review QI meeting minutes and GB documents for evidence of: Oversight of the risk management program, including regular reviews and approvals Discussion of risk reports, trends, and mitigation progress Decisions linking risk findings to QAPI initiatives and resource allocation Interview leadership and staff regarding: Understanding of the risk management program and their roles within it Awareness of reporting mechanisms for risks and incidents Knowledge of how risk management integrates with QAPI efforts.
10-C-3	Near-miss events must be reported, analyzed, and tracked. Measures must be implemented to prevent the event from reoccurring.	Ensure the facility has a structured, non-punitive process for reporting, analyzing, and addressing near-miss events to prevent future incidents and enhance patient safety. The process must include clear reporting mechanisms, thorough analysis, implementation of corrective actions, and ongoing monitoring to ensure effectiveness. **<u>Evaluating Compliance:</u>** Review policies for: Outline for a non-punitive near-miss reporting process, including: Definitions and examples of near-miss events Confidential reporting mechanisms Steps for analysis (e.g., root cause analysis RCA) Procedures for implementing and monitoring corrective actions Confirmation the policy encourages staff to report without fear of retaliation Review of documentation for near-miss events for: Consistently reported and documented in a centralized system Analysis to identify root causes and contributing factors Tracked to ensure timely resolution and follow-up Evidence of corrective actions Review QI meeting minutes and GB documents for evidence of: Discussion of near-miss trends, analyses, and corrective actions Decisions regarding resource allocation for prevention strategies Oversight of implemented changes and their impact on safety Interview staff regarding:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Understanding of what constitutes a near-miss event How and where to report near-misses Knowledge of recent near-miss events and resulting practice changes Confidence in the non-punitive nature of the reporting system.
10-C-4	A definition of an adverse incident must be documented in policy and procedure, including near miss events.	Verify the facility explicitly defines "adverse incident" and "near miss event" in its policies and procedures to standardize reporting, analysis, and prevention efforts. Clear definitions promote consistent identification, documentation, and response to events that could impact patient safety, fostering a culture of transparency and continuous improvement. **<u>Evaluating Compliance:</u>** Review policies for: Precise definitions: Adverse event: event that results in unintended harm to a patient Near misses: event that could have resulted in harm but was intercepted or did not impact patient care Confirm policy includes: Examples of each event type Reporting procedures for adverse incidents and near misses Distinctions between events requiring immediate action vs. those for preventive analysis Interview staff regarding: Understanding difference between adverse incidents and near misses Awareness of reporting protocols for both event types.
10-C-5	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.	Verify all safety incidents, complaints, adverse events, and near misses are thoroughly investigated, and their results are systematically reported in Quality Assurance Performance Improvement (QAPI) meetings. This process promotes accountability, transparency, and data-driven improvements to enhance safety and care quality. **<u>Evaluating Compliance</u>** Review policies for: Directive to immediately report safety incidents, complaints, adverse events, and near misses Structured investigation processes Timely reporting of investigation findings to QAPI meetings Action plans to address identified issues and prevent recurrence Definition of roles and responsibilities for reporting, investigating, and escalating events Interview staff regarding: Understanding of reporting procedures for all event types, investigation processes, & their role in them How event findings are shared in QAPI meetings and evidence of practice changes.
10-C-6	Adverse events must be tracked and trended on a defined basis.	Verify all adverse events are thoroughly tracked and analyzed, and their results are regularly reported in Quality Assurance Performance Improvement (QAPI) meetings. This process promotes accountability, transparency, and data-driven improvements to enhance safety and care quality.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Evaluating Compliance Review policies for: Mandate to regularly tracking and trend adverse events Defined intervals for analysis and reporting Use of standardized tools to visualize trends Specified roles for data collection, analysis, and reporting. Directive to escalate significant trends to leadership and QAPI committees Interview staff regarding: Understanding of how adverse events are reported, tracked, and trended Awareness of recent trends and their implications for patient safety.
10-C-7	All staff must be educated in risk management activities on commencement of employment and annually thereafter, and when there is an identified need.	Verify all staff members possess the fundamental knowledge required to identify, report, and mitigate risks within their roles, fostering a consistent and proactive culture of safety and risk awareness throughout the organization. **Evaluating Compliance:** Review policies for: Mandate for risk management (RM) education content Frequency of training (on hire, annual, updates) Interview staff regarding comprehension of RM activities and practical application Review personnel records for evidence of compliance with risk management education: May include training logs, completion certificates, electronic learning management system records, or performance appraisal notes.
10-C-8	The facility should have a process to monitor, track and trend patient satisfaction (e.g. surveys or assessments) and implement actions to improve patient satisfaction as necessary.	Verify the facility has a structured, data-driven approach for understanding the patient experience. This process must move beyond simple data collection to include analysis and the implementation of corrective actions aimed at continuous improvement. **Evaluating Compliance:** Review policies for defined process for the collection, analysis, and response to patient satisfaction data Review documents to confirm analysis of patient satisfaction is ongoing to monitor, track, and identify trends Review QI meeting minutes and GB documents for evidence that: Patient satisfaction data is reviewed Decisions are made to implement improvement actions and allocate resources Interview staff and leaders regarding: Awareness of process to determine patient satisfaction outcomes and recent trends Confirmation that corrective actions (specific changes) are implemented to improve patient experience.
10-C-9	The facility must conduct an ongoing review of patient complaints and grievances, including defined response times.	Verify the facility has an effective, systematic, and timely process for addressing patient complaints and grievances. This process must be proactive, using reviewed data not just to resolve individual cases but to identify trends and drive systemic improvements in patient care and safety.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Evaluating Compliance: Review policies for handling complaints and grievances: Steps to investigate complaints Defined response times for investigation and for formal response Review documents from patient complaint and grievance logs/files for evidence of: Timely and thorough investigation and actions taken Communication with the patient Confirm the resolution was completed within the facility's defined response timeframes Review QI meeting minutes and GB documents for evidence of: Ongoing, aggregate review of complaint data Discussion of trends, patterns, and resulting actions aimed at preventing future occurrences Interview staff regarding knowledge of the process and its outcomes.
