

2023 EDITION



# ACCREDITATION REQUIREMENTS FOR OFFICE-BASED SURGERY



# Foreword

## How We Work

Accreditation Commission for Health Care, Inc. (ACHC) offers healthcare organizations an objective, standards-based review of the services they provide using an educational approach. We support improvement in patient care and safety by sharing knowledge and expertise.

ACHC offers a range of accreditation programs to meet the needs of organizations across the continuum of care. This manual is intended for use by those offering surgical/procedural services in a business occupancy or office-based setting (OBS). Our goal is to help each organization maximize its potential to improve outcomes for its specific patient population. We recognize that organizations may find a variety of ways in which to comply with the accreditation requirements. For example, an independent practice may assign multiple responsibilities to a single individual or contract with external sources to provide needed expertise. Either approach can be fully compliant; our goal is to confirm that required policies are relevant to the organization, and that patient care and related operational practice follows these as defined.

The ACHC process supports customer success throughout the accreditation cycle: before, during, and after the onsite survey.

## Account Advisors

Each organization is assigned an Account Advisor to serve as the primary point of contact with our office. Your Account Advisor will answer process and billing questions, provide helpful timeline and documentation resources, and serve as your contact when you report changes within your organization.

## Standards Interpretation

Clinical Review Specialists are easily accessible by phone or email to respond to questions about applicability of standards or interpretation of requirements. They will help you understand deficiencies identified during an ACHC survey and how to develop an effective Plan of Correction.

## Using the Manual

We recommend that you use this manual as a tool for on-going self-assessment of your organization's adherence to the standards. This ensures that your organization is always ready for external review and avoids the need for a flurry of "ramp up" activities in anticipation of a survey. More importantly, periodic self-assessment supports a culture of quality with regard to your ability to render care safely and effectively. At their core, these standards represent a validated risk-reduction strategy for the organization. Compliance will not prevent every adverse event but will diminish the likelihood of their occurrence.

## Standards Format

Chapters 1–16 of this manual describe the requirements that must be met for accreditation. Each requirement has four components:

- 1 STANDARD** states the requirement to be met.
- 2 SCORE** identifies the compliance evaluation options available for the standard.
- 3 REQUIRED ELEMENTS/ADDITIONAL REQUIREMENTS** provides further detail.
- 4 SURVEY PROCEDURE** identifies what ACHC Surveyors will review to assess compliance.

ACHC		CHAPTER 01. GOVERNING BODY	
<b>Standard 01.00.01</b>	<b>1</b>	Score:	<b>2</b>
<b>Legal Entity</b>		<input type="radio"/> C	<input type="radio"/> NC
The organization is a legal entity or a defined subcomponent of a legal entity and meets applicable governmental laws.			
<b>Required Elements/Additional Information</b>		<b>Notes</b>	
The organization maintains documentation to support that it is compliant with applicable laws and regulations regarding its designation as a healthcare entity.			
The legal entity may be incorporated (including an S-corporation), a sole proprietorship, a limited liability company, or other legally organized professional group.			
The organization seeking accreditation may be a defined subcomponent of a larger legal entity. The subcomponent does not need to be its own legal entity. There must be documentation defining the subcomponent.			
The organization seeking accreditation, whether a legal entity or subcomponent thereof, must have its own policies and procedures.			
<b>SHARED STAFFING AND PHYSICAL SPACE</b>			
If the organization's nursing or other staff provide shared services with or to other organizations, the organization seeking accreditation must independently comply with all requirements governing the organization.			
<b>Survey Procedure</b>			
<b>Interview and Document Review</b>			
<ul style="list-style-type: none"> <li>■ Determine whether it is permissible under licensure or related requirements for an organization to share its physical space with another entity.</li> <li>■ Where permitted under licensure and regulations, if the organization shares physical space with another healthcare provider and there are similarities that are common to the accredited organization and the other healthcare provider, citations must be issued to the accredited organization.</li> </ul>			
<b>Standard 01.00.02</b>		Score:	
<b>Compliance with Laws and Regulations</b>		<input type="radio"/> C	<input type="radio"/> NC
The organization must comply with applicable licensure, permit, certification, and/or registration requirements.			
<b>Required Elements/Additional Information</b>		<b>Notes</b>	
The organization maintains documentation of licensure, permits and certifications, and registrations, as applicable, including reports of inspections.			

## Meeting the Standard

Each standard is identified by an ACHC Surveyor as Compliant or Not Compliant. Some standards may include an option of 'Not Applicable' based on the scope of services offered by the organization.

**COMPLIANT (C)** indicates that there is evidence that the organization fully meets the requirement.

**NOT COMPLIANT (NC)** indicates there is less than full compliance with the requirement or no evidence of compliance with the requirement.

**NOT APPLICABLE (NA)** indicates that the standard does not apply to the organization being surveyed.

## Reference to Days

Time frames indicated in "days," refers to calendar days. When the time frame is limited, i.e., Monday through Friday, we will use the term "business days."

## Chapter Introductions

At the beginning of some chapters, introductory information is included to describe the basis of that chapter's standards in order to determine applicability. These chapters are:

- |                                      |                         |                           |
|--------------------------------------|-------------------------|---------------------------|
| 07. Emergency Management             | 10. Surgical Services   | 14. Radiological Services |
| 09. Patient Assessment and Discharge | 11. Anesthesia Services | 16. Life Safety           |
|                                      | 13. Laboratory Services |                           |



# Table of Contents

Foreword.....	i
Table of Contents.....	iii
01 Governing Body.....	1
02 Administration .....	13
03 Professional Staff.....	25
04 Quality Assessment and Performance Improvement.....	37
05 Infection Prevention and Control .....	53
06 Patient Rights.....	73
07 Emergency Management.....	87
08 Healthcare Records.....	101
09 Patient Assessment and Discharge.....	107
10 Surgical Services.....	123
11 Anesthesia Services.....	139
12 Pharmaceutical Services.....	149
13 Laboratory Services.....	161
14 Radiological Services.....	175
15 Physical Environment.....	185
Appendix	
16 Life Safety.....	211
Glossary and Acronym List.....	239



01

**GOVERNING  
BODY**



**Standard 01.00.01  
Legal Entity**

Score:  
 C  NC

The organization is a legal entity or a defined subcomponent of a legal entity and meets applicable governmental laws.

**Required Elements/Additional Information**

Notes

The organization maintains documentation to support that it is compliant with applicable laws and regulations regarding its designation as a healthcare entity.

The legal entity may be incorporated (including an S-corporation), a sole proprietorship, a limited liability company, or other legally organized professional group.

The organization seeking accreditation may be a defined subcomponent of a larger legal entity. The subcomponent does not need to be its own legal entity, but there must be documentation defining the subcomponent.

The organization seeking accreditation, whether a legal entity or subcomponent thereof, must have its own policies and procedures.

**SHARED STAFFING AND PHYSICAL SPACE**

If the organization’s nursing or other staff provide shared services with or to other organizations, the organization seeking accreditation must independently comply with all requirements governing the organization.

**Survey Procedure**

**Interview and Document Review**

- Determine whether it is permissible under licensure or related requirements for an organization to share its physical space with another entity.
- Where permitted under laws and regulations, if the organization shares common space with another healthcare provider and there are deficiencies that are common to the accredited organization and the other healthcare provider, citations must be issued to the accredited organization.

**Standard 01.00.02  
Compliance with Laws and Regulations**

Score:  
 C  NC

The organization must comply with applicable licensure, permit, certification, and/or registration requirements.

**Required Elements/Additional Information**

Notes

The organization maintains documentation of licensure, permits and certifications, and registrations, as applicable, including reports of inspections.



The survey focuses on current compliance. For an organization that has corrected an issue prior to the survey and demonstrates compliance with the standards at the time of the survey, the organization will be assessed on the current compliant activity. If the organization has identified an issue and begun corrective actions but is not yet in compliance at the time of the survey, the standard will be assessed as noncompliant.

**Survey Procedure**

**Document Review**

- Determine prior to the survey whether a license, permit, certification, registration, or other regulatory authorization is required for the organization.
  - » If there is access to regulatory files, review the organization's regulatory approval status. Otherwise, review the organization's regulatory authorization to practice, if applicable.

**Standard 01.01.01  
Governing Body**

Score:  
 C  NC

The organization must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies and procedures governing the organization's total operation.

**Required Elements/Additional Information**

Notes

A designated governing body exercises oversight and retains ultimate responsibility for all organization activities.

The governing body responsibilities include but are not limited to:

- Establishing written policies and procedures that govern all operations within the organization.
- Ensuring that the policies and procedures are implemented.
- Monitoring internal compliance with the organization's policies and procedures.
- Assessing those policies and procedures periodically to determine whether they need revision.
- Directly overseeing:
  - » The organization's written quality assessment performance improvement (QAPI) program with the goal of improving patient care.
  - » The quality of the organization's healthcare services.
  - » The safety of the organization's environment.
  - » Development and maintenance of a written emergency management plan.

**ORGANIZATIONS WITH A SINGLE OWNER**

If the organization has one owner, that individual constitutes the governing body unless a governing body with multiple members is established.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- How frequently the governing body meets and the typical items on its meeting agendas.
- The organizational chart. Identify who provides management of each of the departments.

Verify:

- Meeting minutes or other evidence shows that the organization’s policies and procedures have been formally adopted by the governing body.
- Meeting minutes or other evidence shows how the governing body ensures that its policies and procedures are implemented, how it monitors internal compliance, and reassesses the organization’s policies and procedures.
  - » For example, is there evidence of data collected and submitted to the governing body related to specific organization policies and procedures?
- Meeting minutes or other evidence shows how the governing body exercises ongoing oversight of and accountability for the organization’s QAPI program.

**Standard 01.01.02  
Governing Body Responsibilities**

Score:  
 C    NC

The organization must have written bylaws or a similar document that sets forth the governing body’s roles and responsibilities.

**Required Elements/Additional Information**

Notes

Written bylaws (or a similar document, such as policies) define:

- How members of the governing body are selected, the number of members, terms in office, duties, and procedures for removal.
- Frequency of governance meetings and a requirement to maintain meeting minutes reflecting attendance and deliberations leading to actions.
- Responsibility for, at least:
  - » Adoption and review of governance bylaws/policies.
  - » Implementation of the financial accounting system.
  - » Review and action on all legal and ethical matters as they relate to the organization and its staff.





- » Establishing a non-discrimination policy regarding race, creed, gender, and national origin that applies to staff and patients and is in compliance with applicable non-discrimination law.
- » Provision of resources adequate for safe, quality care including, but not limited to:
  - Personnel.
  - Equipment and supplies.
  - Safety of the environment.
  - Disaster preparedness.

**Survey Procedure**

**Interview**

Verify:

- By interviewing the person responsible for compliance, that all requirements are met.

**Standard 01.01.03  
Approval of the Scope of Procedures**

Score:  
 C  NC

The governing body approves the written scope of procedures performed and anesthesia/sedation administered in the organization. The scope of procedures performed and anesthesia/sedation administered must be periodically reviewed at least every three years with changes to the written scope approved by the governing body.

**Required Elements/Additional Information**

Notes

The governing body has defined, in writing, the time frame for review of the scope of procedures and anesthesia/sedation administered in the organization and requires review at least every three years. If the scope changes, the written scope must be amended to reflect the changes and approved by the governing body.

Documentation of approvals and for added procedures and types of anesthesia/sedation include at a minimum:

- Age-specific criteria.
- Surgical or procedural risk.
- Limitations based upon assigned personnel and/or equipment.
- Competency and scope of practice for personnel.
- Equipment available.
- That each laser type or other light emitting devices (LEDs) (e.g., LEDs for skin cancer therapy) available at the organization and the procedures approved for its use in the facility is based on the manufacturers' recommendations.

<b>Survey Procedure</b>
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The governing body has defined the time frame for review.</li> <li>■ Governing body meeting minutes confirm approval of procedures and that all required elements were considered.</li> </ul>

<b>Standard 01.01.04 Accounting System</b>	<p>Score:</p> <p><input type="checkbox"/> C <input type="checkbox"/> NC</p>
--	---

The governing body approves a financial accounting system, including a short- and long-term budgeting and financial management system that adequately addresses the resource needs of the organization based upon the approved scope of services, and is prepared according to generally accepted accounting principles.

<b>Required Elements/Additional Information</b>	Notes
<p>The governing body reviews reports generated from the financial management system.</p> <p>The organization may contract for financial accounting and management services, including:</p> <ul style="list-style-type: none"> <li>■ Bookkeeping.</li> <li>■ Assistance in development of procedures for billing and accounting systems and/or development of an operating budget.</li> <li>■ Purchase of supplies in bulk form.</li> <li>■ The preparation of financial statements.</li> </ul> <p>A financial management system prepared according to generally accepted accounting principles may require annual financial audits. The governing body receives a report of the results of the annual audit and approves the report following review. Recommendations made in the audit, such as updates to the budgeting system, are made, as necessary.</p>	

<b>Survey Procedure</b>
<p><b>Interview and Document Review</b></p> <p>Discuss and assess:</p> <ul style="list-style-type: none"> <li>■ The organizational budget, the budgeting system, and the financial planning and management process with the leadership designated with overseeing the finances.</li> </ul> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has had an annual review of the accounting system.</li> <li>■ Annual reports have been submitted to the governing body.</li> </ul>



<b>Standard 01.01.05 Organizational Leadership</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The governing body establishes a leadership structure to support the operations of the organization.

The governing body selects administrative leadership to whom it delegates day-to-day operational oversight.

Required Elements/Additional Information	Notes
--	-------

The governing body delegates day-to-day operational responsibilities to administrative, financial, healthcare, or other personnel. Delegations of governing body authority are documented for each leadership position, which has a written position description that specifies:

- The education, experience, and other required qualifications for the role.
- The duties, responsibilities, and authority of the role.
- A letter of appointment.

The leadership team may include (but is not limited to):

- Chief Executive Officer, Administrator, or equivalent.
- Medical Director or Service/Clinical Director(s).
- Manager/Director for nursing and/or other patient care staff.
- Other management members.

If the organization has a CEO, an appropriate staff member is designated, in writing, as responsible for operational oversight of the organization in the absence of the CEO.

### Survey Procedure

#### Interview and Document Review

Verify:

- The organizational chart addresses leadership positions.
- Position descriptions approved by the governing body address the qualifications and responsibilities of each leadership position.
- Criteria for selecting and evaluating these individuals are based on the written position descriptions. Single-owners may serve in the role of governing body and administrative leadership, if qualified.

Discuss and assess:

- With a member of the governing body (if possible), how responsibility is delegated and accountability is established.
- With various staff members, the delegation of duties and the accountability process.
- With various staff members, how a leadership absence is

communicated and who is in charge during that time.

**Standard 01.01.06  
Clinical Director**

Score:  
 C  NC  NA

When appropriate, the governing body appoints a clinical director and defines the clinical director's qualification and management responsibilities in a written position description.

**Required Elements/Additional Information**

Notes

A licensed healthcare professional appointed to this position provides direct, day-to-day oversight of all health care provided and is responsible to the governing body.

If the organization is owned and operated by a solo healthcare professional, a formal appointment as clinical director is not necessary.

**Survey Procedure**

**Document Review**

Verify:

- If the organization has a clinical director, there is a written position description that identifies the qualifications, duties, and responsibilities, and a letter of appointment to this position.
- The clinical director meets the criteria established by the governing body in the position description.

**Standard 01.02.01  
Contract Services**

Score:  
 C  NC

When services are provided through a contract, the governing body must ensure that these services are provided in a safe and effective manner.

**Required Elements/Additional Information**

Notes

The organization may contract with third parties for the provision of services, including maintenance of the organization's environment. Such a contract does not relieve the governing body from its responsibility to oversee delivery of these services and that the contract services are provided safely and effectively.

Contractor services must be included in the organization's QAPI program to measure the quality of the services provided and to ensure the contract requirements are met.

Examples:

If the organization contracts for cleaning services, including its ORs/procedures rooms,

- The governing body is responsible for the sanitary condition of the organization and must exercise oversight of its contractor to ensure that standard sanitary practices are employed.

If the organization contracts for the provision of nursing services,

- The organization remains responsible for ensuring that all contract nurses are properly licensed, trained, and oriented to perform their duties within the organization.
- The organization is responsible for the direction of nursing staff, regardless of whether they are employees or provided under contract.

If the organization contracts for the provision of anesthesia services,

- The organization remains responsible for reviewing the credentials of all anesthesia professionals providing anesthesia services and grants them privileges to do so.

If the organization contracts for the provision of receptionist services (e.g., with an associated, adjacent physician practice),

- The organization is responsible for ensuring that such services are provided in a manner that complies with the requirements for patients' rights.

**Note:** If employees of an entity other than the organization perform services while the organization is in operation, and the organization has no contract or other formal documentation of an arrangement with the other entity that governs the provision of such services, then the governing body fails to exercise its responsibility for the administration of the organization's programs.

## Survey Procedure

### Interview and Document Review

Discuss and assess:

- How the organization evaluates the safety and effectiveness of the services provided by each contractor, including how contractor services are incorporated into its QAPI program.
  - » Select several contractors from the list and ask for documentation of the most recent evaluations.
- The process used to correct deficiencies in contracted services.
  - » Ask if there are any cases in which an organization has identified deficiencies and taken corrective action. If so, review documentation of these cases.

Verify:

- There is a complete list of currently contracted services.
- Verify that credentials, privileges, evidence of education and training, periodic evaluation, etc., are maintained in the personnel files of contract personnel.

### **Note:** Shared Space

If the organization is one that shares space with other entities, verify whether it contracts or has some other formalized arrangement with any of those other entities for services when the organization is in operation.

**Standard 01.02.02  
Hospital Transfer Agreement**

Score:  
 C  NC

The organization must have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the organization. Requirements include:

- A current written transfer agreement with a hospital.

OR

- A policy that healthcare professionals performing procedures at the organization have admitting privileges at a local hospital.

OR

- A written agreement with a healthcare professional or healthcare professional group with admitting privileges at a local hospital.

OR

- Periodic written communication with a local hospital as to the organization’s scope of operations and the patient population served.

**Required Elements/Additional Information**

Notes

The organization must be able to transfer a patient immediately to a local hospital when the patient experiences a medical emergency that the organization is not capable of handling. A “local” hospital means the organization is to consider the most appropriate facility to which it will transport a patient in the event of an emergency.

An “effective procedure” encompasses:

- Policies: Written policies and procedures address the circumstances warranting emergency transfer, including who makes the transfer decision, the documentation that must accompany the transferred patient, and the procedure for accomplishing the transfer safely and expeditiously including communicating with the receiving hospital.
  - » There must be evidence that staff are aware of and can implement the organization’s policy immediately upon the development of a medical emergency.
- Provision of emergency care and initial stabilizing treatment within the organization’s capabilities until the patient is transferred.
- Arrangement for immediate emergency transport of the patient. (It is acceptable if the organization contacts the ambulance service via 911 to arrange emergency transport unless applicable law requires additional arrangements, but the organization is responsible for communicating with the receiving hospital to facilitate the transfer.)

**TRANSFER AGREEMENT**

A transfer agreement is a written agreement, signed by authorized representatives of the organization and the hospital, in which the

hospital agrees to accept the transfer of patients who need inpatient hospital care, including emergency care. Generally, transfer agreements establish the respective responsibilities of each party to the agreement, such as the process for arranging a transfer, etc.

A transfer agreement may have an expiration date, or it may have terms stating that it remains in effect until and unless one of the parties has terminated the transfer agreement.

#### **HEALTHCARE PROFESSIONALS WITH HOSPITAL PRIVILEGES**

If the organization does not have a written transfer agreement, this standard may be met by each healthcare professional performing an invasive procedure having admitting privileges at a local hospital. The organization must have a policy requiring privileges at a location hospital.