10-C-10	A system is in place for leadership to receive and resolve in a timely manner any ethical dilemmas such as decisions not to treat, to discontinue treatment, or treat against the patient's wishes.	Verify leadership plays an active role in resolving ethical dilemmas. The primary goal is to verify the existence of a defined, accessible, and effective process that ensures ethical dilemmas are escalated to leadership promptly and resolved in a manner that protects patient rights, safety, and well-being. **Evaluating Compliance:** Review policies for: Procedures for step-by-step system for identifying, reporting, escalating, and resolving ethical dilemmas Defined roles/responsibilities for leadership involvement Defined timeframes for resolution Review any documentation of past ethical dilemmas for evidence of: Timely escalation to leadership Discussions and rationales for final decision and resolution Review QI meeting minutes and GB documents for evidence that ethical dilemmas are received, discussed, and resolved by leadership.
10-C-11	A policy should document the competencies of staff handling specialized equipment.	Verify all staff operating specialized equipment have been assessed and documented as proficient, minimizing risk to patient and staff safety and ensuring the equipment is used correctly and effectively. **Evaluating Compliance:** Review policies for: Process for initial and ongoing competency assessment for staff using all specialized equipment Criteria for determining which equipment requires validated competency Method of competency validation/frequency (e.g., upon hire, annually, after new equipment is introduced) Documentation standards (e.g., training logs, competency assessments in personnel file) Interview clinical staff and managers regarding: Specific pieces of equipment requiring competency validation Reporting process for insufficient competency or if they have not been trained on a new device Review personnel files for evidence of:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Competency assessments that align with the policy requirements for each type of equipment used Cross-reference list of specialized equipment with staff competency.
10-C-12	A system is in effect for documenting, reporting, and follow-up on any patient and family complaints and grievances. Complaints and grievances must be formally addressed at Quality Improvement meetings. The complaints must be addressed by appropriate staff with the patient/family even if no immediate resolution is available.	Verify all patient and family complaints and grievances are captured in a consistent, formal system that guarantees they are documented, investigated, addressed with the patient/family, and used for organizational learning and quality improvement. **Evaluating Compliance:** Review policies for: Procedures for receiving, documenting, classifying, investigating, and responding to patient/family concerns Required timeframes for responses and escalation Specification of staff roles/responsibilities Mandate to review complaints at QAPI meetings Review complaint logs for evidence of: Documentation of complaints and evidence of investigation Follow-up communication with the patient/family Adherence to defined response timeframes Review QI meeting minutes and GB documents for evidence of complaint data, investigation, resolution Interview staff regarding: Awareness of routine complaint versus formal grievance Reporting mechanisms for complaints.
10-C-13	The facility must have a written policy to make their complaint process publicly available, via posting within the facility, on the website, by distribution to patients, or through other means that eliminates barriers to patient awareness of such process.	Verify the facility provides clear communication of the complaint process, by posting procedures within the facility, on the website, by distribution to patients, or through other means that eliminate barriers to patient awareness of such process. **Evaluating Compliance:** Interview staff regarding how the complaint reporting process is disclosed to patients (e.g., clearly posted within the facility, written information given to patients at admission, on the website) Observe the patient admission process to confirm that patients are made aware Inspect waiting areas for evidence of postings (if applicable).
Sub-section D: Peer Review		
10-D-4	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.	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. **Evaluating Compliance:** Review of policies for requirement that:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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.
10-D-12	To be compliant, a copy of a Business Agreement must be signed by each physician working outside the facility participating in peer review, and a copy must be retained on file in the facility.	To ensure all external physicians participating in the facility's peer review process are legally bound by a Business Agreement (BA) that defines the terms of their engagement, protects confidential information, and formalizes their role in quality improvement activities. This safeguards the integrity of the peer review process and ensures compliance with contractual and regulatory obligations. **Evaluating Compliance:** Review policies for: Procedures related to peer review and contractor agreements Mandate the execution of a BA with external peer reviewers prior to their participation in activities Specify record retention requirements. Review documents to ensure compliant external peer review process: Master BA document contains essential elements, such as: scope of services, confidentiality clauses, terms, and data protection provisions. Obtain a list of all external physicians who've participated in peer review: Audit individual files to confirm a BA is dated/signed prior to involvement in peer review activities Interview the Medical Director, Quality/Compliance coordinator, Administrative Director, or individual responsible for managing peer review to assess their understanding/requirement for a BA with external peer reviewers.
10-D-13	If peer review sources external to the facility are used to evaluate the delivery of medical care, an agreement to conduct peer review is so written as to waive the confidentiality of the clinical records.	Verify, that when external entities or individuals are engaged to perform peer review, a formal agreement is in place that explicitly permits the sharing of confidential patient health information (PHI) for the purpose of quality review. **Evaluating Compliance:** Review policies for: Process for engaging external reviewers Mandates the use of an agreement containing confidentiality waiver Requires the agreement to be fully executed prior to any review of clinical records Review language in external peer review agreement for specific contractual language: Waiving confidentiality for clinical records solely for the purposes of conducting the peer review activity Precise, unambiguous, and compliant with applicable privacy laws Review documents for external peer review to ensure:

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		Fully executed agreement containing the explicit confidentiality waiver is on file Date of agreement/signature precedes the date of record sharing Interview staff and leadership regarding: Legal and regulatory necessity for the confidentiality waiver for external peer review Ability to articulate the process for ensuring the correct agreement is on file before access to clinical records.
10-D-14	Peer review may be done by a recognized peer review organization or a physician, podiatrist, or oral and maxillofacial surgeon other than the operating surgeon.	Verify peer review is conducted objectively by a qualified, independent entity or individual who is not the operating surgeon, thereby promoting impartial evaluation, minimizing bias, and fostering meaningful quality improvement. **<u>Evaluating Compliance:</u>** Review policies for: Procedures defining who is authorized to perform reviews Alignment with any state-specific regulatory exceptions Review documents for peer reviewer credentials and ensure reviewers are authorized: Physician from a recognized external organization *-OR-* A physician, podiatrist, or oral and maxillofacial surgeon with appropriate credentials who was not the operating surgeon for the case(s) being reviewed Review documents of peer review records to ensure they: Include all required elements as defined by facility policy Demonstrate a thorough, objective evaluation Review QI meeting minutes and GB documents for evidence of: Process for selecting reviewers ensures independence and objectivity. Peer review findings are reviewed Interview the Medical Director, Quality coordinator, and participating peer reviewers regarding how reviewers: Are selected (recognized external organization, internal independent peer reviewer) Maintain their independence from the cases they review.
10-D-15	Peer review is conducted and contains, at a minimum, the following review of each clinical record subject to peer review: • 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 • Documentation of the discussion of any complications	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. **<u>Evaluating Compliance:</u>** 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:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		Discussions address deficiencies (or exceptions) related to the seven elements Corrective actions are documented Interview the Medical Director, Quality coordinator, and participating peer reviewers regarding: Seven elements required for review and the criteria for "adequacy" in each category How peer review findings are used to improve documentation practices.