Alternatively, the organization may contract with a healthcare professional or healthcare professional group that has privileges at a local hospital. The contract must address the admitting responsibilities of the healthcare professional or healthcare professional group and ensure that the responsibility is for 24/7.

#### **TRANSFER WITHOUT A TRANSFER AGREEMENT OR HEALTHCARE PROFESSIONALS WITH ADMITTING PRIVILEGES**

If a written transfer agreement is not in place, the organization must communicate, in writing, with the local hospital describing its operations and the patient population it serves. The written communication is updated at least annually and when significant changes occur such as the addition of new services. The description of operations and patient population must include, but is not limited to, specialty and types of procedures, level of anesthesia, and demographic and clinical characteristics of the patient population served (e.g., pediatric, adult, geriatric).

#### **EMERGENCY MANAGEMENT TRANSFERS**

Sharing patient information with other healthcare providers is critical during an emergency, especially when patient transfer and evacuation is conducted. The organization must have a method that allows information to be shared in a timely and efficient manner.

Organizations should not delay patient transfers during an emergency to assemble all patient reports, tests, etc., to send with the patient. Organizations are expected to send all necessary patient information that is readily available and should include, at least, patient name, age, date of birth, allergies, current medications, medical diagnoses, blood type, advance directives, and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information.

## Survey Procedure

### Interview and Document Review

Verify:

- If the organization has a transfer agreement with an appropriate local hospital, it has not been terminated by either party.
- If the organization does not have a transfer agreement with an appropriate local hospital, each proceduralist who has privileges to perform procedures in the organization has admitting privileges in an appropriate local hospital. Discuss how the organization ensures that its information is up-to-date.
- If the organization has neither a written transfer agreement nor physicians with admitting privileges at the receiving hospital, there is evidence of annual written communication.
- Policies and procedures for emergency transfer of patients address the essential elements.

Discuss and assess:

- With clinical staff, how a patient medical emergency would be managed.
  - » Do they know the policies and procedures for emergency transfer?
  - » If required by law, identify efforts made to arrange emergency transport besides calling 911.
- Any emergency transfers of patients in the previous 12 months.
  - » If any, review the healthcare records of patients transferred to hospitals to confirm that they were transferred to hospitals that meet the requirements for a local hospital.
  - » If the organization transfers emergency cases to hospital(s) other than local one(s), review the rationale supporting these alternative transfers.





THIS PAGE IS INTENTIONALLY BLANK.



02

# ADMINISTRATION

<b>Standard 02.00.01 Administrative Leadership for Organization Oversight</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The administrator must report to the governing body and is responsible for the day-to-day operations of the organization.

<b>Required Elements/Additional Information</b>	Notes
---	-------

The administrator will prepare periodic reports as defined by the organization, including a summary of all significant occurrences for the governing body's review.

The administrator may delegate day-to-day operational responsibilities to appropriate designees. Delegations of responsibilities are documented in writing.

<b>Survey Procedure</b>	
-------------------------	--

**Interview and Document Review**

Discuss and assess:

- With the leadership, how they delegate responsibility and establish accountability.
- With staff members, the delegation of duties and the accountability process.
- How staff know when the administrator is absent and who is in charge during that absence.
- With the administrator, the latitude allowed in carrying out day-to-day duties.

Verify:

- Inclusion of the administrator reports in the governing body minutes.

<b>Standard 02.00.02 Administrative Leadership Responsibilities</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The administrative leader is responsible for carrying out all duties assigned or delegated to him/her by the governing body, which include, but are not limited to:

- Oversight of Quality Assessment/Performance Improvement.
- Monitoring and reviewing ethical behavior.
- Annual review and monitoring of patient rights.
- Evaluation of equipment.
- Establishment of a staff development program.
- Establishment of an emergency response protocol.

<b>Required Elements/Additional Information</b>	Notes
---	-------

There is demonstrated leadership support in the quality improvement process.

There is a process to monitor and review ethical behavior of all staff,

which includes adherence to professional ethics as defined by professional bodies and organizations to which the staff belong.

The administrator is responsible for observing staff to ensure compliance with patient rights.

The administrative leadership:

- Conducts periodic evaluation of the adequacy, appropriateness, state of repair, and quantity of facility equipment, and for planning and procuring equipment, as appropriate.
- Establishes a staff development program that includes, but is not limited to, initial orientation and opportunity for continuing job-related education.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- Governing body meeting minutes from the previous 12 months reflect that activities were conducted in response to governing body directives.
- The policy for ethical behavior, if appropriate, and how behavior is monitored.
- There is a staff development program.

Discuss and assess:

- With leadership, how the requirements for patient rights are met.
- With all levels of staff, their equipment needs and what input they have had in the equipment evaluation and procurement process.

Observe:

- Equipment for adequacy and state of repair.

**Standard 02.00.03  
Patient Care Services Director**

Score:  
 C  NC

The services of the organization must be directed and staffed to ensure that all patient care needs are met.

**Required Elements/Additional Information**

Notes

There must be sufficient staff with the appropriate qualifications to ensure the needs of all patients are met. There is ongoing assessment of patients' care needs and plans to meet identified needs.

If there is not a designated individual to provide oversight of the patient care services, policies and procedures provide guidance.

The number and types of staff needed depend on the volume and

types of procedures the organization performs. The supervision of non-licensed staff ensures that they have appropriate oversight by a designated individual.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The source of direction for patient care (e.g., individual or policies and procedures).
- Staff are appropriately qualified for the tasks they are asked to perform.

Observe:

- The staffing available for patients undergoing procedures during the survey is sufficient to address each patient’s needs.

**Standard 02.00.04  
Fraud and Abuse Assessment**

Score:  
 C  NC

The organization ensures there is an assessment of potential risks related to fraud and abuse. The assessment includes a periodic self-audit (at least yearly and more frequently if errors are found) to determine whether:

- Bills are correctly coded and accurately reflect the services provided.
- Services or items provided are reasonable and necessary.
- Healthcare records contain sufficient documentation to support charges

**Required Elements/Additional Information**

Notes

The purpose of the audit is to confirm compliance with accurate and appropriate billing and coding practices.

The identification of errors should result in changes in policy, training, and communication for the parties involved.

- A baseline audit establishes a consistent methodology for selecting and examining records, and this methodology serves as a basis for subsequent audits.

**Survey Procedure**

**Interview**

- By interviewing the person responsible for compliance, verify that all requirements are met.



<b>Standard 02.00.05</b> <b>Administrative Processes: Required Policies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization leadership has established policies addressing:

- Key administrative functions.
- Scheduling of appointments.
- Cancellation of appointments.
- Rescheduling of appointments.
- Patient portal messaging.
- Documentation of telephone or electronic messages including the date and time of the call, message, and timely forwarding to the appropriate individual.

Required Elements/Additional Information	Notes
<p>Policies should be sufficiently complete to serve as a ready reference for administrative personnel.</p> <p>The process for handling messages specifically addresses:</p> <ul style="list-style-type: none"> <li>■ Patient inquiries.</li> <li>■ Receiving messages.</li> <li>■ Recording messages.</li> <li>■ The timely forwarding of messages to the appropriate individual.</li> </ul>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has the required administrative policies.</li> <li>■ Through interview with administrative staff, that policies cover all areas of need.</li> </ul>	

<b>Standard 02.00.06</b> <b>Hours of Operation</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization has mechanisms that provide sufficient information for a patient with “after-hours” questions, including:

- Who to call/where to go for an emergency.
- What to do for routine care inquiries.

Required Elements/Additional Information	Notes
<p>Normal hours of operation are posted. The organization ensures that the after-hours information is accurate and appropriate for the scope of services and patient population served.</p> <p>The information is available when the patient visits the organization or contacts the organization electronically or by telephone.</p>	

<b>Survey Procedure</b>	
<b>Observation</b>	
<ul style="list-style-type: none"> <li>■ Phone the organization’s main number after hours to check for compliance.</li> <li>■ Look for posted hours of operation and signage suggesting where to go for after-hours care.</li> </ul>	
<b>Standard 02.01.01 Human Resources Policies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>The organization has written human resource (HR) policies and procedures that are:</p> <ul style="list-style-type: none"> <li>■ Reviewed annually by the administrator or designate.</li> <li>■ Available to each employee.</li> </ul>	
<b>Required Elements/Additional Information</b>	Notes
Policies address all government requirements and conditions of employment, including benefits, advancement, and evaluations.	
<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Written policies meet all elements of this standard.</li> <li>■ Policies and revisions have been reviewed annually by the administrator of the organization.</li> <li>■ Policies are accessible to the staff.</li> <li>■ Through staff interviews, that HR policies are familiar.</li> </ul>	
<b>Standard 02.01.02 Employment Requirements</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>The organization must verify that all employees, including contracted employees, meet applicable requirements for employment, including but not limited to:</p> <ul style="list-style-type: none"> <li>■ Licensure.</li> <li>■ Certification.</li> <li>■ Registration.</li> <li>■ Permits (such as food handler’s permits).</li> <li>■ Qualifications as defined in the job description.</li> </ul>	
<b>Required Elements/Additional Information</b>	Notes
<p>Primary source verifications are in place to conform to state practice acts and applicable governmental laws and regulations.</p> <p>Mechanisms are established to verify with the appropriate licensing agency all initial and renewal licenses, certificates, registration, and permits required to conform to state practice acts or government</p>	



regulations.

Practice in a facility by an individual without appropriate state license or certification is grounds for loss of accreditation by the facility.

New graduates provide services within the scope of their practice acts. If the applicable government regulations permit new graduates to function as “license pending,” all mandated provisions are enforced.

Healthcare providers whose licensure, certification, registration, or permit lapses or is placed under revocation, suspension, stipulation, etc., conform to all such provisions.

The state licensing or practice act is available to those responsible for ensuring compliance with regulations.

**Survey Procedure**

**Document Review**

Verify:

- The appropriate authority has validated all new personnel for licensure, certificate, registration, or permit renewals.
  - » This will include all disciplines defined in the state practice acts or association standards as requiring certification/licensure/registration for facility employment.
- The organization has established a policy and follows procedures for determining that all personnel meet the requirements of the job description.
- Facility policy is explicit regarding actions to be taken with examination failures and registration lapses/revocations/suspensions/stipulations.

**Standard 02.01.03  
Position Descriptions**

Score:  
 C  NC

The organization has written descriptions for all personnel positions including leadership, contract staff, and employees not covered by the credentialing and privileging of healthcare professionals.

Position descriptions include:

- Job title.
- Duties and responsibilities.
- Licensure, certification, or registration in accordance with applicable law and regulations, and consistent with state scope of practice.

**Required Elements/Additional Information**

Notes

Job descriptions are updated periodically to reflect the position’s tasks.

Job descriptions are provided to staff.



<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ Job descriptions include required items.</li> <li>■ By interviewing selected staff, that actual duties align with job descriptions.</li> </ul>	
<b>Standard 02.01.04 Adequate Staffing Requirements</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
The organization establishes staffing and training requirements to support all its functions, including: <ul style="list-style-type: none"> <li>■ Adequate staffing to carry out all administrative functions and approved clinical procedures.</li> <li>■ A mechanism for routinely assessing the adequacy of staff to meet the level of services offered.</li> </ul>	
<b>Required Elements/Additional Information</b>	Notes
Staffing reflects the scope of services. Considerations include the number of patients cared for when the organization is open and providing services.  Non-licensed personnel who work with patients are under the supervision of licensed staff.  The organization has adequate staff to perform administrative functions including, but not limited to, support for: <ul style="list-style-type: none"> <li>■ Services such as appointments, patient intake, retrieval and filing clinical records, and processing/submitting patient insurance claim information.</li> <li>■ Clinical activities including patient care, letters, dictation, and referral activities.</li> <li>■ Administrative functions including minutes of meetings, purchasing, billing, secretarial, administrative support, etc.</li> </ul>	
<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
Review and assess: <ul style="list-style-type: none"> <li>■ The organization's written policy that establishes staffing requirements. Review evidence of recruiting efforts.</li> </ul> Discuss and assess: <ul style="list-style-type: none"> <li>■ With selected staff, how staffing is evaluated for patient needs.</li> <li>■ The adequacy of staffing and where backup occurs. During walk-arounds, look for delays in patient intake, check-out process, and scheduling of follow-up appointments.</li> </ul>	



- How supervision of non-licensed personnel is achieved.

**Standard 02.01.05  
Personnel Records**

Score:  
 C  NC

The organization must maintain records for employee and contracted staff.

**Required Elements/Additional Information**

Notes

Personnel records contain basic personnel information received at time of hire and ongoing information including:

- Qualifications for the position including education, training, skills, and experience.
- Current license, certification, or registration, as applicable.
- Orientation.
- Competency assessments.
- Training provided (annual or as indicated).
- Evaluations.

Documentation is maintained for all employees and healthcare providers who have a time-limited license, certification, or registration. Employees and healthcare providers are required to notify the administrator of any lapses or revocation, suspension, stipulation, etc. In addition, if the organization becomes aware of any lapses, revocation, suspension, or stipulation, the employee is notified immediately upon receipt of this information and appropriate steps are taken to restrict activities as required.

Records are maintained to protect confidentiality of the information.

**Survey Procedure**

**Interview and Document Review**

Verify:

- All personnel have a personnel file.
- Contracted staff and temporary staff files include documentation of the required items.

**Standard 02.01.06  
Orientation Plan**

Score:  
 C  NC

The organization has a written orientation plan that includes:

- Ethics and corporate compliance, if applicable.
- Patient's rights.
- Fire safety.
- Quality improvement including adverse events.
- Assessment of patient's risk for self-harm.
- Patient confidentiality.
- Infection prevention and control, including blood-borne pathogens.

- Management of an incapacitated or impaired healthcare provider.
- Handling hazardous waste.
- Communication with outside entities.

Required Elements/Additional Information	Notes
<p>New employees receive orientation to the overall organizational policies and job-specific requirements.</p> <p>The organization has a written plan for the orientation of new employees.</p> <p>Policies define performance expectations that the employee must demonstrate to progress through and complete the training, and the time period for observation following the training to determine when the employee is capable of independently performing their duties.</p> <p>Staff are oriented on how to respond to inquiries from outside entities, including the media, inquiries about healthcare providers and employees, and critical events. Staff are trained on procedures when a regulatory or legal representative presents at the center, such as when serving a subpoena.</p>	
Survey Procedure	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ A written orientation plan addresses all standard requirements.</li> <li>■ Orientation was completed for all new employees.</li> </ul>	

<p><b>Standard 02.01.07</b> <b>Staff Training</b></p>	<p>Score:</p> <p><input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>The organization has a written plan for providing training when necessary and at least annually.</p>	

Required Elements/Additional Information	Notes
<p>Training may address results of competency assessments, quality reviews, peer review, personal requests, new procedures, or techniques, etc.</p> <p>At a minimum, annual training addresses the elements of orientation:</p> <ul style="list-style-type: none"> <li>■ Ethics and corporate compliance, if applicable.</li> <li>■ Patient's rights.</li> <li>■ Fire safety.</li> <li>■ Quality improvement, including adverse events.</li> <li>■ Assessment of patient's risk for self-harm.</li> <li>■ Patient confidentiality.</li> <li>■ Infection prevention and control, including blood-borne pathogens.</li> </ul>	



- Management of an incapacitated or impaired healthcare provider.
- Handling hazardous waste.
- Communication with outside entities.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The written training plan includes appropriate lesson plans.
- There is a process for assessing staff training needs.

Discuss and assess:

- Adequacy of training with selected personnel.

**Standard 02.01.08**

**Staff Training: Identification of Patients at Risk for Harm**

Score:

C  NC

Organization staff must be trained to identify environmental safety risks at the time of new employee orientation and annually thereafter.

**Required Elements/Additional Information**

Notes

Organizations must provide the appropriate level of education and training to staff regarding:

- The identification of patients at risk of harm to self or others.
- The identification of environmental, processes, people, materials, or equipment that pose patient safety risk.
- Mitigation strategies.

Staff training is provided for:

- Direct employees.
- Contractors.
- Per diem staff.
- Other individuals providing clinical care under arrangement.

Organizations have the flexibility to tailor the training to the particular services that staff provide and the patient populations they serve.

Organizations are expected to provide education and training to all new staff upon orientation:

- Whenever policies and procedures change.
- Annually, thereafter.

**Survey Procedure**

**Document Review**

Verify:

- The requirement is met with initial orientation and documented.

- The requirement is included with annual training and documented.
- Personnel files include documentation that employees receive this information during orientation and annually thereafter.

**Standard 02.01.09  
Employee Evaluations**

Score:  
 C  NC

The organization conducts employee appraisals to assess the individual's ability to perform job responsibilities. At a minimum, appraisals are conducted annually.

**Required Elements/Additional Information**

Notes

Annual employee appraisals are based on the job responsibilities in written job descriptions. These appraisals become a permanent entry in the personnel records.

Appraisals are conducted in accordance with applicable law and regulations.

**Survey Procedure**

**Document Review**

Verify:

- Organizational policies address the annual assessment.
- Employee evaluations are performed for all organization personnel.

**Standard 02.01.10  
Assessment of Staff Competency**

Score:  
 C  NC

The organization must have an objective process for assessing the competency of each staff member.

Competency assessment is performed at least annually and at intervals as defined by the organization.

**Required Elements/Additional Information**

Notes

Competency assessments are based on written criteria addressing important elements of the job the employee routinely performs.

**Survey Procedure**

**Document Review**

Verify:

- Organizational policies on assessment of competence.
- Staff competency assessments are conducted at least annually and in accordance with organization policy.



<b>Standard 02.02.01 Credentialing the Employees of Healthcare Professionals</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization maintains a credentials file for individuals employed by healthcare professionals privileged by the organization and providing services in the organization.

The credential file must include:

- A current resume including education, training, and work experience.
- Evidence of current licensure, as appropriate for the position.
- Evidence of malpractice coverage provided by their employer.
- A signed statement attesting to:
  - » Receipt of the organization job description.
  - » Agreement to abide by the policies of the organization.
  - » Agreement to function within the scope of the organization’s job description.
  - » Understanding that the privileges at the organization expire upon termination of the healthcare professional.

Required Elements/Additional Information	Notes
<p>The organization must have a process to:</p> <ul style="list-style-type: none"> <li>■ Credential the employees of healthcare professionals brought into the organization to assist with procedures.</li> <li>■ Verify the training and license of these individuals.</li> </ul> <p>A process is in place for an evaluation of the individual and the organization has a policy for contributing to the evaluation.</p> <p>The organization has a process for disciplinary action for the healthcare professional when the healthcare professional’s employee does not perform adequately in the organization.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization maintains credentials files for non-privileged practitioners who are employees of privileged healthcare professionals providing services.                     <ul style="list-style-type: none"> <li>» Does each file contain evidence of qualifications, current license, resume, and job description?</li> </ul> </li> </ul>	



03

**PROFESSIONAL  
STAFF**

<b>Standard 03.00.01 Professional Staff</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The governing body must provide for the professional staff structure.

Required Elements/Additional Information	Notes
<p>The organization of the professional staff is defined by and accountable to the governing body. The organization must have a written policy that indicates how the professional staff is held accountable by the governing body.</p> <ul style="list-style-type: none"> <li>■ If the professional staff is an organized staff, the governing body approves the professional staff bylaws.</li> <li>■ In the absence of an organized professional staff, policies and procedures are written to address oversight of the healthcare professionals.</li> <li>■ In the case of a sole proprietor or owner, professional staff requirements are in writing and implemented. The governing body or its equivalent provides oversight for professional staff.</li> <li>■ An organization may be owned and operated by one healthcare professional, who could be both the sole member of the governing body and the sole member of the organization's professional staff. In such cases, the healthcare professional owner must implement a formal written process for complying with all professional staff requirements.</li> </ul>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ There is a policy detailing how the governing body holds the professional staff accountable.</li> </ul>	

<b>Standard 03.00.02 Organized Professional Staff</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

If the professional staff is organized into a specific body, there must be a written process for the governing body to approve professional staff bylaws and applicable rules and regulations of that body.