SECTION 11: PERSONNEL

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Personnel		
11-A-2	All personnel are provided with a code of ethics or behavior that governs their conduct when communicating with fellow staff or the public.	Verify every member of staff is formally introduced to a clear set of behavioral expectations, promoting a respectful, professional, and ethical workplace culture. The goal is to proactively define and prevent misconduct in all communications, thereby protecting staff well-being, patient satisfaction, and the organization's reputation. **Evaluating Compliance:** Review policies for: Facility's official "Code of Conduct" or "Code of Ethics" Addressing expected behaviors in internal and external communications Interview staff to assess regarding their understanding of: Facility's Code of Ethics/Conduct and its application Key behavioral expectations, especially related to respectful communication with colleagues and patients Reporting process for observed violations Review training curricula to confirm content on the Code of Conduct Review personnel files for evidence that each individual has received, understood, and agreed to abide by the Code of Conduct.
Sub-section B: Medical Director & Facility Director		
11-B-7	The Facility Director must be actively involved in the direction and management of the facility.	Verify the Facility Director is substantively engaged in the operational, clinical, and strategic leadership of the facility, providing consistent oversight and accountability. **Evaluating Compliance:** Review documents to determine Facility Director's active involvement: 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.

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
11-B-8	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.	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. **Evaluating Compliance:** Review specific policy in question to confirm it: Explicitly assigns the monitoring responsibility to the Facility Director Outlines methods for this oversight Review documents demonstrating active monitoring by the Facility Director's, including: 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: Facility Director's monitoring activities lead to concrete actions, policy revisions, or staff education Interview staff regarding: Awareness of policy requirements and understanding that Facility Director is responsible for compliance Corroboration that monitoring and feedback routinely occur Confirm the Facility Director's ability to describe their specific monitoring process for this policy, including the frequency, methods, and recent findings.
11-B-10	The Medical Director must be involved in planning and budgeting for the facility's range of services.	Verify the Medical Director provides essential clinical input into strategic resource allocation, aligning financial planning with patient safety and quality care delivery. **Evaluating Compliance:** Review documents for evidence of Medical Director (Med Dir) participation in facility operations, including: Strategic plans for developing budgets (equipment procurement, staffing) Governing Body meeting minutes (discussions on service expansion) Interview administrative leadership to assess the Director's involvement in the planning process Confirm that administrative leaders recognize this contribution Interview the Medical Director regarding how clinical needs inform budgetary decisions.
11-B-11	The Medical Director signs an Attestation that the direction and management of the facility is under his/her management.	Verify the Medical Director has formally accepted of legal and operational responsibility for the facility's clinical direction and management. **Evaluating Compliance:** Review the attestation form in the Medical Director's file to confirm: It is signed, dated, and specific to their management role The attestation's language matches governing body requirements Interview the Medical Director regarding their acceptance of direct responsibility for the facility's management and clinical direction.