Required Elements/Additional Information	Notes
<p>The professional staff oversees and approves all health care delivered and ensures healthcare providers are licensed/authorized to practice by the jurisdiction in which the organization is located and are operating within the scope of their licenses/authorizations.</p> <p>Bylaws and applicable rules and regulations are approved by the professional staff prior to their approval by the governing body.</p> <p>The bylaws address all elements described in standard 03.00.03.</p> <p>Criteria for professional staff positions (e.g., officers) are established.</p>	





Members appointed to the positions meet the written criteria.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization's policies define the nature and structure of the professional staff.
- There are written professional staff position requirements and descriptions (e.g., officers).
- Through interviews with members of the professional staff, that their function within the organization is consistent with the bylaws and position descriptions, if applicable.
- The organizational chart supports the approval process.

**Standard 03.00.03  
Professional Staff: Policies**

Score:  
 C  NC

The professional staff must establish written policies in accordance with applicable law and regulations. These written policies may be included in the professional staff bylaws and rules and regulations, if applicable. The policies must address:

- Categories of practitioners eligible for privileges.
- Process for initial and reappointment to the professional staff.
- Credentialing process.
- Privileging process.
- Periodic review of the clinical privileges offered.
- A code of ethics.

**Required Elements/Additional Information**

Notes

For patient safety and quality of care, the organization ensures that individuals who provide professional services are working within their scope of practice, are privileged, and meet appropriate professional standards.

The organization has written and implemented policies regarding:

- The categories of practitioners eligible for privileges. These may include:
  - » Physicians, dentists, and podiatrists.
  - » Other healthcare professionals, as applicable, such as CRNAs, nurse practitioners, physician assistants, RN first assistants, and anesthesiologist assistants.
  - » Contracted or part-time licensed professional staff.
- The delineation of privileges offered for each category of practitioner, consistent with procedures offered.
- The periodic review of the clinical privileges offered at the organization.
- Procedure for the removal of a healthcare professional

demonstrating signs of impairment during provision of healthcare services.

- The credentialing and privileging process, including:
  - » Requirements for initial, renewal, and revised privileges applications.
  - » Eligibility requirements for privileges, including education, training, and experience.
  - » Eligibility requirements including licensure, registrations, and certifications, as applicable.
  - » Evidence of current competencies including peer and/or faculty references.
  - » The requirement that the governing body grants privileges to those practitioners meeting the established eligibility requirements based on professional staff recommendations.
  - » Requirements for medical malpractice insurance from an acceptable carrier and specified coverage amounts.
  - » Verification of information provided on the application, including the identity of the applicant.
  - » Establishment of a renewal cycle that is no longer than 36 months.
  - » The process used to evaluate the performance of each practitioner applying for renewal of privileges, including the process for the denial, reduction, restriction, suspension, or termination of privileges and reporting to the National Practitioner Data Bank (NPDB), if applicable.
    - Policies address the circumstances that require reporting to the NPDB and outline the responsibilities for reporting. For more information regarding which situations must be reported, visit the NPDB website at: <https://www.npdb.hrsa.gov/index.jsp>.
    - The process includes the reappraisal of privileges outside the periodic reappraisal schedule for issues relating to professional competency (e.g., adverse event) or misconduct (e.g., ethical violation).
  - » Notification to the applicant of the governing body's decision to grant, deny, reduce, restrict, suspend, or terminate privileges.
  - » The requirement that practitioners with privileges adhere to the organization's Code of Ethics.
- A process to review appeals and conduct hearings following denial, reduction, restriction, suspension, or termination of privileges.

If the organization is located outside the jurisdiction of the United States, it complies with its country's comparable requirements.

### Survey Procedure

#### Document Review

Verify:

- Written policies address all requirements.

#### Standard 03.01.01 Professional Staff: Applications

Score:

C  NC

Applicants for privileges and/or members of the professional staff must include documentation to support their legal and professional qualification for privileges requested.

#### Required Elements/Additional Information

Notes

An application is considered complete when all required information and supporting documents have been received.

The governing body considers recommendations from qualified healthcare professionals on the current competence of applicants for privileges.

- Recommendations from other healthcare professionals must be in writing and include a supporting rationale.
- The qualified healthcare professionals providing recommendations may be current members of the organization's professional staff or healthcare professionals not practicing in the organization.
  - » It is preferred, but not required, that the healthcare professional providing the recommendation work in the same specialty as the healthcare professional being reviewed.
- When the governing body is a solo healthcare professional, the recommendations must come from another healthcare professional in the same professional classification.

The organization has a process to confirm application information through primary source verification (PSV) for initial application and reapplication when additional training has been completed since the previous credentialing period. PSV is required for:

- Verification of professional school attendance and completion, including start and end date.
- Verification of postgraduate and other training programs attendance, including start and end date.
  - » Sources for PSV for U.S.-based organizations may include, but are not limited to:
    - American Medical Association (AMA).
    - American Osteopathic Association (AOA).
    - Educational Commission for Foreign Medical Graduates

(ECFMG).

- American Dental Association (ADA).
- Applicable schools or postgraduate training programs, or other acceptable sources if the school or program closed or copies of original documents cannot be obtained.

The following documentation is required for initial and renewal applications:

- Current professional state license/authorization/registration to practice, if required.
- Current federal and state Drug Enforcement Administration (DEA) (or equivalent) registration, if required.
- Medical malpractice insurance coverage if the organization is located in the United States.
  - » The organization may accept self-reported information for medical malpractice insurance coverage consistent with written policies of the governing body.
- Discharge papers for United States military veterans, **if applicable**.
  - » If other than honorable discharge, an explanation is provided.
- Current Board Certification, if required, through contact with applicable certifying entities. U.S.-based examples include:
  - » American Medical Association (AMA).
  - » American Board of Medical Specialties (ABMS).
  - » American Osteopathic Association (AOA).
  - » Educational Commission for Foreign Medical Graduates (ECFMG).
  - » National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA).
- For U.S.-based organizations, the NPDB must be queried with initial and each subsequent application for appointment. (The NPDB may be accessed through its website <https://www.npdb.hrsa.gov/>.)
- For U.S.-based organizations: Office of the Inspector General (OIG) Query.
  - » The OIG Exclusions List identifies practitioners excluded from participation in Medicare or Medicaid due to violations relating to fraud and abuse. For more information, visit the OIG website: <https://exclusions.oig.hhs.gov/>.
  - » The organization should evaluate the information to determine if the requested privileges are impacted. An organization that has a practitioner on the OIG Exclusions List may be subject to civil monetary penalties and may not



be reimbursed for services provided.

- A statement signed by the applicant attesting to:
  - » Any voluntary or involuntary reductions, restrictions, or limitations in licensing and privileges or professional staff membership at any hospital or healthcare organization.
  - » Current physical and mental health status that does not interfere with his/her ability to perform the requested privileges.

**Note:** Organizations should consider the applicability of disability nondiscrimination laws to credentialing and privileging policies and processes.

- » Commitment to abide by the policies of the organization.
- » Accurate and complete information provided in the application.

**Survey Procedure**

**Document Review**

Verify:

- Inclusion of all identified items with current supporting documentation based on review of a sample of credentials files (10% but not fewer than 10 files). In the sample, include a mix of practitioners (e.g., surgeons, anesthesiologists, CRNAs, nurse practitioners, RN first assists, etc.).
- The process for primary source verification of the information is specified.
- Queries with initial applications and reappointments provide evidence the practitioner is not on the OIG Exclusions List.

**Standard 03.01.02  
Professional Staff: Credentialing**

Score:  
 C  NC

A credentialing file is maintained for each applicant requesting professional staff privileges.

**Required Elements/Additional Information**

Notes

All information submitted in the application for privileges must be maintained, including for those applicants not awarded privileges.

The credentialing files for all professional staff that have been granted clinical privileges include, at a minimum:

- Evidence of professional qualifications for the clinical privileges sought (verification of education, licensure, certification, etc.).
- Evidence of current competence (e.g., procedural logs, peer review activities).
- Evidence of reappraisal prior to renewal of privileges.
- Evidence the governing body reviewed recommendations for professional staff privileges prior to granting initial privileges

and with each renewal.

- Letter granting, denying, reducing, restricting, or terminating privileges signed by the governing body including the specific scope of privileges granted and duration of privileges.

**Survey Procedure**

**Document Review**

Verify:

- There is a credentialing file for each provider applying for clinical privileges and it contains all required elements.

**Standard 03.01.03  
Use of a Credentials Verification Organization (CVO)**

Score:

- C  NC  NA

If the professional staff uses a CVO or other entity for credentials verification purposes, there must be:

- A written contract that defines the services to be provided and requires compliance with these standards.
- Written policies and procedures to direct the CVO, which specify the required elements of the credentialing process.

**Required Elements/Additional Information**

Notes

An organization may use a CVO to perform the credentialing aspects of the process. The organization may also contract with another entity, such as a hospital, to perform the credentialing aspects of the process.

The governing body is responsible to ensure the CVO follows the credentialing requirements in the standards.

If an organization uses a CVO, there must be a written agreement/contract that defines the expectations for the credentialing process, including:

- Verification of all requirements of the application.
- Indications for primary source verification.
- Turnaround time for verification completion.
- Reporting any unusual findings or concerns to the governing body.

**Survey Procedure**

**Document Review**

Verify:

- A formal written contract with the CVO or entity defines their services.
- The CVO or entity uses the same credentialing requirements established in these standards including primary verification.
- Through review of written policies, all requirements are



addressed.

**Standard 03.01.04  
Professional Staff: Privileges**

Score:  
 C  NC

The professional staff makes written recommendations to the governing body regarding each applicant for privileges after legal and professional qualifications have been verified and assessed.

**Required Elements/Additional Information**

Notes

The professional staff makes written recommendations to the governing body for initial, renewed, and revised privileges, which specify in detail the types of procedures the practitioner may perform within the organization.

- The recommendation is based on the information provided in the application.
- It is not sufficient for the governing body to grant privileges to “perform surgery” or even to perform “orthopedic surgery.” For example, an organization that specializes in orthopedic surgery of various types must specify which types of procedures each surgeon is privileged to perform.

The professional staff makes recommendations to the governing body only for legally and professionally qualified practitioners.

The privileges granted fall within the practitioner’s scope of practice.

“Professionally qualified” means that:

- The practitioner has demonstrated competence in the area for which privileges are sought.
- Competence is demonstrated through evidence of specialized training and experience (e.g., certification by a nationally recognized professional board).

The organization’s governing body is not required to accept the recommendation provided by professional staff. However, when the organization’s governing body makes a decision contrary to the recommendation, it documents its rationale.

Based on the information provided, the governing body may decide to:

- Award the privileges as requested.
- Amend the requested privileges by contracting or expanding them.
- Deny awarding the requested privileges.
- For renewal of privileges, withdraw the practitioner’s privileges entirely.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- The organization’s process for granting clinical privileges with its leadership.

Verify:

- Each practitioner’s credentialing file provides evidence that they are legally and professionally qualified to exercise the privileges granted them by the organization.
  - » Review the credentialing files of all anesthesia providers.
  - » Review the credentialing files of all professional practitioners requiring privileges (e.g., nurse practitioners and physician assistants).
  - » Review the credentialing files of all surgical technicians if privileges are required.

**Standard 03.01.05  
Professional Staff: Reappraisal and Renewal of Privileges**

Score:

C  NC

Professional staff privileges must be periodically reappraised for renewal by the governing body.

**Required Elements/Additional Information**

Notes

The governing body must have a written process for reappraising the professional staff privileges granted to each practitioner at least every 36 months.

The reappraisal information must include:

- A review of the practitioner’s current credentials.
- The practitioner’s organization-specific records, including measures employed in the organization’s Quality Assurance Performance Improvement program, such as:
  - » Emergency transfers to hospitals.
  - » Post-surgical infection rates.
  - » Other surgical or procedural complications.
- Information necessary for an adequate review, if the review is triggered by an event or incident between reappraisals.

**REQUESTS FOR NEW PRIVILEGES**

The governing body must have a written reappraisal process to be used any time a practitioner seeks to perform procedures outside the scope of previously granted privileges. The process must include:

- Credentialing for the new privileges.
- Determination by the governing body if the new privileges requested require proctoring by a practitioner with the same privileges to perform that procedure or if peer review is to be



done shortly after the procedure, and how many procedures should be proctored or reviewed before the practitioner is granted unrestricted privileges for the new privilege.

### SOLE MEMBER OF THE GOVERNING BODY

The healthcare professional owner must undergo a reappraisal as defined in the written policies for professional staff.

- The organization has a written process for another healthcare professional to review the credentials and performance of the healthcare professional owner and submit a written recommendation for privileges to the governing body. This individual may be:
  - » Another healthcare professional at the organization.
  - » Another healthcare professional from, for example, a local hospital, a healthcare regulatory board, or a specialty healthcare association.
    - It is preferred, but not required, that the second healthcare professional be of the same specialty being reviewed.
- The healthcare professional owner cannot grant himself/herself clinical privileges except in his/her role as the governing body based on documented evaluation/recommendation from a second healthcare professional.

## Survey Procedure

### Interview and Document Review

Discuss and assess:

- The organization's process to re-evaluate the professional qualifications of practitioners with privileges to practice in the organization with leadership.

Verify:

- Professional staff privileges are reviewed and approved by the governing body at least every three years.
- Credentialing files for all practitioners with privileges reflect reappraisal within the timeframe specified in the written professional staff policy.
  - » All practitioners granted clinical privileges were reappraised at least every 36 months.
  - » Reappraisals include evidence that data on the practitioner's practice within the organization is considered along with the practitioner's credentials.
  - » The reappraisal process includes consideration of practitioner performance, including data from quality indicators.

<b>Standard 03.02.01</b> <b>Management of an Incapacitated or Impaired Healthcare Provider</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>The professional staff has written provisions for identifying and appropriate management of an incapacitated or impaired healthcare provider, and these are known to staff.</p>	
<b>Required Elements/Additional Information</b>	Notes
<p>Staff are aware of the provisions and resources for the identification and appropriate management of an incapacitated or impaired healthcare provider, including their removal during a procedure.</p>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Discuss and assess:</p> <ul style="list-style-type: none"> <li>■ Review the procedure defined in the professional staff bylaws or policies and procedures regarding management of an incapacitated or impaired healthcare provider and interview staff to evaluate knowledge of those provisions.</li> </ul> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Through review of documentation that the process is followed if relevant situations have occurred.</li> </ul>	

THIS PAGE IS INTENTIONALLY BLANK.

---

04

**QUALITY  
ASSESSMENT  
AND  
PERFORMANCE  
IMPROVEMENT**



**Standard 04.00.01**  
**Quality Assessment and Performance Improvement**

Score:  
 C  NC

The organization must develop, implement, and maintain an ongoing, data-driven Quality Assessment Performance Improvement (QAPI) program that demonstrates measurable improvement in patient health outcomes and improves patient safety by using quality indicators or performance measures associated with improved health outcomes.

**Required Elements/Additional Information**

Notes

An organization must have a proactive, comprehensive, and ongoing approach to improving the quality and safety of the services it delivers.

Each organization has the flexibility to develop its own program, but the program must be:

- Ongoing.  
Evidence of this would include, but is not limited to, collection of quality data at regular intervals; analysis and evaluation of the updated data at regular intervals; records of actions taken to address quality problems identified in the analyses; and new data collection to determine if the corrective actions were effective.
- Data-driven.  
The program must identify in a systematic manner what data it will collect to measure various aspects of quality of care; the frequency of data collection; how the data will be collected and analyzed; and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

Organizations employ a systems approach to:

- Evaluating systems and processes.
- Identifying problems that have occurred or that might result from the organization's practices.
- Getting to root causes of problems.

The focus of the QAPI program is not on whether an organization has any deficient practices, but on whether:

- It has an effective, ongoing system in place for identifying problematic events, policies, or practices and taking actions to remedy them.
- It follows up on these remedial actions to determine if they were effective in improving performance and quality.

An organization's QAPI program must be designed to improve both patient health outcomes and patient safety in the organization.

Ongoing, systematic monitoring of established indicators are used, such as:

- **Outcome indicators that measure the results of care** with a focus on topics like complication rates, healthcare-associated infection rates, cases exceeding 24 hours, transfers to hospitals, wrong site surgeries, etc.
- **Process of care indicators that measure how often the standard of care was met** for patients with a diagnosis related to that standard. For example, process of care measures might focus on the administration and timing of prophylactic antibiotics.
- **Patient perception indicators that measure the patient's experience** of the care he/she received in the organization.

### Survey Procedure

#### Interview and Document Review

Discuss and assess:

- Leadership's description of the QAPI program, including staff responsibilities for QAPI and the quality/safety indicators being tracked.
- With staff, the rationale used to select particular indicators that the organization has chosen to track.
  - » Are they based on nationally-recognized recommendations? If not, what evidence does the organization have that the indicators it has chosen are associated with improvement in patient health outcomes and safety?

Verify:

- The criteria are being satisfied as evidence of a quality program that is:
  - » Ongoing.
  - » Data-driven.

#### Standard 04.00.02 Governing Body Responsibilities

Score:

C  NC

The governing body must ensure that the QAPI program:

- Is defined, implemented, and maintained by the organization.
- Addresses the organization's identified priorities and evaluates improvements for their effectiveness.
- Specifies data collection methods, frequency, and details.
- Clearly establishes the expectations for safety.
- Allocates sufficient staff, time, information systems resources, and training for implementation.
- Includes an annual review and approval of the plan.

**Required Elements/Additional Information**

Notes

The governing body must ensure that the organization's QAPI program:

- Is defined in a written plan and addresses the organization's overall scope and complexity.
- Is implemented, with knowledge of the program by the organization's staff supported by written evidence.
- Evaluates changes designed to improve performance to determine whether they are effective and takes appropriate actions to make further changes as needed.
- Reports the program's findings and outcomes to the governing body and communicates the program's findings and outcomes to staff, as appropriate.
- Has sufficient resources (i.e., the organization's governing body must allocate sufficient and qualified staff and other resources to support the program). Resources dedicated to the QAPI program must be commensurate with the organization's overall scope and complexity.

**Survey Procedure****Interview and Document Review**

Verify:

- The QAPI program includes all the items described in the standard.
- The governing body reviews all elements of the QAPI program (e.g., through meeting minutes).
- Planned data collection and analyses occurred.

Discuss and assess:

- How the governing body is involved in the QAPI program.
  - » Does leadership display ready knowledge of the program's structure and activities?
  - » If a contractor is used for some portions of the program, does the organization's leadership closely monitor the contractor's activities?
- Ask for evidence of changes made as a result of QAPI program activities.
- With staff identified as having a role in the QAPI program, whether they actually perform QAPI functions and for what percentage of their time.

**Standard 04.01.01**  
**QAPI Plan**

Score:

 C  NC

The organization must have a written quality plan that details how quality activities will be performed.

**Required Elements/Additional Information**

Notes

The QAPI plan describes how indicators are identified, how data are gathered and analyzed, use of analysis findings, corrective actions, and evaluation of corrective action. The plan describes in detail the annual activities for each department or group within the organization.

The plan must address, at a minimum:

- The quality measures for contractor services and how they will be monitored.
- Implementation on an ongoing basis.
- Use of quality and patient safety indicators that reflect appropriate prioritization.
- Indicator data to be collected, how it will be collected, how frequently it will be collected, etc.
- Uses of the data collected and analysis to improve the organization's performance.
- Evaluation of the effectiveness of corrective actions.
- Oversight responsibility for QAPI activities, either by an individual with appropriate leadership authority or a committee. If the organization has a QAPI committee, the composition, including, at a minimum, representatives from leadership, the professional staff, nursing, and others that contribute to the organization's operations.

The QAPI plan provides for review of at least the following:

- Scope and quality of services provided including contractual services.
- Medication errors.
- Unanticipated event reports.
- Selected patient safety indicators (e.g., burns, falls, wrong site, etc.).
- Effectiveness of pain management.
- Infection prevention and control.
- Patient death.
- Unplanned patient transfers/admissions.
- Blood transfusions.
- Patient satisfaction survey results.
- Patient/family complaints/grievances.





- Healthcare record reviews.

Annually, the plan must set priorities for performance improvement activities that focus on:

- High-risk, high-volume, and problem-prone areas.
- Incidence, prevalence, and severity of problems in those areas.
- Health outcomes, patient safety, and quality of care.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- Understanding of the organization’s QAPI activities with members of leadership and the staff .

Verify:

- The organization has a written annual QAPI plan that meets the requirements.
- The plan includes services provided through the contract.

**Standard 04.01.02  
Use of Data Collected**

Score:

C  NC

The organization must use the data collected to:

- Monitor the effectiveness and safety of its services and the quality of its care.
- Identify opportunities that could lead to improvements and changes in its patient care.

**Required Elements/Additional Information**

Notes

The organization must actively collect data related to the measures and at the intervals called for by its QAPI program.

Quality indicators are identified, and data is collected for:

- All patient care services and other services provided at the organization.
- All contracted services.

The organization must analyze the data it collects to monitor performance (i.e., to determine what the data suggest about the organization’s quality of care and the effectiveness and safety of its services).

- Analysis must take place at regular intervals to avoid excess time elapsing before the organization detects problem areas needing correction. In the case of data related to unanticipated events, the organization must use the data to analyze the cause(s) of the events.
- Data collection and analysis must be conducted by personnel with appropriate qualifications to collect and interpret

quantitative data.

The organization may choose to use contractors for technical aspects of the QAPI program, including analysis of data, but the organization is expected to actively involve organization staff in the program, and the organization's leadership retains responsibility for the ongoing management of the program, even when a contractor is used.

Analysis of the data must be used to identify areas in which there is room for improvement in the organization's performance, as well as follow-up actions taken to improve performance. A monitoring system is likely to find areas of performance that are weaker than others. These identified areas of weakness present opportunities for the organization to make changes in its systems, policies, or procedures that result in improved patient care.

Once the organization's analysis of its data has identified opportunities for improvement, the organization must develop specific changes in its policies, procedures, equipment, etc., as applicable, to accomplish improvements in the identified areas of weakness. In addition, an organization must implement preventive strategies designed to reduce the likelihood of the problem occurring again.

## Survey Procedure

### Interview and Document Review

Verify:

- Through review of the QAPI plan that collection of quality indicator data relates to patient care and other relevant organization services.
- The organization tracks and monitors the quality of services provided by outside entities (e.g., laboratory services).
- Using examples of quality and unanticipated event data collected, that:
  - » The organization collects data on all indicators/ measures identified in its QAPI program.
  - » Data collection is at the frequency specified in its QAPI program.

Discuss and assess:

- Examples of instances when QAPI data was used to identify opportunities for improving processes for providing care.
- How the improvements were evaluated for effectiveness and sustained improvement.



<b>Standard 04.01.03 Benchmarking</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The program must establish goals based on external performance metrics in order to evaluate services furnished in the organization.

<b>Required Elements/Additional Information</b>	Notes
---	-------

The organization must identify a threshold, or goal, for each quality indicator. Activities to improve performance are assessed in relation to meeting the established threshold. The organization may reassess the threshold indicator based on new information.

The organization must identify pertinent external quality indicators to be used for comparison purposes with the internal indicators. Relevant external indicators may include:

- Peer-reviewed published studies.
- Active participation in a study with other organization(s).
- Active studies conducted by third parties, such as professional associations.

<b>Survey Procedure</b>	
-------------------------	--

**Interview and Document Review**

Verify:

- QAPI metrics include identified thresholds or goals.

Discuss and assess:

- How the thresholds or goals were identified with the person or representative from the committee designated to oversee QAPI.

<b>Standard 04.01.04 Performance Improvement Projects</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the organization’s services and operations and be documented.

<b>Required Elements/Additional Information</b>	Notes
---	-------

Every organization must undertake one or more specific performance improvement project(s) each year.

Projects must be based on the types of services the organization furnishes and/or other aspects of the organization’s operations. Each year’s planned projects are delineated in the QAPI plan’s annual approval.

The organization must keep records of its performance improvement projects.

- Each project must, at a minimum, include an explanation of

why the project was undertaken.

- » The explanation must indicate what data collected in the organization or based on recommendations of nationally recognized organizations leads the organization to believe that the project's activities will result in improvements in patient health outcomes and safety in the organization.
- For projects that are underway during a survey, the organization must be able to explain activities the project entails and how the impact of the project is being monitored.
  - » Unless the project has just begun, the organization must be able to provide evidence that it is collecting data that will enable it to assess the project's effectiveness.
- For projects that are completed, the organization must be able to show documentation that explains:
  - » The result(s) of the project.
  - » Actions taken, if any, in response to those results.

## Survey Procedure

### Interview and Document Review

Verify:

- The QAPI program documents a plan for annual performance improvement projects.
- Documentation exists for performance improvement projects currently underway, as well as those completed in the prior year.
- Documentation indicates the rationale for undertaking each project.
- Documentation for completed project(s) includes the project's results.
  - » If a project was unsuccessful, determine what actions were taken as a result of that information.
  - » If the project was successful, ask the organization how it is sustaining the improvement.

Discuss and assess:

- Through staff interviews, whether data indicated a problem in the area targeted for improvement or whether nationally recognized guidelines suggested the activities.



**Standard 04.01.05**  
**QAPI Implementation Oversight**

Score:  
 C  NC

QAPI activities are directed by an individual designated by the governing body or QAPI committee.

If an individual is chosen, this individual has evidence of training in the principles of QAPI and may involve others in the organization and/or outside consultants with training and experience in quality management to assist in developing and implementing meaningful studies with the goal of continuous improvement.

**Required Elements/Additional Information**

Notes

The designated individual in charge of the quality program may have other assigned duties, but there must be sufficient time allotted to the QAPI program to support all aspects covered by the standards. There should be documentation of formal training or experience in quality-related matters sufficient to prepare the individual for their expected duties.

If the organization chooses to have a quality committee in place of a designated individual, it may meet as a function of a larger committee.

- At least one committee member has received training or has experience in quality-related matters.
- There are established expectations for minimum attendance required at meetings (e.g., a defined quorum).
- Minutes must be kept in sufficient detail to be able to track the progress of the quality program.

The designated individual or quality committee reviews quality reports to identify patterns, trends, and potential opportunities for improvement in the quality of care provided.

The data is collected and reviewed by the designated individual or quality committee at the frequency established by the governing body or at least quarterly.

- There is a mechanism for communicating the activities of the QAPI program throughout the organization.

**Survey Procedure**

**Document Review**

Verify:

- The organization has assigned responsibility for the QAPI program to an individual or committee.
- If responsibility is assigned to an individual:
  - » This individual has received QAPI training as evidenced by documentation of their training and experience in quality.
  - » The amount of time this individual spends on the QAPI



<p>program is adequate based on scope.</p> <ul style="list-style-type: none"> <li>■ If a committee is established in place of a designated individual, the QAPI plan identifies the committee membership.                     <ul style="list-style-type: none"> <li>» Members include leadership, professional staff, nursing, and others consistent with the QAPI Plan.</li> <li>» The QAPI committee meets at least quarterly.</li> <li>» Committee members attended meetings at a frequency consistent with the policy.</li> <li>» Meeting minutes track QAPI activities over time until resolution.</li> </ul> </li> </ul>	
---	--

<b>Standard 04.01.06 End-of-Year Quality Report</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization must write an annual end-of-year report as an integral part of the QAPI program, based on the annual plan, which details all quality activities and their progress or resolution during the year.

The report must be submitted to the governing body for review and approval.

<b>Required Elements/Additional Information</b>	Notes
<p>The end-of-year quality report includes a review of the leadership’s activities in support of the program.</p> <p>The annual quality report serves as the basis for development of the subsequent year’s annual plan.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The last three annual QAPI reports include a summary of the year’s quality activities and progress.</li> </ul>	

<b>Standard 04.02.01 Performance Improvement Activities: Unanticipated Patient Events</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

Performance improvement activities must track unanticipated patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

<b>Required Elements/Additional Information</b>	Notes
<p>The organization has methods to ensure that unanticipated events are included in the QAPI program to the extent possible. Unanticipated events are investigated to identify their cause, and corrective actions to prevent future events are implemented to be sustainable over time.</p> <p>For example, in addition to stopping the immediate cause (staff</p>	



error, equipment failure, etc.) of the unanticipated event, the organization must investigate the underlying root cause(s).

The organization must implement preventive strategies throughout the facility targeting unanticipated patient events and ensure that all staff are familiar with these strategies.

The organization must report events in accordance with applicable law and regulations. The organization has an established mechanism to meet reporting requirements.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- Data collection and analysis with the responsible individual to verify their understanding of investigating unanticipated events and, when required, reporting the events.

Verify:

- Unanticipated patient events are tracked and analyzed, corrective action is implemented, and improvement is sustained.
- Unanticipated patient event tracking and analysis includes causes identified and improvements implemented.
- The process used to identify the causes of unanticipated events and the resultant action(s).

**Standard 04.02.02  
Performance Improvement Activities: Review of Transfusions and Transfusion Reactions**

Score:

C  NC  NA

Performance improvement activities must track:

- All blood transfusions.
- All blood transfusion reactions.

**Required Elements/Additional Information**

Notes

Transfusion reviews include:

- Adherence to policy expectations.
- Recommendations for improvement in transfusion procedures, if appropriate.

In single healthcare provider practices, processes are established for another healthcare provider of similar training to perform this review.



<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>Quality committee and/or governing body meeting minutes provide evidence of activity.</li> </ul>	
<b>Standard 04.02.03 Performance Improvement Activities: Review of Unplanned Transfers</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
Performance improvement activities must track all unplanned transfers to a higher level of care to determine if appropriate care and evaluation had been rendered.	
<b>Required Elements/Additional Information</b>	Notes
<p>The organization has identified a process for reviewing unplanned transfers. As appropriate, the findings of the review are included in QAPI activities and/or peer review actions.</p> <p>In single healthcare provider practices, processes are established for another healthcare provider of similar training to perform this review.</p>	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>Quality committee and/or governing body meeting minutes confirm activity.</li> </ul>	
<b>Standard 04.02.04 Performance Improvement Activities: Review of All Deaths</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
Performance improvement activities must track any deaths occurring in the organization or after transferring to a higher level of care and determine if appropriate care and evaluation had been rendered.	
<b>Required Elements/Additional Information</b>	Notes
<p>The organization has identified a process for reviewing all deaths. As appropriate, the findings of the review are included in QAPI activities and/or peer review actions.</p> <p>In single healthcare provider practices, processes are established for another healthcare provider of similar training to perform this review.</p>	
<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
Discuss and assess: <ul style="list-style-type: none"> <li>Procedures with leadership and ask for examples of activity</li> </ul>	





or minutes to verify activity.

Verify:

- All deaths in the organization are evaluated to determine if appropriate care had been rendered.

<b>Standard 04.02.05 Performance Improvement Activities: Review of Clinical Records</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

Performance improvement activities must include at least annual review of clinical records for adherence to established policies for documentation, completion, legibility, etc.

<b>Required Elements/Additional Information</b>	Notes
Clinical record reviews may be based on prior identification of areas for improvement. A sample of records for all healthcare providers is included.	
<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
Discuss and assess:	
<ul style="list-style-type: none"> <li>■ Record review with medical director <b>or practice manager.</b></li> </ul>	
Verify:	
<ul style="list-style-type: none"> <li>■ Quality committee and/or governing body meeting minutes confirm activity.</li> </ul>	

<b>Standard 04.02.06 Performance Improvement Activities: Patient Satisfaction Survey</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization must **have a process** to determine the level of satisfaction **for patients and families** with at least:

- The quality of care delivered.
- The environment of care.
- The caregiving process.

<b>Required Elements/Additional Information</b>	Notes
<p>The organization has a process to obtain patient feedback. If the organization conducts patient satisfaction surveys through a sampling method, that method is defined, including the time frames for collecting the survey, analyzing the results, and providing information through the established QAPI processes.</p> <p>Results are reviewed by the individual assigned responsibility for the QAPI program or the quality committee and used to improve services.</p>	



**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- With staff, examples of how the organization has used the results of **feedback**.

Verify:

- Patient satisfaction surveys relate to quality activities over the last 24 months.

**Standard 04.02.07  
Performance Improvement Activities: Patient Complaints and Grievances**

Score:

C  NC

The organization must:

- Track, aggregate, and analyze patient complaints/grievances on an established schedule.
- Submit complaints/grievances-related data and analysis for review in the QAPI program.
- Include a summary of complaints/grievances in the annual quality report.

**Required Elements/Additional Information**

Notes

Trending and analysis of patient complaints identifies sources of patient dissatisfaction. These represent opportunities for the organization to make changes.

Increasing trends in complaints or a sudden increase in complaints over a short period of time should serve to initiate at least a management-level review.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- Examples of actions taken as a result of patient complaint review with leadership.

Verify:

- Quality committee and/or governing body meeting minutes document analysis of patient complaints.

**Standard 04.03.01  
Risk Management Program**

Score:

C  NC

The organization leadership develops a risk management program to assess organizational risks and develop strategies for removal.

**Required Elements/Additional Information**

Notes

The risk management program reviews data to identify potential risks including, but not limited to.

- Unanticipated events.
- Deaths.
- Complaints and grievances.
- Patient falls.
- Medication errors.
- Medical malpractice claims.
- Complaints.
- Data security risks.

The program incorporates review of individual events and quality improvement activities. The organization has identified a process for staff to report all unanticipated events.

### Survey Procedure

#### Document Review

Verify:

- The organization has a written risk management program.
- Minutes or records of risk management activities provide evidence of data collection, analysis, and action.



THIS PAGE IS INTENTIONALLY BLANK.



05

**INFECTION  
PREVENTION  
AND  
CONTROL**



**Standard 05.00.01  
Infection Prevention and Control Program**

Score:  
 C  NC

The organization must maintain an ongoing and written infection prevention and control program that seeks to prevent and minimize infections and communicable diseases.

**Required Elements/Additional Information**

Notes

The organization's infection prevention and control program must:

- Provide a functional and sanitary environment for services to avoid sources and transmission of infections and communicable diseases.
- Be based on nationally recognized infection prevention and control guidelines.
- Be directed by a designated healthcare professional with training in infection prevention and control.
- Be integrated into the QAPI program.
- Include actions to prevent, identify, and manage infections and communicable diseases.
- Include a mechanism to immediately implement corrective actions and preventive measures that improve the prevention and control of infection within the organization.

**Survey Procedure**

**Interview and Document Review**

- Compliance with infection prevention and control program requirements will be assessed by all Surveyors throughout the survey event.

**Standard 05.00.02  
Infection Prevention and Control Program Development**

Score:  
 C  NC

The organization must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases that is based on the consideration, selection, and implementation of nationally recognized infection prevention and control guidelines and/or recommendations.

**Required Elements/Additional Information**

Notes

Documentation reflects the organization's consideration, selection, and implementation of nationally recognized guidelines and/or recommendations.

As part of the ongoing program, the organization must have an active surveillance component that addresses both patients and personnel working in the facility.

Surveillance includes infection detection through ongoing data collection and analysis.

Policies and procedures describe how the organization will address

the elements of the standard. Contracted services, including personnel, follow the organization's policies and procedures.

The organization selects one or more sets of nationally recognized guidelines to address the following key functions of an effective infection prevention and control program:

- Maintenance of a sanitary environment.
- Development and implementation of infection prevention and control (IPC) activities related to personnel, which, for purposes of this standard, includes all professional staff, employees, on-site contract workers, and volunteers (e.g., nursing staff employed by an associated physician practice and working in the organization, housekeeping staff).
- Mitigation of risks associated with healthcare-associated infections.
- Identification of infections.
- Monitoring compliance with all policies, procedures, protocols, and other IPC program requirements.
- Program evaluation and revision, when indicated.

#### PERSONNEL-RELATED ACTIVITIES

The following apply to employed staff and contracted personnel:

- Evaluating immunization status for specific infectious diseases.
- Policies articulating the authority and circumstances under which the organization screens personnel for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as required under applicable public health authorities (e.g., local, state, and federal).
- Policies articulating when infected personnel are restricted from providing direct patient care or required to remain away from the facility entirely.
- Training for new personnel and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases.
- Mechanisms to evaluate personnel and patient exposure to infections and communicable diseases.

**Note:** U.S.-based organizations that promulgate nationally recognized infection and communicable disease prevention and control guidelines and/or recommendations include:

- » The Centers for Disease Control and Prevention (CDC).
- » Association for Professionals in Infection Control and Epidemiology (APIC).
- » Society for Healthcare Epidemiology of America (SHEA).
- » Association of periOperative Registered Nurses (AORN).

- » Anesthesia Patient Safety Foundation (APSF). Internationally recognized organizations include the World Health Organization (WHO) and the respective nation’s standards.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- There is an ongoing program for the prevention, control, and investigation of infections and communicable diseases among patients and personnel, including contract workers and volunteers.
- Policies and procedures of the IPC program are implemented. Specifically, determine whether the organization:
  - » Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good hand hygiene).
  - » Performs monitoring/tracking activities to identify infections.
  - » Monitors compliance with all IPC program requirements.
- Documentation that the organization has developed the written policies and procedures of the program based on nationally recognized infection prevention and control guidelines and/or recommendations.

**Standard 05.00.03  
Written Plan for Infection Prevention and Control Program**

Score:  
 C  NC

The infection prevention and control program has a written plan for preventing, identifying, and managing infections and communicable diseases and for implementing corrective and prevention measures that result in improvement.

**Required Elements/Additional Information**

Notes

The written plan is specific to each area of the organization, including, but not limited to:

- Waiting room(s).
- Patient room(s).
- Recovery room(s).
- Surgical and procedural areas.
- Clean and sterile supply areas.
- Other clinical areas.

The infection prevention and control program’s plan of action addresses:

- Maintenance of a sanitary environment.
- Development and implementation of infection prevention and



- control measures related to organization personnel.
- Mitigation of risks associated with patient infections present upon admission.
- Mitigation of risks contributing to healthcare-associated infections.
- Active surveillance.
- Visitors.
- Monitoring compliance with all policies, procedures, protocols, and other Infection Prevention and Control Program requirements.
- Plan evaluation and revision of the plan, when indicated.
- Coordination as required by applicable law and regulations with emergency preparedness and public health authorities (e.g., federal, state, and local) to address communicable and infectious disease threats and outbreaks.
- Compliance with reportable disease requirements of applicable public health authorities.

#### **MITIGATION OF RISKS CONTRIBUTING TO HEALTHCARE-ASSOCIATED INFECTIONS (HAI)**

HAI is defined as a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s).

There must be no evidence that the infection was present or incubating at the time of admission to the organization.

HAIs may be caused by infectious agents from endogenous or exogenous sources.

- Endogenous sources are body sites, such as the skin, nose, mouth, gastrointestinal tract, or vagina, that are normally inhabited by microorganisms.
- Exogenous sources are those external to the patient, such as patient care personnel, visitors, patient care equipment, medical devices, or the healthcare environment.

#### **HAI RISK MITIGATION MEASURES**

- Implementing appropriate prophylaxis to prevent surgical site infection (SSI), including, but not limited to:
  - » Protocol for antibiotic prophylaxis:
    - Selection of appropriate antibiotic.
    - Timeliness of antibiotic administration.
    - Appropriate duration and frequency of antibiotic therapy.
  - » Strict observance of aseptic technique.
  - » Sterilization or high-level disinfection of instruments, as appropriate.