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11-B-12	The Medical Director must ensure that the facility meets all local, regional and country regulations including those relating to employment health and safety, building, environmental protection, reportable diseases, and waste management.	Verify the Medical Director is held accountable for the facility's comprehensive regulatory compliance, ensuring a safe, lawful, and ethically operated environment for patients and staff. **Evaluating Compliance:** Review policies, audit reports, and inspection certificates (e.g., fire safety, biomedical waste, OSHA) to: Verify compliance with applicable regulations Review meeting minutes to confirm the Medical Director's participation in action plans for regulatory issues Confirm the Medical Director's job description includes oversight for regulatory compliance.
11-B-13	The Medical Director shall document the strategic plan for the facility.	Verify the Medical Director provides direct leadership in establishing the facility's clinical and operational goals, driving continuous quality improvement and strategic growth. **Evaluating Compliance:** Review administrative and governance policies for: Process for developing and documenting the strategic plan Mandate for approval by the Medical Director Review strategic plan document for Medical Director approval (signed, dated) Review Quality Assurance/Performance Improvement and leadership meeting minutes for: Evidence the strategic plan is actively used to guide decisions, resource allocation, and initiative planning Interview the Medical Director regarding their personal role in developing strategic plan and its key objectives.
11-B-14	The Medical Director should document the staffing levels and what qualifications are required for each position based on the services offered at the facility.	Verify the facility's staffing model is formally documented and rationally designed, with personnel qualifications directly matched to the clinical services provided, thereby ensuring patient safety and quality of care. **Evaluating Compliance:** Review the facility's written staffing plan to verify documentation of: Required positions, staffing levels, and specific qualifications for each role (e.g., licenses, certifications) Cross-reference the staffing plan with the facility's list of offered services to confirm alignment Interview the Medical Director regarding involvement in and understanding of the staffing plan Confirm hiring managers understand and implement these documented requirements.
11-B-15	The Medical Director must annually review credentialing and performance for all practitioners, staff and volunteers annually, including contract employees.	Verify the Medical Director provides active oversight of the competency and performance of all individuals within the facility, ensuring they are qualified to deliver safe and effective patient care. **Evaluating Compliance:** Review policies regarding credentialing and performance evaluation to confirm a requirement for: Medical Director review for all personnel categories (practitioners, staff, volunteers, contractors) At least annually Review Governing Body meeting minutes for evidence of: Discussions of annual review process Outcomes from the review Interview the Medical Director and HR/Credentialing Manager regarding the annual review process, including:

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		Any differences in performance reviews for employees versus contractors Examples of any recent actions taken Review personnel and credentialing files for evidence of the Medical Director's annual review and approval (e.g., signed forms, dated checklists, electronic approvals).
11-B-16	The Medical Director should review and maintain a record of the performance of all practitioners, staff and volunteers at least annually, including contract employees. This should include a record of corrective actions and educational activities.	Verify the Medical Director actively oversees and documents the ongoing competency and performance of all personnel to maintain quality care standards. **Evaluating Compliance:** Interview the Medical Director's regarding: Annual review process Examples of corrective actions implemented Confirm HR staff can demonstrate the Medical Director's active participation in the review system Review personnel files for evidence of annual performance review, including: Educational activities Corrective actions Medical Director's review and approval.
11-B-17	Each personnel file has evidence of general facility-specific orientation and training related to the individual's job duties.	Verify the facility provides all staff with facility orientation (e.g., safety protocols, patient rights, medical record security) and position-specific training (e.g., steam sterilization, environmental cleaning) to minimize risk to staff, ensure regulatory compliance, and improve patient safety and operational efficiency. **Evaluating Compliance:** Review policies for training requirements, including: Directive to provide facility orientation and position-specific training Specifying generalized orientation content (for all staff, contractors, and physicians) Interview leadership regarding: How/when is general orientation administered What material is reviewed with all staff (e.g., policies, safety protocols, patient rights) How position-specific training is administered (e.g., in-services, via preceptor) Review personnel records for evidence of: Training (initial/annual/updates for new facility policies) Competency validation for position-specific tasks (when applicable).
Sub-section C: Surgeons/Proceduralists/Etc.		
11-C-2	Procedures must be performed in a safe manner by qualified physicians, advanced practice registered nurses, physician assistants, or other licensed healthcare professionals who have been granted clinical privileges by the governing body in	Verify all procedures are performed safely by healthcare practitioners who are properly credentialed, privileged, and working within their legally authorized scope of practice. **Evaluating Compliance:** Review policies for credentialing/privileging healthcare practitioners for:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
	accordance within their scope of practice, state law, and approved policies and procedures of the facility.	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 (GB) setting scope of practice) Mandate that practitioners must practice within their delineated scope Interview schedulers regarding steps to ensure procedures align with delineation of privileges Review credentialing files for evidence of GB-approved delineation of clinical privileges Cross-check operative log with credentialing files to confirm cases by only privileged practitioners.
11-C-6	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.	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. **<u>Evaluating Compliance:</u>** 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.
11-C-8	Members of the medical staff, including both directly employed and contract medical staff, must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The facility grants privileges in accordance with recommendations from qualified medical/dental personnel.	Verify all members of the medical staff undergo a thorough credentialing process (including review of education, training, licensure, certifications, experience, and disciplinary history) to ensure professional qualification and competence and meet regulatory and accreditation requirements. **<u>Evaluating Compliance:</u>** 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:

Standard ID	Standard / Regulatory Reference	Interpretive Guidance
		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 Recommendation by qualified medical/dental peers (concerning practitioner's competence) Scope of privileges granted to the practitioner by the Governing Body (delineation of privileges) Rational for any privileges granted against peer recommendation (when applicable) Confirm re-credentialing is performed at least every three (3) years.
11-C-20	The practitioners shall be required to show evidence of hospital privileges including scope of practice relevant to the procedures performed in the facility.	Verify the scope of privileges granted to practitioners aligns with current hospital privileges, to ensure professional qualification and competence. **Evaluating Compliance:** Review policies for credentialing/privileging healthcare practitioners for: Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Requirement that practitioners have hospital privileges for the procedures requested 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 validation of hospital privileges Review credentialing files for evidence of: Current hospital privileges for the procedures requested by the practitioner Scope of privileges granted to the practitioner by the Governing Body (delineation of privileges) Confirm hospital and facility privileges align.
Sub-section D: Anesthesia Providers		
11-D-21	The qualified individual responsible for supervising the administration of anesthesia must have knowledge of anesthetics and resuscitative techniques appropriate for the type of anesthesia being administered.	Verify all staff, responsible for supervising the patient during anesthesia delivery, are competent to detect variances in patient stability and meet the patient's medical needs in case of an emergency. **Evaluating Compliance:** Review policies for: Alignment with any state or country 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 Review Governing Body meeting minutes for evidence of: Discussions and review of candidate qualifications Outcomes (approvals, denials) and delineation of privileges (including supervision)

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		Interview staff regarding protocols for physicians providing/supervising anesthesia care Observe practice to validate continuous presence of supervisor Review clinical records for evidence of: Name of person administering anesthesia (name, credentials) Documentation of physician supervisor (name, credentials) Review credentialing files for evidence of: Physician scope of privileges includes supervision of anesthesia administration Current ACLS certificate (must include skills verification).
Sub-section F: Nurse Staffing		
11-F-7	The Polyclinic has at least one (1) full time registered nurse and at least one (1) assistant nurse (AN).	Verify staffing schedules, employment records, and personnel files to confirm that the RN and AN positions are filled by qualified individuals who meet licensure and credentialing requirements and are scheduled as full-time staff. **Evaluating Compliance:** Review personnel files for the presence of licensure/certification Review staff schedules for the presence of an RN and a AN
Sub-section H: Personnel Records		
11-H-2	The facility maintains a manual outlining personnel policies that is reviewed annually and updated as needed.	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. **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)
11-H-4	The facility maintains a personnel file for all clinical and administrative employees, including direct and contract employees.	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. 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