- Implementing measures to avoid overuse of antibiotics, including consideration of the antimicrobial spectrum, duration, and patient selection.
- Other organization mitigation measures:
  - » Strict hand hygiene protocols among personnel and vendors, including use of alcohol-based hand sanitizers.
  - » Measures specific to the prevention of infections caused by organisms that are antibiotic resistant.
  - » Measures specific to safe injection and safe infusion practices.
  - » Requiring disinfectants and germicides to be used in accordance with the manufacturer's instructions.
  - » Appropriate use of equipment, including air filtration equipment, UV lights, personal protective devices used by personnel (as described in the OSHA standards), and other equipment used to control the spread of infectious agents.
  - » Educating patients, visitors, personnel, and others about infections and communicable diseases and methods to reduce transmission in the organization and in the community.
  - » Prevention and control protocols for those individuals who may present as a risk for the transmission of infectious agents by the airborne or droplet route. For example, the organization may take actions including prompt physical separation, respiratory hygiene/cough etiquette protocols, and appropriate isolation precautions based on the routes of transmission of the suspected infection.

### IDENTIFYING INFECTIONS

The organization must develop and implement interventions to address issues identified through its detection activities, and then evaluate the effectiveness of interventions through further data collection and analysis.

The organization must conduct comprehensive monitoring to identify infection risks or communicable diseases.

- The organization documents its monitoring/tracking activities, including the measures selected for monitoring, and collection and analysis methods.
- Activities are conducted in accordance with recognized infection control surveillance practices.

### POST-DISCHARGE INFECTIONS

Organizations have a process to follow up on each patient after discharge to identify and track infections associated with the patient's stay in the organization.

- If the organization learns of a disease that is reportable under



applicable law and regulations (e.g., state, local), it is appropriately communicated to authorities.

Organizations may delegate portions of this follow-up responsibility to the healthcare professionals on staff who will see the patients in their office post-discharge if the process includes a means of ensuring that the results of the follow-up are reported back to the organization and documented in the patient’s healthcare record.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The written IPC program comprehensively addresses all required elements.
- The plan addresses all areas of the organization’s physical space.
- HAI measures include:
  - » Appropriate prophylaxis for surgical sites.
  - » Documentation of HAI monitoring.
  - » Education to staff and patients.
- Infections and infection rates are tracked.
- The organization monitors and follows up on post-discharge infections.

**Standard 05.00.04  
Infection Prevention and Control Program Officer**

Score:  
 C  NC

The infection prevention and control program is under the direction of a designated and qualified licensed healthcare professional who has specialized training in infection prevention and control.

**Required Elements/Additional Information**

Notes

The organization must designate, in writing, a qualified, licensed healthcare professional who will lead the facility’s IPC program.

The organization verifies that the individual has had training in the principles and methods of infection prevention and control.

**Note:** Certification in infection prevention and control, such as that offered by the Certification Board of Infection Control and Epidemiology (CBIC), while highly desirable, is not required, so long as there is documentation of training that qualifies the individual to lead an IPC program.

The individual selected to lead IPC must maintain his/her qualifications through ongoing education and training, which can be demonstrated by participation in infection prevention and control courses, or in meetings organized by recognized professional

societies, such as APIC and SHEA.

Resources must be adequate to accomplish the tasks required for the IPC program. The organization should consider the type of services offered at the facility as well as the patient population in determining the size and scope of the resources it commits to infection prevention and control.

**Survey Procedure**

**Document Review**

Verify:

- A qualified individual has been designated with responsibility for leading the IPC program.
- The personnel file of the IPC lead confirms that he/she is qualified through ongoing education, training, or certification to oversee the program.

**Standard 05.00.05  
Integration with Quality Assurance and Performance Improvement**

Score:  
 C  NC

The infection prevention and control program is an integral part of the organization's quality assessment and performance improvement program.

**Required Elements/Additional Information**

Notes

Infection prevention and control (IPC) data and program activities are an ongoing component of the QAPI program, and actions are taken in response to data analyses to improve IPC performance.

The organization must take steps to determine whether personnel adhere to the IPC policies and procedures in practice.

The organization must demonstrate that it has a process in place for regularly assessing IPC compliance.

**Survey Procedure**

**Document Review**

Verify:

- The organization's QAPI program includes measures/indicators and activities related to IPC on an ongoing basis.
  - » For example, regulatory or national association monitoring tools and ongoing personnel competencies are periodically validated.
- QAPI IPC activities result in specific actions designed to improve infection prevention and control within the organization.

**Standard 05.00.06**  
**Sanitary Environment**

Score:

 C  NC

The organization must provide a functional and sanitary environment for the provision of services by adhering to professionally acceptable standards of practice.

**Required Elements/Additional Information**

Notes

The organization's environment of care is maintained to avoid sources and transmission of infections and communicable diseases.

All areas of the organization are clean and sanitary. This includes the:

- Waiting area(s).
- Pre-procedural prep area(s), the recovery room(s).
- Operating or procedure rooms.
- Sterile processing areas.

The organization appropriately monitors housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and sanitary environment.

**POLICIES**

Policies and procedures for a sanitary and functional environment address:

- Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation.
- Maintaining safe air handling systems in areas of special ventilation, such as operating rooms and sterile processing areas.
- Storage of non-sterile and food supplies per national guidelines, law, and regulations.
- Techniques for food sanitation if employee food storage and eating areas are provided.
- Techniques for cleaning and disinfecting patient care equipment, environmental surfaces, carpeting, and furniture.
- Techniques for disposal of regulated and nonregulated waste.
- Techniques for pest and rodent control.
- Robotic disinfection, chemical or light-based, including personnel use and safety, if applicable.

These activities are conducted in accordance with nationally-recognized guidelines.

**Survey Procedure**
**Observation, Interview, and Document Review**

Verify:

- By observation, cleanliness throughout the organization,

including waiting area(s), recovery room(s), the OR/procedure rooms, floors, horizontal surfaces, patient equipment, air inlets, mechanical rooms, supply/storage areas, etc.

- » The environment is free of dirt, dust, rust, and insects.
- » Doors, floors, walls, ceilings, fixtures, base coats, and finishes maintain integrity.
- The organization has a procedure for decontamination after gross spills of blood or other bodily fluids.
- Used sharps are disposed of properly.

Discuss and assess:

- Frequency of cleaning/disinfection and use of suitable EPA-registered agents. Review documentation to confirm what personnel communicate in interviews.

**Standard 05.01.01  
Decontamination and Sterilization Policies and Procedures**

Score:  
 C  NC

The organization has written policies and procedures for decontamination and sterilization:

- Based on the manufacturer’s instructions and nationally recognized guidelines.
- Approved by the professional staff.

**Required Elements/Additional Information**

Notes

Policies and procedures are consistent with the manufacturer’s instructions and nationally recognized guidelines such as, in the U.S., the CDC, CDC-HICPAC, AORN, and AAMI, etc.

All policies and procedures are reviewed and approved by the professional staff every three years, at minimum, or more often, as needed.

Personnel follow the policies and procedures.

**Survey Procedure**

**Document Review**

Verify:

- Written policies and procedures meet the standard.
- Policies and procedures have been approved by the professional staff.
- If located in the U.S., does the organization reuse devices marketed for single use? If so, does it send them to an FDA-approved vendor for reprocessing?



<b>Standard 05.01.02 Cleaning and Decontaminating Instruments</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization has written policies and procedures related to:

- The collecting, receiving, cleaning, and decontamination of instruments.
- The selection of appropriate cleaning/detergent agents and determination of dilution ratios.
- The appropriate personal protective equipment (PPE) to be worn during the cleaning and decontamination procedures.

Required Elements/Additional Information	Notes
<p>The process for cleaning instruments to remove blood and debris must include:</p> <ul style="list-style-type: none"> <li>■ Visually inspection of instruments after initial cleaning to ensure removal of biofilm, debris, dried blood, and detergent residue prior to wrapping and assembly for sterilization. If any of these are not completely removed, the instruments are re-cleaned.</li> <li>■ Inspection of scissors, forceps, trocars, and other instruments for damage such as burs, cracks, dullness, rust, and other evidence of damage. Damaged instruments are removed from use.</li> <li>■ Open position for instruments with ratchets in preparation for sterilization.</li> </ul> <p>The organization ensures any surgical instruments with debris, dried blood, bone fragments, or dark spots are returned for cleaning and re-sterilization.</p>	
<b>Survey Procedure</b>	
<p><b>Observation and Document Review</b></p> <p>Observe and assess:</p> <ul style="list-style-type: none"> <li>■ The procedure for cleaning and decontaminating instruments.</li> </ul> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Practice is consistent with written policies and procedures.</li> <li>■ Personnel have received training and are competent with cleaning and decontaminating procedures.</li> </ul>	

<b>Standard 05.01.03 Cleaning and Sterilization of Surgical Instruments and Scopes</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization ensures that personnel are competent to perform cleaning and sterilization procedures.

The organization has written policies and procedures related to the training of personnel to ensure competence with the cleaning and decontamination of instruments.

Required Elements/Additional Information	Notes
<p>Personnel responsible for decontamination and sterilization duties have received training and have access to the written policies and procedures.</p> <p>The organization trains its personnel on:</p> <ul style="list-style-type: none"> <li>■ The appropriate PPE to wear during the cleaning and decontamination procedures.</li> <li>■ The cleaning and decontamination policies and procedures including the visual inspection of instruments.</li> <li>■ The selection of cleaning/detergents and the appropriate dilution ratios in accordance with the manufacturer’s instructions.</li> </ul> <p>Competency testing is performed at periodic intervals and is documented.</p>	
<p><b>Survey Procedure</b></p> <p><b>Observation, Interview, and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Written policies and procedures meet the standard.</li> <li>■ Through observation or interview confirm that personnel are competent with cleaning, sterilization, and storage of surgical instruments and scopes.</li> </ul> <p>Observe and assess:</p> <ul style="list-style-type: none"> <li>■ Scopes (if applicable to the setting), for debris in the gears and bioburden on the surfaces. <ul style="list-style-type: none"> <li>» Scopes are cleaned, rinsed, and wrapped during transport.</li> <li>» Cleaned scopes are stored so that they do not touch the floor or other instruments.</li> </ul> </li> <li>■ By opening at least one surgical instrument tray that: <ul style="list-style-type: none"> <li>» Ratcheted instruments are in the open position for sterilization.</li> <li>» There is no evidence of rust, debris, dried blood, bone fragments, or dark spots on the instruments.</li> </ul> </li> </ul>	
<p><b>Standard 05.01.04</b> <b>Monitor Effectiveness of Sterilization Cycles</b></p>	<p>Score:</p> <p><input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>The organization has policies and procedures related to:</p> <ul style="list-style-type: none"> <li>■ Use of bacteriologic spore tests (BST) with every load of any type of pressurized gas or liquid sterilization.</li> <li>■ BST run at least weekly in all steam sterilizers.</li> <li>■ Chemical indicator use with each package going through a sterilizer cycle.</li> </ul>	





<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>The organization monitors the effectiveness of every sterilization cycle. The organization is responsible for monitoring vendor quality control. Testing is accomplished, whether or not a load is processed, to document unit capacity.</p> <p>Gas or liquid sterilization is defined as ethylene oxide, carbon dioxide, hydrogen peroxide, or any other non-steam sterilization process.</p> <p>Chemical indicators can be any of several types to demonstrate the product has gone through a sterilization process.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Logs for each type of quality control mechanism to ensure that frequencies are within the guidelines.</li> </ul>	
<p><b>Standard 05.01.05 Sterilization Data Requirements</b></p>	<p>Score: <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>The organization requires temperature and pressure readings to be recorded and maintained for every sterilized load.</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>A written policy requires that for each sterilizer load (e.g., low-temperature sterilization devices, such as equipment for cleaning endoscopes and reprocessing equipment), readings are maintained. The policy specifies how long the readings are retained. The readings may be automatically printed values or handwritten, including the person's name or initials, time, and date.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has and follows its written policy.</li> <li>■ Records are maintained for temperature and pressure readings for every sterilized load in the quality control logs.</li> </ul>	

<b>Standard 05.01.06</b> <b>Load Control Numbers</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>The organization has a written policy and procedures related to load control numbers, which require identification of the equipment used, the sterilization cycle, and date for each sterilized item.</p>	
<b>Required Elements/Additional Information</b>	Notes
<p>There is a written policy and procedure used to track sterilized items to a specific sterilizer load.</p>	
<b>Survey Procedure</b>	
<b>Document Review</b>	
<p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has and follows written policy and procedures.</li> <li>■ The organization has a load control mechanism.</li> </ul>	
<b>Standard 05.01.07</b> <b>Cold Sterilization or High-Level Disinfection</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>The organization has written policies and procedures related to cold sterilization and high-level disinfection procedures used.</p>	
<b>Required Elements/Additional Information</b>	Notes
<p>The written policies and procedures include:</p> <ul style="list-style-type: none"> <li>■ Easily accessible manufacturer’s instructions for use of automated and manual equipment.</li> <li>■ Indications for cold sterilization or high-level disinfection.</li> <li>■ Procedural steps for cold sterilization or high-level disinfection in accordance with the manufacturer’s instructions.</li> <li>■ Cleaning and rinsing of scopes in accordance with the manufacturer’s instructions.</li> </ul>	
<b>Survey Procedure</b>	
<b>Document Review</b>	
<p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has and follows its written policies and procedures.</li> <li>■ The manufacturer’s instructions for use are available to personnel.</li> </ul>	



<b>Standard 05.01.08</b> <b>Immediate-Use Steam Sterilization in Surgical Settings</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization has written policies related to immediate-use steam sterilization (IUSS).

Required Elements/Additional Information	Notes
<p>IUSS is not a substitute for an inadequate supply of instruments and should only be used in rare circumstances.</p> <p>Written policies are based on the device manufacturer’s written instructions for reprocessing any reusable device and must be followed. The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer capabilities, and the packaging.</p> <p>The organization adopts policies regarding parameters required to achieve sterilization, including the physical monitoring of each IUSS cycle. These policies include:</p> <ul style="list-style-type: none"> <li>■ Adherence to the manufacturer’s instructions for sterilization.</li> <li>■ Identification of devices that are NOT compatible with IUSS.</li> <li>■ Identification of the appropriate physical monitors (time, temperature, pressure) for each IUSS cycle.</li> <li>■ Identification of:                             <ul style="list-style-type: none"> <li>» Indications for use of a chemical indicator.</li> <li>» Indications for use of a biological indicator.</li> <li>» Sterilization procedure.</li> <li>» Use of labels.</li> <li>» Frequency of testing.</li> </ul> </li> </ul>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has and follows its written policy.</li> <li>■ Instrument(s) designated to undergo IUSS are first cleaned and disinfected following the manufacturer’s instructions.</li> <li>■ All personnel who perform IUSS:                             <ul style="list-style-type: none"> <li>» Have the necessary time, equipment, supplies, and facilities readily available.</li> <li>» Have been trained and are able to correctly follow the manufacturer’s IFU(s) for each instrument, sterilizer, container, and cleaning supply used for IUSS.</li> <li>» Have had their competency initially verified before they undertake IUSS, and periodically thereafter.</li> </ul> </li> </ul>	

<b>Standard 05.01.09</b> <b>Preparing, Assembling, Wrapping, and the Distribution of Sterile Equipment and Supplies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization has written policies related to preparing, assembling, wrapping, and the distribution of sterile equipment and supplies.

Required Elements/Additional Information	Notes
The written policies address each step of the process in detail.	
<b>Survey Procedure</b>	
<b>Observation and Document Review</b>  Verify: <ul style="list-style-type: none"> <li>■ The organization follows its written policies.</li> <li>■ Personnel have received training and are competent with preparing, assembling, wrapping, and the distribution of instruments.</li> </ul>	

<b>Standard 05.01.10</b> <b>Sterile Supply Storage</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization has written policies related to:

- The shelf life for each type of sterilized product.
- Storage of sterile packages in compliance with the manufacturer’s instructions

Required Elements/Additional Information	Notes
The organization must have an effective process to ensure the integrity of sterile supplies. <ul style="list-style-type: none"> <li>■ The shelf life for each type of sterile package, whether commercially prepared or sterilized in the organization, is identified.</li> <li>■ The cloth packaging standards are significantly more restrictive than for sealed liquid-resistant containers.</li> <li>■ Storage areas are monitored for humidity and a log is maintained.</li> <li>■ Sterile supplies are stored in accordance with national guidelines and applicable law and regulations.</li> </ul>	
<b>Survey Procedure</b>	
<b>Observation and Document Review</b>  Verify: <ul style="list-style-type: none"> <li>■ The organization has and follows its written policies.</li> <li>■ Humidity logs are maintained.</li> <li>■ Cloth or other containers that that may be exposed to moisture, or for which the integrity of the wrapping has been</li> </ul>	



compromised are appropriately managed.

<b>Standard 05.01.11 Process for Monitoring Supplies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

- The organization has written policies and procedures related to:
- Monitoring sterile packages and supplies to ensure none have reached expiration date.
  - Monitoring sterile packages to ensure the integrity has not been compromised.
  - Disposing/reprocessing patient care supplies/equipment that are outdated or contaminated.
  - Monitoring product recalls and the removal of relevant products.

Required Elements/Additional Information	Notes
<p>The organization must have written policies and procedures to ensure the integrity of supplies.</p> <p>The policies and procedures define a process for products recalled due to ineffective sterilization. This process must include:</p> <ul style="list-style-type: none"> <li>■ Notifying the healthcare professional(s) of patients for whom these supplies may have been used.</li> <li>■ Removal of the products from patient care.</li> </ul>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has and follows its policies and procedures.</li> </ul>	

<b>Standard 05.01.12 Temporary Equipment</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
--	--

The organization has written policies and procedures that address the inspection, decontamination, and sterilization of instruments brought into the organization on a temporary basis.

Required Elements/Additional Information	Notes
<p>Written policies and procedures addressing “loaner” instruments borrowed from a vendor for a specific procedure identify that such instruments are considered contaminated.</p> <p>The organization is responsible for the decontamination and sterilization of the instruments prior to the procedure, consistent with the manufacturer’s instructions for use.</p>	

<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ The organization follows its written policies and procedures.</li> </ul>	
<b>Standard 05.02.01 Post-Exposure Protocol</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
The organization has written post-exposure protocols, based on current regulatory or nationally recognized guidelines or recommendations, for the observation, treatment, and reporting of all patients, personnel, or public who have an “exposure incident.”	
<b>Required Elements/Additional Information</b>	Notes
An “exposure incident” may include specific eye, mouth, other mucus membrane, nonintact skin, or parenteral contact with blood or other potentially infectious materials.	
Organizations located in the U.S must maintain compliance with OSHA Standard 1910.1030 (b). International organizations follow their national requirements or, if there are none, the equivalent of the OSHA Standard 1910.1030 (b).	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Review and assess:	
<ul style="list-style-type: none"> <li>■ Written post-exposure protocols for all potential exposures.</li> <li>■ Copies of guidelines or recommendations that were used for developing the protocols.</li> </ul>	
<b>Standard 05.03.01 Clean Linen</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
The organization has written policies that address:	
<ul style="list-style-type: none"> <li>■ The amount of clean linen to be available for the care and comfort of patients.</li> <li>■ The storage of clean linen in a manner that reduces the potential for airborne or surface contamination to prevent the spread of disease.</li> </ul>	
<b>Required Elements/Additional Information</b>	Notes
Clean inventory is transported in a manner that prevents exposure to dust, soil, and other contaminants from transport carts and/or wheels.	
The lowest shelves of the clean linen storage and transportation carts are enclosed and not open to the spread of dust and other potential contaminants.	



<b>Survey Procedure</b>	
<b>Observation and Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ The required written policies.</li> <li>■ Clean linen is stored in compliance with the policies.</li> <li>■ The bottom shelves of the linen storage and the transport carts are enclosed.</li> </ul>	
<b>Standard 05.03.02 Linen Management</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
The organization has written policies and procedures addressing the processing of linen to reduce the likelihood of cross-contamination and provide a safe environment.	
<b>Required Elements/Additional Information</b>	<b>Notes</b>
The organization’s written policies and procedures for processing linen address the use, collection, storage, transportation, and laundering of linen, and are based on nationally recognized guidelines and/or recommendations (e.g., CDC, OSHA, APIC, Association for Linen Management (ALM), and Healthcare Laundry Accreditation Council (HLAC)).	
Soiled linen is stored in non-patient care areas.	
Measures are taken to reduce the potential for particles becoming airborne and/or liquids dripping from, or absorbing into, any holding device.	
Linen transported in and out of the facility is contained and covered. Clean linen provided by an off-site laundry is packaged prior to transport to prevent inadvertent contamination from dust, soil, and other contaminants during loading, delivery, and unloading. Contaminated containers are sanitized before use to transport clean linen.	
<b>Survey Procedure</b>	
<b>Observation and Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ The organization has the required written policies and procedures.</li> <li>■ Soiled linen is collected and stored in compliance with written policies and procedures.</li> </ul>	

**Standard 05.03.03  
Internal Laundry**

Score:

C  NC  NA

An organization providing its own laundry services has written policies and procedures based on nationally recognized guidelines and/or recommendations.

**Required Elements/Additional Information**

Notes

When laundering occurs in the facility, the cycles consist of flush, main wash, bleaching, rinsing, and scouring, and the procedures are based on nationally recognized guidelines and/or recommendations (e.g., CDC, OSHA, ALM, APIC).

When hot water is used, it is maintained at an appropriate temperature for the appropriate length of time. Low water temperatures are appropriately matched with chlorine bleach or other laundry additives for cleaning and decontamination.

Staff are trained on the use of laundry products.

Monitoring activities and maintenance of equipment are documented.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Water temperature logs.
- Staff training.
- Storage and use of laundry products.
- Maintenance of equipment.
- Staff transport and handle linen in compliance with the policies and procedures.



THIS PAGE IS INTENTIONALLY BLANK.



06

**PATIENT  
RIGHTS**

**Standard 06.00.01  
Patient Rights**

Score:

 C  NC

The organization must:

- Inform the patient or the patient's representative or surrogate of the patient's rights.
- Protect and promote the exercise of these rights.
- Provide the written notice of patient rights for patients waiting for treatment or to the patient's representative or surrogate, if applicable.

**Required Elements/Additional Information**

Notes

The organization informs each of its patients, and/or the patient's representative in the case of minor patients or designated representatives or surrogates in other situations, of the patient's rights.

- All policies, procedures, and actions are consistent with the protection of the patients' rights articulated in this standard.
- The organization actively promotes patients exercising their rights.

The organization ensures that a written notice of patient rights is provided to the patient or the patient's representative or surrogate, if applicable, prior to the initiation of treatment. The notice may be posted either in a conspicuous location and/or provided directly to the patient.

**PATIENT'S REPRESENTATIVE**

The patient's representative or surrogate is an individual designated by the patient, in accordance with applicable law and regulations, to make healthcare decisions on behalf of the individual or to otherwise assist the patient during his/her treatment by the organization.

- Designation may be in writing, (e.g., advance directive or medical power of attorney) or may be oral (verbal).
- Written designation may occur before the patient presents to the organization or during the organization's registration process.
- Oral designation may take place at any time during the patient's visit in the organization. The patient's representative or surrogate includes, but is not limited to, a family member or friend who accompanies the patient.
- Depending on the designation the patient has made, the patient's representative or surrogate may make all healthcare decisions for the patient during his/her visit to the organization, or may act in a more limited role, for example, as a liaison between the patient and the organization to help the patient communicate, understand, remember, and cope with the interactions that take place during the visit, and explain



any instructions to the patient that are delivered by the organization staff.

- If a patient is unable to fully communicate directly with the organization staff, then the organization may give patient rights information to the patient’s representative or surrogate.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- Patients (or their representatives or surrogates, as applicable) are provided with notice of their rights, consistent with these standards.
- The exercise of patient rights is promoted, consistent with these standards.
- Posted notices contain the same information as the individual written notice provided to patients or their representatives/surrogates.

**Standard 06.00.02  
Informed Consent**

Score:  
 C  NC

The patient has the right to be fully informed about a treatment or procedure and the expected outcome before it is performed.

**Required Elements/Additional Information**

Notes

The right to make informed decisions means that the patient or patient’s representative is given the information needed regarding his/her care and to enable him/her to evaluate a proposed procedure before agreeing to the procedure.

The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis, and prognosis.

The right includes the patient's participation in the development of their plan of care, including providing consent to, or refusal of, medical or procedural interventions, and planning for care after discharge from the organization.

Information must be provided in a manner that the patient or the patient's representative can understand to ensure that the patient can effectively exercise the right to make informed decisions.

Information includes potential short and longer-term risks and benefits of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible healthcare professional’s judgment.

- Informed consent must be obtained, and the informed consent form must be signed by the patient or, as appropriate,

the patient's representative, and placed in the patient's healthcare record prior to the procedure.

It is acceptable for the organization to require the healthcare professional who performs procedures in the organization to obtain the patient's informed consent outside of the organization, prior to the date of the procedure, because this might allow more time for discussion between the patient and healthcare professional than would be feasible on the date of the procedure. In such cases, the healthcare professional must follow the organization's informed consent process. The organization is responsible for ensuring an informed consent process is in place for each patient.

The organization's procedure and anesthesia informed consent policy describes:

- Documentation of informed consent (i.e., for the procedure and proposed anesthesia plan in one form or separate forms).
- Who may obtain the patient's informed consent.
- The circumstances under which a patient's representative, rather than the patient, may give informed consent for a procedure and the anesthesia.
- The content of the informed consent form and instructions for completing it.
- The process used to obtain informed consent, including how informed consent is documented in the healthcare record.
- Mechanisms to obtain the consent in a language understood by the patient.
- Mechanisms that ensure that the informed consent is properly executed and is in the patient's healthcare record prior to the surgery.
- How the executed informed consent documentation is incorporated into the patient's healthcare record prior to the procedure if the informed consent is obtained outside of the organization.

If there are additional legal requirements for informed consent, the organization must comply with those requirements.

## Survey Procedure

### Interview and Document Review

Verify:

- The organization has an informed consent policy that meets the regulatory requirements.
- The survey sample of healthcare records includes documentation that informed consent was obtained prior to the procedure.
- The patient's or, as appropriate, the patient's representative



signed consent was obtained prior to the procedure.

- Informed consent was documented for patients receiving care on the day of the survey.

Discuss and assess:

- Whether patients recall being asked to consent to the procedure, and whether the risks and benefits were discussed with them at that time.

**Standard 06.00.03  
Advance Directives**

Score:  
 C  NC

The organization must:

- Provide the patient or, as appropriate, the patient’s representative, with written information concerning its policies on advance directives, including a description of applicable health and safety laws and regulations and, if requested, required advance directive forms.
- Inform the patient or, as appropriate, the patient’s representative, of the patient’s right to make informed decisions regarding the patient’s care.
- Document in a prominent part of the patient’s current healthcare record whether or not the individual has executed an advance directive.

**Required Elements/Additional Information**

Notes

An advance directive is a written instruction, such as a living will or durable power of attorney for healthcare, recognized under applicable law and regulations (whether statutory or as recognized by the courts), relating to the provision of healthcare when the individual who has issued the directive is incapacitated.

Each patient has the right to formulate an advance directive consistent with applicable law and regulations and to have organization staff implement and comply with the advance directive, subject to the organization’s limitations on the basis of conscience.

To the degree permitted by law and regulations, and to the maximum extent practicable, the organization must respect the patient’s wishes and follow that process.

The organization must provide the items below to the patient or the patient’s representative, as appropriate, prior to the start of the procedure:

- Information on the organization’s policies on advance directives.
- A description of the applicable state health and safety laws.
- If requested, official advance directive forms, if such exist.

A statement of limitation must:

- Clarify any differences between organization-wide conscience objections and those that may be raised by individual organization staff.

- Identify the legal authority permitting such objections.
- Describe the range of healthcare conditions and procedures affected by the objections.
- For example, the organization's notice of limitation could, if permitted by law, indicate that it would always attempt to resuscitate a patient and transfer that patient to a hospital in the event of clinical deterioration.

The patient may wish to delegate his/her right to make informed decisions to another person, even though the patient is not incapacitated.

- To the extent permitted by law and regulations, the organization must respect such delegation.
- In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the organization must consult the patient's advance directives, medical power of attorney, or patient representative or surrogate, if any of these are available.
- In the advance directive or the medical power of attorney, the patient may provide guidance as to his/her wishes in certain situations or may delegate decision-making to another individual as permitted by state law. If such an individual has been selected by the patient, or if a person willing and able under applicable law and regulations is available to make treatment decisions, relevant information should be provided to the representative or surrogate, so that informed healthcare decisions can be made for the patient.
- However, as soon as the patient is able to be informed of his/her rights, the organization should also provide that information to the patient.

### **DOCUMENTATION OF ADVANCE DIRECTIVES**

The organization must document in the patient's healthcare record for the current procedure scheduled at the organization whether or not the patient has executed an advance directive.

- This documentation must be placed in a prominent part of the healthcare record where it will be readily noticeable by any staff providing clinical services to the patient.
- The documentation requirement applies even if the organization is unable to comply with the patient's advance directive on the basis of conscience or a state law limitation.
- If the patient with an advance directive is transferred from the organization to another healthcare facility (e.g., if there is an emergency transfer to a hospital), a copy of the patient's advance directive is provided with the healthcare record when the patient is transferred.



**Survey Procedure**

**Interview and Document Review**

- Verify:
- Policies and procedures related to the advanced directive requirements conform to the requirements.
  - The written notice of the organization’s advance directive policies and applicable law contains all required information.
    - » If there is a statement of limitations based on conscience or applicable law, it includes all required information.
    - » If the applicable governmental entity with jurisdiction over the organization has an official advance directive form, the organization provides these forms upon request to patients.
  - Through review of patient records that the organization documents provision of required advance directive information to the patient or the patient’s representative prior to the start of the procedure.
  - Each record in the survey sample prominently displays information as to whether or not there is an advance directive in effect for the patient.
    - » Is the information displayed in a manner such that patients with advance directives can be readily distinguished from patients without an advance directive?
  - The organization educates its staff regarding advance directives and promoting informed decisions.
    - » Does the organization have a training class or any educational materials available for the staff regarding advance directives and informed patient decision-making?
    - » Interview staff to determine their knowledge of the advance directives of the patients in their care.

**Standard 06.00.04  
Representation of Patients Declared Incompetent by the State**

Score:  
 C  NC

If a patient is adjudged incompetent under applicable law and regulations by a court of proper jurisdiction or another appropriate legal entity, the rights of the patient are exercised by the person appointed under that law to act on the patient’s behalf.

If a patient has not been adjudged incompetent under applicable law by a court of proper jurisdiction, any legal representative or surrogate designated by the patient in accordance with state law may exercise the patient’s rights to the extent allowed by applicable law and regulations.

**Required Elements/Additional Information**

Notes

A patient who has been adjudged incompetent under an applicable legal process is not capable of exercising his/her rights independently.



For such patients, the person appointed under applicable law to act on the patient's behalf may exercise any and all of the rights afforded to any organization patient.

**Survey Procedure**

**Document Review**

Verify:

- There is a policy addressing the exercise of rights on behalf of a patient judged legally incompetent.
- There is a policy addressing the delegation by a patient of the exercise of rights to a representative.

**Standard 06.00.05  
Disclosure of Financial Interests or Ownership**

Score:  
 C  NC

The organization must disclose in writing healthcare professionals who have financial interest or ownership in the organization.

**Required Elements/Additional Information**

Notes

An organization that has healthcare professional owners or investors must provide written notice to the patient or the patient's representative or surrogate prior to the start of a procedure, that such owners have a financial interest in the organization.

The intent of this disclosure requirement is to assist the patient in making an informed decision about his/her care by making the patient or the patient's representative or surrogate aware that healthcare professionals who refer their patients to the organization for procedures or healthcare professionals who perform procedures in the organization also have an ownership or financial interest in the organization.

Information should be provided in a manner that is not only technically correct, but also easily understood by persons not familiar with financial statements, legal documents, or technical language. The organization should also be aware of the age and the cognitive abilities of its patients in developing its written notice.

**Survey Procedure**

**Interview and Document Review**

If the organization indicates it has physicians with ownership/financial interest in the organization, verify:

- The organization has policies and procedures, consistent with the requirements, to make the required disclosures to patients.
- The written notice of disclosure is provided to all patients in advance of the date of the procedure.

Discuss and assess:



- Staff knowledge and understanding of the physician ownership notice requirements, including the process for delivering the notice.
- Whether patients were aware that the organization has physician owners/investors.

**Standard 06.01.01  
Exercise of Rights and Respect for Property and Person**

Score:  
 C  NC

The patient has the right to be free from any act of discrimination or reprisal.

**Required Elements/Additional Information**

Notes

The organization may not take punitive action or discriminate against a patient. This includes retaliation or discrimination against a patient merely because he/she has exercised his/her rights.

The organization's patients' rights policies and procedures must indicate that the organization does not engage in reprisals or discriminatory behavior.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization's policies and procedures reflect that patients or their representatives or surrogates may exercise their rights without fear of reprisal.

Discuss and assess:

- Whether staff are aware that the organization may not discriminate against patients or take punitive actions against any patient as a reprisal for some act on the patient's part.

**Note:** If the survey is related to a complaint alleging that an organization ignored a patient's grievance, include that healthcare record in the sample and review it to determine if there is any evidence of a grievance and action to respond to the grievance.

**Standard 06.01.02  
Privacy and Safety**

Score:  
 C  NC

The patient has the right to:

- Personal privacy.
- Receive care in a safe setting.
- Be free from all forms of abuse or harassment.

**Required Elements/Additional Information**

Notes

The underlying principle of this standard 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 medical/procedural care, and when requested, as appropriate.

The organization staff follow current standards of practice for patient environmental safety, infection prevention and control, and security. The organization staff also provide protection for the patient's emotional health and safety as well as the patient's physical safety. Respect, dignity, and comfort would be components of an emotionally safe environment.

People not involved in the care of the patient are not present without the patient's consent.

- Reasonable privacy is provided when staff visits the patient to discuss clinical care issues or conduct any examination.
- A patient's right to privacy may be limited in situations when a person must be continuously observed, such as when there is an emergency and transfer to a hospital is pending.

The organization provides for each patient to receive care in an environment that a reasonable person would consider to be safe.

The organization must have mechanisms/methods in place to ensure that patients are free from all forms of abuse, neglect, or harassment.

In most situations, security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc., are not generally affected by this requirement.

## Survey Procedure

### Observation, Interview, and Document Review

Verify:

- That patients are provided privacy during examinations, activities concerning personal hygiene, and discussions regarding their health status or health care, and any other appropriate situations.
- Patient and staff incident and accident reports identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with a safe environment in the organization.
- Safety, infection control, and security documentation indicate that the organization is identifying problems, evaluating those problems, and taking steps to ensure a safe patient environment.
- Policy and procedures identify steps the facility takes to curtail unwanted visitors and/or contaminated materials.

Discuss and assess:

- Whether staff and/or patients have any concerns about the safety of the setting.



<b>Standard 06.02.01 Right to Voice Grievances</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The patient has the right to voice grievances regarding treatment or care that is (or fails to be) provided.

All alleged violations/grievances relating, but not limited to, mistreatment, neglect, or verbal, mental, sexual, or physical abuse must be fully documented.

The organization must provide the patient, the patient’s representative, or the patient’s surrogate with written notice of how it addressed the grievance including the name of an organization contact person, the steps taken to investigate the grievance, the result of the grievance process, and the date the grievance process was completed.

Required Elements/Additional Information	Notes
--	-------

A patient grievance or complaint regarding the patient’s care, abuse, neglect, or organization compliance issues may be written or verbal and presented formally or informally to the organization by a patient or a patient’s representative.

A written complaint must always be addressed through the complaint or grievance process. This includes written complaints from a current patient, a released/discharged patient, or a patient’s representative.

Billing issues are not usually considered grievances for the purposes of this standard.

As part of its obligation to notify patients of their rights, the organization must inform the patient and/or the patient’s representative or surrogate of the organization’s grievance process, including how to file a grievance.

The organization ensures that documentation of the grievance includes, at a minimum:

- The date, time, and location of the alleged occurrence generating the grievance.
- The names of all individuals involved.
- A description of the behavior within the organization that is alleged to have constituted mistreatment, neglect, abuse, or other serious harm.

**SATISFACTION SURVEYS—COMPLAINTS**

Information from patient satisfaction surveys conducted by the organization is not usually considered a grievance.

However, if an identified patient writes or attaches a written complaint on the survey and requests resolution, the complaint must be treated as a grievance.

If an identified patient writes or attaches a complaint to the survey, but does not request resolution, the organization should treat this as a

grievance if the organization would usually treat such a complaint as a grievance.

**WRITTEN RESPONSE TO PATIENT**

The organization’s written response to the patient or the patient’s representative or surrogate regarding each grievance may not be a form letter with generic statements about grievance process steps and results.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization has a written policy addressing the grievance process.
- The process addresses how grievances are documented, how they are to be submitted, how they are to be investigated, and how the findings are to be used to dispose of the grievance.
- Grievances that the organization received during the past year are documented.
- Files demonstrate that grievances are properly documented and handled in accordance with the organization’s policy and the standard’s requirements.
- In the case of a complaint survey concerning a grievance, ask to see grievances submitted at the time of the grievance that triggered the complaint survey.

Discuss and assess:

- Whether staff are aware of the grievance policies.
- If patients and/or representatives or surrogates know how to file a grievance and who to contact if they have a complaint/grievance.

**Standard 06.02.02  
Submission and Investigation of Grievances: Documentation**

Score:  
 C  NC

The organization has procedures for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the organization.

**Required Elements/Additional Information**

Notes

Grievances making allegations related to mistreatment, neglect, verbal, mental, sexual, or physical abuse, or other serious allegations of harm must be fully documented. All pertinent details of the allegation must be recorded and retained in the organization’s files.

- All grievances alleging mistreatment, neglect, or abuse that are submitted to any organization staff member, whether verbally or in writing, are reported immediately (i.e., as soon as possible) and at least on the same day by the staff member to an

organization official who has authority to address grievances.

The organization's policies and procedures address the following, at a minimum:

- The person(s) with authority to respond to grievances.
- Time frames for reporting, investigating, responding to, and reporting, if required.
- Required documentation components, including, at a minimum, the original grievance, the staff member who received the grievance, staff report of the grievance, the investigation process, final resolution, and the date of response to the person who submitted the grievance.
- The acceptable methods for responding to the person who is submitting the grievance.

The organization educates staff on the process for reporting all grievances, including to whom they should report the grievance.

The organization incorporates the grievances into its quality assessment and performance improvement program to evaluate any systemic problems indicated by the grievance that require resolution.

In its written response to any grievance, the organization is not required to include statements that could be used in a legal action against the organization, but the organization should provide adequate information to address the specific grievance.

### **REPORTING A CONFIRMED GRIEVANCE TO AUTHORITIES**

If the organization confirms that the alleged mistreatment, abuse, neglect, or other serious harm took place, then it is obligated to report the event to the appropriate governmental authority.

Depending on the specifics of the case, the appropriate authority(ies) might include local police, a healthcare professional licensing board, a governmental agency that licenses the organization, a government ombudsman, etc.