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		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). **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.
11-H-5	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.	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 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. **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).
11-H-6	Each personnel record contains resume of training and experience.	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. **Evaluating Compliance:** Review personnel files for evidence of: Job application (for non-clinical staff) Resume or CV Specialized training certificates (or certifications) Confirm evidence of specialized training when essential to the position.
11-H-8	Each personnel record contains date of employment.	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. **Evaluating Compliance:** Review personnel files for evidence of date of hire (or contract commencement).
11-H-9	Each personnel record contains description of duties.	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,

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		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. **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).
11-H-10	Each personnel record contains on-going records of inoculations or refusals in accordance with local, state/provincial or federal/national requirements.	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. **Evaluating Compliance:** Review policies for: Alignment with state-specific requirements for vaccinations Alignment with state-specific requirements for Tb screening/testing Acceptable vaccine records (documented injections, vaccine registry records, titer level, declination) Review personnel files for evidence of vaccination administration or refusal.
11-H-12	Each personnel record contains current certification or license if required by the state, province, region, or country.	Verify the personnel file includes documentation of current certification or license (when required) to verify qualifications, maintain compliance with state, province, regional or country regulations, and ensure patient safety. **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).
Sub-section I: Personnel Training		
11-I-1	Each personnel record has evidence of annual hazard safety training.	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 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.

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		Evaluating Compliance: 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.
11-I-2	Each personnel record has evidence of annual blood borne pathogen training.	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 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. **Evaluating Compliance:** 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.
11-I-3	Each personnel record has evidence of annual standard precaution training.	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. Online training courses are acceptable when the content is reviewed/approved by the facility annually. **Evaluating Compliance:** Review personnel files for evidence of annual standard precaution training for all clinical staff.
11-I-4	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.	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. **Evaluating Compliance:** Review training materials to ensure content is comprehensive for a healthcare facility, at a minimum including: 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) Review personnel files for evidence of annual fire safety training for all staff.
11-I-5	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	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

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	Life Support (PALS) for each operating room and PACU team member, depending on the patient population served.	sufficient BLS certification (initial, ongoing) must be intended for healthcare professionals (not lay people) and include a didactic component *and* a hands-on skills check ACLS (and/or PALS) certification (initial, ongoing) must be obtained from the American Heart Association (or equivalent) that includes a didactic component *and* a hands-on skills demonstration of airway management and automated external defibrillator (AED) use 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. **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.
11-I-10	The operating room personnel are familiar with the equipment and procedures utilized in treating emergencies, as discussed in standards section 5-C: Emergency Protocols.	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. **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).
11-I-13	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.	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 accessed initially and periodically. **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).

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11-I-15	Operating room personnel have adequate knowledge to treat malignant hyperthermia, cardiopulmonary resuscitation, and anaphylactic emergencies.	Verify all operating room personnel receive emergency training to enable swift, coordinated responses to medical emergencies, including Malignant Hyperthermia, Cardiopulmonary Resuscitation, and Anaphylaxis. 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. **Evaluating Compliance:** Review training materials for required content Interview OR staff regarding: Emergency responses (activating a code, when to contact EMS, use of resuscitation forms) Location of emergency items (e.g., crash cart with ACLS drugs, MH drugs, succinylcholine) Process for patient transfer to the hospital Review personnel files for evidence of training (initial, annual, updates).
11-I-16	Health care professionals providing dental, surgical, and anesthesia services are prepared to respond to medical emergencies that may occur in conjunction with the services provided.	Verify all healthcare professionals providing dental, surgical, and anesthesia services receive emergency training to enable swift, coordinated responses to medical emergencies common to the services provided. The facility must provide training upon hire (or when contracted staff begin working in the facility), annually, and when updates to emergency response protocols are updated. **Evaluating Compliance:** Review training materials to confirm content aligns with risks from facility services Interview OR staff regarding: Emergency responses (activating a code, when to contact EMS, use of resuscitation forms) Location of emergency items (e.g., crash cart with ACLS drugs, MH drugs, succinylcholine) Process for patient transfer to the hospital Review personnel files for evidence of training (initial, annual, updates).

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)(I) 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

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