The organization should contact the appropriate authority promptly after it concludes its investigation that verifies a grievance.

## **Survey Procedure**

### **Interview and Document Review**

Verify:

- The grievance policies and procedures separately address the process for investigating grievances alleging mistreatment, abuse, neglect, or other serious harm and address all required elements of the standard.

Discuss and assess:

- How staff would handle a grievance alleging mistreatment, abuse, neglect, or other serious harm, including to whom the

grievance would be reported.

- With the person authorized to handle such grievances whether he/she understands the requirements to fully document the allegation, conduct a prompt investigation, and to report substantiated grievances to the proper authority.
  - » Ask if the organization has had any grievances alleging mistreatment, neglect, abuse, or other serious harm.
  - » If yes, review the documentation for one or more such grievances. If such grievances were substantiated, verify that documentation of the findings are reported to the appropriate authority.

<b>Standard 06.03.01 Use of Restraints</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The patient has the right to be free from unnecessary use of physical or chemical restraint as a means of coercion, convenience, or retaliation.

<b>Required Elements/Additional Information</b>	Notes
<p>The organization has policies and procedures addressing the use of restraints, including defining restraints.</p> <p>Restraints are used only when an order in accordance with law and regulations is given by a healthcare provider who is authorized by the organization and.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policies and procedures appropriately address the use of restraints.</li> <li>■ The organization's use of restraints aligns with policy.</li> </ul>	



THIS PAGE IS INTENTIONALLY BLANK.





07

**EMERGENCY  
MANAGEMENT**

The purpose of this chapter is to ensure office-based surgical settings provide adequate planning for both natural and man-made disasters. Organizations must coordinate compliance for these standards and those of other regulatory agencies.

There are three key areas of focus for maintaining access to healthcare services during an emergency:

- Safeguarding human resources.
- Maintaining business operations.
- Protecting physical resources.

The standards in this chapter are broken into sections addressing Planning, Procedures, and Training and Testing.

**PLANNING**

<b>Standard 07.00.01 Emergency Management</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization must comply with all applicable governmental (e.g., federal, state, and local) emergency management requirements.

The organization must develop and maintain an emergency management program utilizing an all-hazards approach.

Required Elements/Additional Information	Notes
--	-------

The organization must have an emergency management program that includes:

- Planning (including a risk assessment (Hazard Vulnerability Analysis)).
- A written plan, policies and procedures.
- Communication.
- Training and testing.

Emergency management requirements focus on continuity of operations, not recovery of operations, hazard mitigation, or business continuity. Facilities may choose to include planning for recovery of operations, hazard mitigation, and business continuity in their emergency management program, but these items are not a requirement.

The emergency management program must describe an organization’s comprehensive approach to meeting the health, safety, and security needs of the staff and patient population during an emergency. The program must also address how the organization will coordinate with other healthcare facilities and the community during an emergency.

The program must be reviewed and updated as necessary to comply with regulatory requirements. In addition, at a minimum, organization leadership must review the emergency management program

Notes



annually for relevance and accuracy.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The written emergency management includes the four key elements described.
- The emergency management program is reviewed every year.

Discuss and assess:

- With organization leadership, their description of the organization’s emergency management program.

**Standard 07.00.02  
Hazard Vulnerability Analysis (HVA)**

Score:  
 C  NC

The organization conducts a documented, facility-based, and community-based risk assessment (i.e., Hazard Vulnerability Analysis (HVA)) to ascertain conceivable threats and disasters that could affect the organization’s ability to operate its facilities or to provide services to its patients, and the probability of those events occurring.

The organization must identify likely hazards for their community service area (e.g., natural disaster, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel, nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and develop appropriate responses that will ensure the safety and wellbeing of patients.

The HVA is documented and reviewed annually by the governing body for relevance and accuracy.

**Required Elements/Additional Information**

Notes

Prior to establishing an emergency operations plan, the organization must assess risk (i.e., HVA) based on an all-hazards approach. All-hazards planning does not specifically address every possible threat but ensures that organizations will have the capacity and capability to address a broad range of related emergencies.

There must be evidence that the organization has considered the following when developing the all-hazards risk assessment:

- Identification of all business functions essential to the organizations’ operations that should be considered during an emergency.
- Identification of all risks or emergencies that the organization may reasonably expect to confront.
- Identification of all contingencies for which the organization should plan.
- The organization’s location, including all locations where the organization delivers patient care or services, or has business operations.

- Assessment of the extent to which natural or man-made emergencies may cause the organization to cease or limit operations.
- Determination of arrangements with other organizations, other healthcare providers or suppliers, or other entities that might be needed to ensure that essential services could be provided during an emergency.

All facilities where patient care is provided are required to have an assessment conducted for hazards, including facilities that the organization may not own but where it provides treatment for its patients.

If the organization has multiple sites, it may choose to create a single HVA that applies to all of the sites of the organization, or an individual HVA for each location.

If the organization participates in a community-based assessment (i.e., HVA) developed by other entities, such as a public health agency, emergency management agency, and/or regional healthcare coalition, or in conjunction with conducting its own facility-based assessment, it is expected that the organization will have a copy of this risk assessment and will work with the entity that developed it to ensure that the organization's emergency plan is in alignment.

Organizations must prioritize the potential hazards to their organization, and these priorities are documented in the HVA. The organization shares their HVA with their community partners to help set priorities with the HVA. Community partners may include:

- The department of public health.
- The department of public safety.
- The department of public works.
- Local municipality representatives.
- Other government agencies.
- Community organizations.
- Vendors.
- Other healthcare organizations.

## Survey Procedure

### Interview and Document Review

Verify:

- The HVA is reviewed by the organization and updated annually.
- The organization has shared or attempted to share their HVA with one or more community partners, if required.



<b>Standard 07.00.03 Emergency Operations Plan</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

A written Emergency Operations Plan (EOP) is developed, maintained, and available to the staff for crisis preparation and response.

The EOP is based on the priorities established in the current Hazard Vulnerability Analysis (HVA) and includes strategies for addressing emergencies identified in the HVA.

Policies and procedures for emergency management are based on the EOP and the HVA.

Required Elements/Additional Information	Notes
<p>The EOP must be integrated into the organization-wide quality assessment performance improvement (QAPI) plan.</p> <p>The EOP provides the framework that will assist an organization in addressing the needs of its patient populations, along with identifying the continuity of business operations, which will provide support during an actual emergency.</p> <p>Plans include, but are not limited to:</p> <ul style="list-style-type: none"> <li>■ Fires in the facility.</li> <li>■ Natural disasters.</li> <li>■ Man-made disasters.</li> <li>■ Public health emergencies (e.g., pandemic).</li> <li>■ Facility-based disasters including, but not limited to:                             <ul style="list-style-type: none"> <li>» Care-related emergencies.</li> <li>» Equipment and utility failures, including but not limited to power, water, gas, etc.</li> <li>» Interruptions in communication, including cyber-attacks.</li> </ul> </li> <li>■ Loss of all or a portion of a facility.                             <ul style="list-style-type: none"> <li>» Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and, in some cases, medications and medical supplies (including medical gases, if applicable).</li> </ul> </li> </ul> <p>If the organization has more than one location, it may choose to have one EOP inclusive of all facilities where patients are treated and cared for, or it may choose to have individual EOPs for each location.</p> <p>If required, the organization shares the details of the EOP with the community's emergency response agencies. The organization assesses the community's abilities to meet the needs of the organization during an emergency event.</p> <p>This involvement with the community and the assessment of the community's abilities is documented.</p>	

**Survey Procedure**

**Interview and Document Review**

Verify:

- The EOP aligns with the potential emergencies identified in the HVA.
- Emergency management is integrated into the organization-wide QAPI plan.
- Emergency management-related data are collected and used to improve the quality of patient care and patient safety. Improvements are monitored to ensure improvement in outcomes/results.
- Leadership can recognize the hazards (e.g., natural, man-made, facility, geographic, etc.) identified in the organization’s risk assessment and how the risk assessment was conducted.
- The plan is reviewed and updated annually by looking for documentation of the date of the review and updates that were made to the plan based on the review.
- Documentation ensures that the EOP was shared with local authorities per the policy of the organization and reviewed against the community emergency management and response plan.

**Standard 07.00.04  
Patient Population**

Score:

C  NC

The emergency operations plan (EOP) must address the organization’s patient population.

**Required Elements/Additional Information**

Notes

When creating the EOP, emergency response considerations reflect all patients (with special attention to at-risk individuals), staff, and visitors within the organization.

At-risk individuals include those who are from diverse cultures, have disabilities, limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency.

Mobility is an important part of effective and timely evacuations, therefore facilities are expected to properly plan to identify patients who would require additional assistance, ensure that means for transport are accessible and available, and that those involved in transport, as well as the patients, are made aware of the procedures to evacuate. The emergency plan must ensure that patients with limited mobility are addressed.



**Survey Procedure**

**Interview and Document Review**

Verify:

- The EOP identifies the organization’s at-risk patients.
- The EOP is applicable to the patient population served.

**Standard 07.00.05  
Continuity of Operations**

Score:  
 C  NC

The Emergency Operations Plan (EOP) must address the continuity of operations, including delegation of authority and succession plans.

**Required Elements/Additional Information**

Notes

Continuity of operations planning generally considers elements such as: essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources.

If the emergency requires the cessation of services, the EOP addresses the orderly cessation of services.

When creating the EOP, consideration should be given to:

- If/how the organization will continue to operate during the emergency event.
- Who is delegated as the authority during the emergency event.
- How the succession of that authority is provided.

Organizations are encouraged to refer to and use resources from various agencies such as FEMA and Assistant Secretary for Management and Response (ASPR) when developing strategies for ensuring continuity of operations.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The EOP provides for the continuity of operations.
- The EOP addresses the delegation of authority during the emergency event, and the succession of that authority.

**Standard 07.00.06  
Collaboration of Resources**

Score:  
 C  NC

The emergency operations plan (EOP) must include a process for notifying applicable government (e.g., local, tribal, regional, state, and federal) emergency management officials of supplies and services that may be provided during a disaster or emergency situation.

Required Elements/Additional Information	Notes
<p>The organization must identify the process and extent of its participation in the community-wide response to a disaster or emergency. The organization must identify services and supplies that it may provide as part of the community's collaborative efforts and provide that information to the applicable government emergency management officials.</p> <p>Organizations are encouraged to participate in a healthcare coalition to assist in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. Planning with officials in advance of an emergency helps determine how such collaborative and cooperative efforts would achieve and foster a smoother, more effective, and more efficient response in the event of a disaster.</p>	
<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
<p>Verify:</p> <ul style="list-style-type: none"> <li>■ The EOP identifies the extent of collaboration with the required authorities during the planning process for emergency management.</li> <li>■ Copies of the EOP have been forwarded to listed collaborative authorities for their use and reference, if required. Evidence of communication beyond making the EOP available to these entities is not required.</li> </ul>	
<b>PROCEDURES</b>	
<p><b>Standard 07.01.01</b> <b>Patient and Staff Tracking</b></p>	<p>Score:  <input type="checkbox"/> C   <input type="checkbox"/> NC   <input type="checkbox"/> NA</p>
<p>The policies and procedures must address a system to track the location of on-duty staff and sheltered patients in the organization's care during an emergency.</p>	
Required Elements/Additional Information	Notes
<p>Tracking patients after an emergency is not a requirement of this standard.</p>	
<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
<p>Verify:</p> <ul style="list-style-type: none"> <li>■ Written policies and procedures are in place to track on-duty staff and sheltered patients in the organization's care during an emergency.</li> </ul>	





<b>Standard 07.01.02 Contact Information</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization must be prepared to contact other organizations in the event of an emergency. The contact list must include the names and contact information for:

- Staff.
- Entities providing services under the arrangement.
- Nearby hospitals and CAHs.
- Applicable government agency emergency management staff (e.g., federal, state, tribal, regional, local).
- Other sources of assistance.

Required Elements/Additional Information	Notes
<p>An organization must have the contact information for those individuals and entities outlined within the standard and must update the contact information for incoming new staff and departing staff throughout the year, and any other changes to information for those individuals and entities on the contact list.</p> <p>Organizations must retain a list of evacuated patients, staff, and visitors.</p> <p>Facilities may also find it prudent to have contact information for other facilities not of the same type. For instance, an organization may find it appropriate to have the contact information of other healthcare facilities within a reasonable geographic area, which could assist in facilitating patient transfers.</p> <p>Organizations have discretion in formatting this information; however, it should be readily available and accessible to leadership and staff during an emergency event. Organizations that use electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access these data during emergencies.</p>	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ The emergency contact list contains the names and contact information of the individuals noted.</li> </ul>	

<b>Standard 07.01.03 Primary and Alternate Means of Communication</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The policies and procedures must include primary and alternate means for communication with the following:

- The organization's staff.
- Applicable government emergency management agencies (e.g., federal, state, tribal, regional, local).

Required Elements/Additional Information	Notes
--	-------

Reliable communication must be maintained by the organization during an emergency event.

The communication plan should include procedures for when and how alternate communication methods are used, and who uses them. In addition, the organization should ensure that its selected alternative means of communication are compatible with the communication systems of other facilities, agencies, and applicable government officials it may communicate with during an emergency.

Backup technology must be considered and used with the consideration that traditional methods of communication may not be available. Alternative methods must be explored and planned for in the written procedure.

Primary and alternate means of communication include:

- Landline telephones.
- Pagers.
- Internet provided by satellite or non-telephone cable systems.
- Cellular telephones.
- Radio transceivers (walkie-talkies).
- Various other radio devices, such as NOAA weather radio and amateur radio (HAM).
- Satellite telephone communication systems.

The communication plan provides written procedures and methods describing how the organization communicates with staff and outside agencies that have a functional role with the organization's response and recovery phases during an emergency event.

Survey Procedure
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policies and procedures cover requirements for primary and alternate communication means with staff and outside agencies.</li> </ul>



<b>Standard 07.01.04 Healthcare Documentation</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

Policies and procedures must address a system of healthcare documentation that preserves patient information, protects the confidentiality of patient information, and secures and maintains the availability of records.

<b>Required Elements/Additional Information</b>	Notes
---	-------

Such policies must comply with applicable laws and regulations (e.g., HIPAA rules) that protect the privacy and security of an individual's protected health information.

This standard does not require any particular type or style of healthcare documentation system and does not require the organization to have the same system as other healthcare providers in their region.

<b>Survey Procedure</b>	
-------------------------	--

**Interview and Document Review**

Verify:

- The policies and procedures address a system of healthcare documentation to be used in the event of an emergency.
- The healthcare documentation system preserves patient information and protects the confidentiality of patient information.
- The patient healthcare records are available during the emergency event.

<b>Standard 07.01.05 Release of Information During an Evacuation</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

In the event of an evacuation, policies and procedures must include a means to release patient information as permitted under applicable regulations pertaining to patient health information.

<b>Required Elements/Additional Information</b>	Notes
---	-------

The HIPAA Privacy Rule specifically permits certain uses and disclosures of protected health information in emergency circumstances and for disaster relief purposes.

A covered entity may use or disclose protected health information to notify or assist in notifying a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for notification purposes must be in accordance with applicable laws and regulations.

A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in

disaster relief efforts, for the purpose of coordinating with such entities uses or disclosures that are permitted by law and regulations.

**Survey Procedure**

**Document Review**

Verify:

- The EOP includes the means to provide patient information to family members, personal representatives, or other individuals responsible for the care of the patient.

**Standard 07.01.06  
Evacuation**

Score:

C  NC

The policies and procedures must address the safe evacuation from the organization, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

**Required Elements/Additional Information**

Notes

The evacuation policies and procedures may be part of the emergency operations plan (EOP) or may be separate. If separate, the EOP must reference where to find the evacuation plan.

When developing the policies and procedures addressing each element listed in the standard, organizations must consider patient population needs as well as their care and treatment. If the organization must evacuate, leadership should consider the care needs of patients to be evacuated. For example, they may need to be accompanied by staff who can provide care and treatment en route to the designated relocation site in the event trained medical professionals are unavailable from the transportation services.

Facility policies and procedures must outline primary and alternate means of communication with external sources for assistance. For instance, primary methods may be considered via regular telephone/digital platform services to contact transportation companies for evacuation or reporting evacuation needs to emergency officials, whereas alternate means account for loss of power or telephone services in the local area. In this event, alternate means may include satellite phones for contacting evacuation assistance.

Organizations may consider multiple transportation options for patient evacuation.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The policies and procedures provide for an emergency



evacuation plan.

- The emergency evacuation plan was reviewed by the local community emergency response agency.
- The policies and procedures considered multiple transportation options for patient evacuation needs.

<b>Standard 07.01.07 Shelter in Place</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The policies and procedures must address, in conjunction with building management, the means to shelter in place for patients and staff who remain in the facility during an emergency event.

Required Elements/Additional Information	Notes
--	-------

Organizations must make plans to shelter all patients in the event that an evacuation cannot be executed. When developing policies and procedures for sheltering in place, factors to consider include the ability of the building(s) to survive a disaster and what proactive steps could be taken prior to an emergency to facilitate sheltering in place or transferring patients to alternate settings if the building was affected by the emergency.

For example, if it is dangerous to evacuate or if the emergency affects available sites for transfer or discharge, then the patients would remain in the building until it was safe to effectuate transfers or discharges.

Organizations must determine their policies based on the type of emergency and the types of patients, staff, and visitors that may be present during an emergency. Based on its emergency plan, an organization could decide to have various approaches to sheltering some or all of its patients and staff. The plan should consider the appropriate facilities in the community to which patients could be transferred in the event of an emergency.

Survey Procedure
------------------

**Document Review**

Verify:

- The policies and procedures address a means to provide shelter for patients, staff, and volunteers who remain in the facility during an emergency.

**TRAINING AND TESTING**

**Standard 07.02.01  
Emergency Training**

Score:  
 C  NC

The organization must develop and maintain training that is based on the emergency operations plan (EOP) and related policies and procedures.

The organization must:

- Provide initial training in emergency management policies and procedures to all new and existing staff, and individuals providing on-site services under an arrangement consistent with their expected role.
- Provide emergency management training when the emergency plan is significantly updated and annually.
- Maintain documentation of all emergency management training.
- Demonstrate staff knowledge of emergency procedures.

**Required Elements/Additional Information**

Notes

A well-organized, effective training program must include initial training for staff in emergency management policies and procedures as well as refresher trainings. The purpose of the emergency training is to demonstrate the effectiveness of the organization's emergency plan and to use the results of the exercises to improve the organization's EOP.

The organization must conduct quarterly fire drills and annual emergency management training in which staff can demonstrate knowledge of emergency procedures. Organizations are expected to delineate responsibilities for all of their organization's workers in their EOP and to determine the appropriate level of training for each professional role. In the event an evacuation is necessary, staff are trained on the meeting place location and mechanisms to track staff, patients, and visitors.

The training program may be part of the EOP, or it may be separate. If separate, the EOP must reference where to find the training program.

For the purposes of this standard, a full-scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses an organization's functional capabilities by simulating a response to an emergency that would impact the organization's operations and its given community.

If the organization participates in the community-wide emergency management plan, a full-scale exercise typically involves multiple agencies, jurisdictions, and disciplines performing functional or operational elements.



<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ All staff (including contract workers and physicians) are educated annually on the emergency management program.</li> </ul>	
<b>Standard 07.02.02 Emergency Exercises</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>The organization must conduct quarterly fire exercises.</p> <p>The organization must conduct one exercise (in addition to the fire response exercises) annually to test the emergency plan:</p> <p>If the organization experiences an actual natural or man-made emergency that requires activation of the emergency plan, the organization may use the event to meet the requirements for an emergency exercise if they prepare an evaluation and after-action improvement plan after the event.</p>	
<b>Required Elements/Additional Information</b>	Notes
<p>The organization's fire drills must consider multiple staff shifts if they exist. An unannounced fire drill is required quarterly for each shift.</p> <p>Evacuation of patients is not required in emergency exercises. The organization may limit exercises to the physical space occupied by the organization.</p> <p>Each implementation (either an actual emergency or an exercise) shall be analyzed and evaluated, and all documentation of the analysis and evaluations (after-action report/critique) must be maintained. The organization uses this information to improve its capability to respond to emergencies, and to make improvements to the EOP. The organization's leadership reviews reports on the exercises, and, as appropriate, submits to applicable government (e.g., state and federal) entities.</p>	
<b>Survey Procedure</b>	
<b>Interview and Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ The evaluation records of the emergency exercises are maintained.</li> <li>■ All after-action plan items have been documented in a report and in the QAPI minutes.</li> <li>■ Each building receives at least one emergency exercise within the past calendar year.</li> </ul>	



08

# HEALTHCARE RECORDS



<b>Standard 08.00.01 Healthcare Records</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization must maintain complete, comprehensive, and accurate healthcare records to document adequate patient care and must ensure the confidentiality of each patient's healthcare record.

Required Elements/Additional Information	Notes
--	-------

The organization must have a healthcare record for each patient, whether it is in paper, electronic format, or a combination, and must protect it from unauthorized disclosure.

Confidentiality must be maintained wherever the healthcare record or portions of it are stored. This includes, but is not limited to, patient care locations, radiology, laboratories, and storage areas.

Survey Procedure
------------------

**Document Review**

Verify:

- The organization's system for documenting healthcare information is structured to maintain each patient's confidentiality.
- Completeness and accuracy by reviewing a sample of active and closed records.

<b>Standard 08.00.02 Organization</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization must develop and maintain a system for the proper collection, storage, and use of patient records.

The organization will maintain patient records for **a time period consistent with state and federal laws and regulations.**

Required Elements/Additional Information	Notes
--	-------

The organization must have a documented system that enables it to systematically develop a unique healthcare record for each patient, permit timely access to the record to support the delivery of care, and provides for appropriate storage, security, and confidentiality of healthcare records.

Records may exist in hard copy, electronic format, or a combination of the two.

The organization has a written policy that addresses:

- Retention of the healthcare records as determined by their use and the organization's policy or longer in accordance with applicable law or regulations.
- Access to archived records.
- Confidentiality consistent with governmental laws and



regulations (e.g., HIPAA).

- The maintenance of patient records in the event the entity closes or is no longer able to treat patients, consistent with governmental laws and regulations.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- With the person responsible for healthcare records, whether the system is structured appropriately.
- How healthcare personnel use the system.

Verify:

- There is a systematic process for maintaining healthcare records for each patient.
- The organization’s system for documenting each patient’s health care maintains patient confidentiality.
- Written policies address:
  - » Retention of healthcare records consistent with state and federal law and regulations.
  - » Maintenance of patient records in the event the organization closes or is no longer able to treat patients.

**Standard 08.00.03  
Form and Content of the Healthcare Record**

Score:  
 C  NC

The organization must maintain a healthcare record for each patient. Every record must be accurate, legible, and promptly completed.

Healthcare records must include at least the following:

- Patient identification.
- Documentation of properly executed informed patient consent.
- Appropriate medical history and results of physical examination (as applicable).
- Pre-operative diagnostic studies (entered before the procedure), if performed.
- Any allergies and abnormal drug and materiel reactions.
- Findings and techniques of the operation including a pathologist’s report on all tissues removed during procedure, except those exempted by the Governing Body.
- Entries related to sedation or anesthesia administration and recovery.
- Documentation of direct patient care provided.
- Discharge diagnosis.
- Advanced directive, if present.

**Required Elements/Additional Information**

Notes

The healthcare record must contain, at a minimum, all required elements listed:

- The identity of the patient must be clear through the use of

identifiers such as name, date of birth, social security number, etc.

- Documentation of a properly executed informed patient consent.
- When required by the organization, an appropriate medical history and physical assessment (H&P) completed within 30 days of the procedure and updated on the day of the procedures is documented.
- If pre-operative diagnostic studies were performed, they must be included in the healthcare record prior to the start of the procedure.
- The patient's history of allergies or abnormal drug and material reactions is documented prior to the procedure, as well as any allergies or abnormal drug and material reactions that occurred during or after the procedure prior to discharge.
- An operative report that describes the surgical techniques and findings.
- A pathologist's report on all tissues or foreign bodies removed during the procedure, unless the governing body has adopted a written policy exempting certain types of removed tissue or foreign bodies from this requirement.
  - » Depending on the type of procedure performed in the organization, tissues may or may not be routinely removed during procedure; the policy on exemption must provide the clinical rationale supporting the exception. No pathologist's report is required when no tissue has been removed.
- Information related to the pre-anesthesia/ pre-sedation evaluation, administration of anesthesia/sedation during the procedure, and the patient's recovery from anesthesia/sedation after the procedure.
- Documentation of care provided by nursing and other staff.
- Documentation of the patient's discharge diagnosis.
- Advanced directive, if present.

The record should also include the patient's disposition, i.e., whether the patient was discharged to home (including to a nursing home for patients already resident in a nursing home at the time of procedure), or transferred to another healthcare facility, including emergent transfers to a hospital.

### Survey Procedure

#### Interview and Document Review

Verify:

- A sample of open and closed records includes all required elements.



- » For open records of patients prior to their procedures, focus on the elements that must be present before procedure (e.g., H&P, immediate pre-surgical assessment, informed consent).
- » For all records, look for documentation of:
  - A history of allergies and abnormal drug and material reactions.
  - Properly executed informed consent.
  - Discharge diagnosis.
- Written policies indicate whether the organization exempts any or all classes of tissue or foreign bodies removed from the requirement for analysis by a pathologist.
  - » Do the policy and its rationale indicate approval by the governing body and a reasonable clinical rationale for the exemptions?

Discuss and assess:

- Knowledge of the policy by providers and staff.

<b>Standard 08.01.01 Release of Patient Information</b>	Score:
	<input type="checkbox"/> C <input type="checkbox"/> NC

The organization has a written policy that addresses the release of patient records and other information.

<b>Required Elements/Additional Information</b>	Notes
The policy requires the patient’s written consent before releasing information not required to be released by law.	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ The organization has a written policy addressing the release of healthcare records.</li> </ul>	

<b>Standard 08.01.02 Healthcare Record Storage</b>	Score:
	<input type="checkbox"/> C <input type="checkbox"/> NC

Healthcare records must be stored in secure locations that:

- Prevent access by unauthorized individuals.
- Are secure from destruction by fire or disaster.
- Have a backup system for electronic records.

<b>Required Elements/Additional Information</b>	Notes
Security measures are in place for electronic healthcare records to prevent unauthorized access. The electronic records must be backed	

up on remote storage medium.

Non-electronic healthcare records are stored in locked areas when not attended to prevent unauthorized access.

Storage must be:

- Within a one-hour fire-rated room with 45-minute doors and approved fire sprinklers.
- OR
- In fire-resistant, lockable file containers in a room with an automatic closer on the door.

The organization's emergency management plan addresses the security of healthcare records.

**Survey Procedure**

**Observation and Interview**

Verify:

- Healthcare records are stored in a location that is secured from fire or disaster.
- Healthcare records stored electronically are secure and accessible for future access.
- Healthcare records are stored in a manner that prevents access by unauthorized individuals.

**Standard 08.01.03  
List of Abbreviations and Symbols**

Score:  
 C  NC

The organization has a written policy and periodically updates a list of acceptable abbreviations and symbols for use in healthcare records.

**Required Elements/Additional Information**

Notes

The organization has trained its staff on the policy regarding the use of abbreviations and symbols.

The list is periodically updated and easily accessible to staff.

**Survey Procedure**

**Document Review**

Verify:

- A current list of acceptable abbreviations and symbols for use in healthcare records.
- Healthcare record reflect compliance with the policy.



<b>Standard 08.01.04</b> <b>Authentication of Healthcare Record</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
The organization has a written policy addressing authentication of healthcare records that: <ul style="list-style-type: none"> <li>■ Requires every entry to be signed, or authenticated, by the healthcare professional making the entry.</li> <li>■ Complies with relevant law and regulations.</li> </ul>	
<b>Required Elements/Additional Information</b>	Notes
The organization's policy addresses: <ul style="list-style-type: none"> <li>■ A method of authenticating provider's signatures and initials.</li> </ul>	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ The organization's policy meets the requirements.</li> <li>■ All records/entries have been signed or authenticated.</li> </ul>	
<b>Standard 08.01.05</b> <b>Documentation of Electronic Advice</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
The organization has a written policy that any advice given to a patient by telephone or electronically, either during or after hours of operation, requires that a summary of that advice be entered into the healthcare record.	
<b>Required Elements/Additional Information</b>	Notes
The policy identifies the required time period for documentation to be entered into the healthcare record.	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ The organization has a written policy regarding the documentation of electronic advice.</li> <li>■ Records reflect policy compliance regarding the documentation of electronic advice.</li> </ul>	



09

**PATIENT  
ASSESSMENT  
AND  
DISCHARGE**



The organization maintains that each patient has the appropriate patient assessments completed, pre- and post-procedure, and the patient is appropriately discharged. This chapter addresses the minimum documentation necessary to document care of a patient.

**Standard 09.00.01  
Patient History and Physical**

Score:  
 C  NC

The organization must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to the procedure. The policy must:

- Include the timeframe for a medical history and physical examination to be completed prior to the procedure, not to exceed 30 days.
- Address at least the following factors: Patient age, diagnosis, the type, and number of procedures scheduled to be performed on the same procedure date, known comorbidities, and the planned anesthesia level.
- Be based on any applicable recognized standards of practice and guidelines, and any applicable laws or regulations.

**Required Elements/Additional Information**

Notes

The purpose of a comprehensive medical history and physical assessment (H&P) is to determine whether there is anything in the patient's overall condition that would affect the planned procedure, such as a medication allergy, or a new or existing comorbid condition that requires additional interventions to reduce risk to the patient, or which may indicate that a particular setting might be inappropriate for the patient's procedure.

The policy identifying those patients who require a medical history and physical examination prior to the procedure addresses each component of the standard and includes:

- Documentation of allergies to drugs and biologicals and allergenic reactions, including unusual drug and materiel reactions.
- A requirement that the H&P specifically indicate that the patient represents an acceptable risk for the procedure.
- When required, histories and physicals are completed no more than 30 days prior to the procedure.
- Documentation of any pre-existing medical conditions and appropriate test results.
- Cases in which the patient is scheduled for two procedures in the organization within a short period of time (the organization may choose to use the same H&P).
- Cases in which the patient is referred to the organization for procedures on the same day as the referral and the referring healthcare professional has indicated it is medically necessary for the patient to have the procedure on the same date.
  - » The H&P may be performed on the same day as the procedure, and may be performed in the organization, as



long as it is conducted by qualified personnel and is comprehensive and performed prior to a patient being prepped for the surgical procedures.

### **QUALIFICATION TO PERFORM H&P**

The medical history and physical examination must be completed and documented by a physician, or other qualified licensed individual practitioner, in accordance with applicable laws or regulations, generally accepted standards of practice, and the organization's policies.

Qualified licensed practitioners include:

- Doctor of medicine or osteopathy.
- Doctor of dental surgery or dental medicine.
- Doctor of podiatric medicine.
- Doctor of optometry.
- Other qualified practitioners.

In all cases, the practitioners included in the definition of a physician must be legally authorized to practice in accordance with applicable laws or regulations where the organization is located and providing services within their authorized scope of practice.

Other qualified practitioners are those licensed practitioners who are authorized in accordance with applicable laws or regulations within their scope of practice to perform an H&P and who are also formally authorized by the organization to conduct an H&P as defined in the job description or privileges (e.g., advanced practice registered nurse and physician assistants).

More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents.

## **Survey Procedure**

### **Document Review**

Verify:

- The organization has a written policy that addresses the required elements. The policy is based on applicable recognized standards of practice and guidelines, and applicable laws or regulations.
- A reviewed sample of open and closed healthcare records reflects:
  - » There is a comprehensive H&P that was completed in accordance with the written policy.
  - » The operating healthcare professional documents any pre-existing medical conditions and appropriate test results in



the healthcare record, before, during and after the procedure.

- » The H&P was performed by a physician, or other qualified licensed individual authorized in accordance with applicable laws, standards of practice, and the organization’s policies.

<b>Standard 09.00.02 Documentation of History and Physical</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The patient’s medical history and physical examination (if any) must be placed in the patient’s healthcare record prior to the procedure.

Required Elements/Additional Information	Notes
<p>When an H&amp;P is required, it is submitted to the organization prior to the patient’s scheduled procedure date to allow sufficient time for review by the organization’s professional staff and procedural planning, including postponement or cancellation of the procedure, if necessary. In the event that the H&amp;P is not received by the organization prior to the patient’s scheduled procedure day, at a minimum, the H&amp;P must be placed in the patient’s healthcare record for consideration prior to the pre-procedure examination and assessment.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The medical history and physical are placed in the healthcare record prior to the procedure.</li> </ul>	

<b>Standard 09.00.03 Pre-Procedure Risk Assessment</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

Upon admission, each patient must have a pre-procedure assessment completed by a healthcare professional who will be performing the procedure in accordance with applicable health and safety laws, standards of practice, and the organization’s policies.

The pre-procedure assessment must include documentation of any allergies to drugs and biologicals including unusual drug and material reactions.

Required Elements/Additional Information	Notes
<p>Assessment of the patient’s risk for the procedure must be conducted immediately prior to the procedure by a physician or other qualified practitioner in accordance with applicable law or regulation, standards of practice, recognized practice guidelines, and organization policies. This assessment is distinct and separate from the evaluation of risk for anesthesia. See standard 09.00.04.</p> <p>The pre-procedure assessment, including updates:</p> <ul style="list-style-type: none"> <li>■ Addresses risks associated with the procedure.</li> </ul>	



- Verifies that the procedure and comorbidities represent an acceptable risk for the patient at the organization.
- Includes other pertinent elements that may be conducted by a licensed practitioner who is credentialed and privileged by the organization to perform an H&P.
- Identifies and documents any allergies, side effects, or unusual reactions the patient may have to drugs and biologicals, including topical reactions. If there are none, this should be documented.
- Must be placed in the patient’s healthcare record before the procedure.

**Survey Procedure**

**Document Review**

Verify:

- Each record contains a pre-procedure assessment.
- A healthcare professional performs those components of the pre-procedure assessment related to evaluation of anesthetic risk and procedural risk.
- The pre-procedure assessment includes documentation of the patient’s allergies or lack of known allergies to drugs and biologicals including abnormal drug and material reactions.

**Standard 09.00.04  
Anesthetic Risk Evaluation**

Score:  
 C    NC

The organization leadership has a policy approved by the professional staff that establishes the requirements for the pre-anesthesia evaluation.

The anesthesia professional or proceduralist with appropriate anesthesia privileges must examine the patient immediately before the procedure to evaluate the risk of anesthesia to be administered.

**Required Elements/Additional Information**

Notes

The policies ensuring that assessment of anesthesia risks is completed just prior to the procedure must address the basis or criteria used within the organization in conducting these risk assessments and must ensure consistency among assessments.

The pre-anesthesia evaluation must be completed and documented prior to the administration of anesthetic agents and includes, at a minimum:

- Review of the medical history, including anesthesia, drug, and allergy history.
- Notation of anesthesia risk according to established standards of practice (e.g., ASA classification of risk); identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the

planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access).

- Additional pre-anesthesia data or information, if applicable and as required in accordance with standard practice prior to administering anesthesia (e.g., stress tests, additional specialist consultation).
- Development of the plan for the patient's anesthesia care, including the type of anesthetic, additional monitors, and postoperative disposition.
- Discussion with the patient (or patient's representative) of the benefits, risks, and complications associated with the proposed anesthesia and any alternatives.
- Airway assessment including an evaluation of dentition, neck flexibility, and mouth opening. In addition, when using a scoring tool such as the Mallampati airway assessment (score status I, II, III, IV), this must be noted.

### EVALUATION

The purpose of the exam immediately before the procedure is to assess, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the procedure that will be performed fall within an acceptable range for a patient having the specific procedure in an office-based setting. The assessment must be specific to each patient; it is not acceptable for an organization to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an organization setting is a sufficient basis to conclude that the risks of the anesthesia are acceptable for every patient.

The requirements for the pre-anesthesia evaluation include:

- Patient interview to assess:
  - » Medical/surgical/procedural history.
  - » Anesthetic history.
  - » Medication history.
  - » Allergies.
- Review of objective diagnostic data (e.g., laboratory, ECG, X-Ray).
- Evaluation of anesthesia risk using physical status classification (e.g., ASA classification).
- Formulation of the anesthetic plan.
- Minimally, a pre-anesthesia assessment of:
  - » Respiratory function.
  - » Cardiovascular function.
  - » Mental status.
  - » Alcohol use and recreational drug use, including marijuana and cannabidiol (CBD).

- » Assessment of airway and patency.

### Survey Procedure

#### Interview and Document Review

Verify:

- Policies and procedures exist for assessment of anesthesia risk.
- The policies include the criteria the organization must use in making the assessments.
- For every healthcare record in the survey sample, there is evidence of an assessment of the patient's risk for the planned anesthesia immediately before the procedure.
- Each patient had a pre-anesthesia evaluation by an anesthesia professional or a proceduralist with appropriate anesthesia privileges.
- The pre-anesthesia evaluation includes the assessment requirements defined by the organization.
- Leadership can point to any cases in which an assessment resulted in a decision not to proceed with the procedure.
  - » If there are no such cases, leadership can provide an explanation for patient selection criteria and how that ensures an acceptable level of anesthesia risk for every patient scheduled for procedures in the organization. For example, do they use patient admission criteria that exclude higher-risk patients? If so, ask to see those criteria.
- The survey sample includes cases in which a patient died or needed to be transferred to a hospital. Discuss the pre-anesthesia assessment of the patient in those cases, preferably with the anesthesia professional or proceduralist with appropriate privileges who conducted the assessments, to explore the basis on which the patient was found to be suitable for the anesthesia.

#### Standard 09.01.01 Intra-Operative Anesthesia Record

Score:

C  NC

The organization leadership has a policy approved by the professional staff that establishes the requirements for documentation on the intra-operative/anesthesia record, completed by the anesthesia provider, including:

- Patient evaluation immediately prior to the anesthetic event.
- Induction methods.
- Placement of lines/devices.
- A time-based record of patient monitoring (e.g., EKG, vital signs ventilation, circulation, oxygenation, level of consciousness, etc.) throughout the procedure.
- A time-based record of the administration of:
  - » Drugs, medical gases, oxygen, and anesthesia agents including name, dosage,

route, and time of administration.

- » Fluids including blood products.
- Patient status upon conclusion of anesthesia.
- Complications, if any, including adverse reactions or problems occurring during anesthesia. Document the time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.

Required Elements/Additional Information	Notes
<p>The anesthesia record documents the patient's condition throughout the course of anesthesia, including:</p> <ul style="list-style-type: none"> <li>■ Continuous recording (electronic, manual, or combination) of status to include blood pressure, cardiac rate/rhythm, respiratory rate, oxygen saturation and end tidal CO<sub>2</sub> (endotracheal intubation), and, if used, brain function monitoring (bispectral index, cerebral oximetry, etc.).</li> <li>■ Effects of medications, agents, and interventions to include untoward outcomes.</li> <li>■ The patient's condition at the end of the procedure and transfer to the next level of care.</li> </ul>	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Policies and procedures meet the standard.</li> <li>■ A sample of anesthesia records for patients who had surgery or a procedure requiring administration of anesthesia reflect required documentation of</li> <li>■ required events, administration of medications, techniques, management, and responses.</li> </ul>	
<b>Standard 09.02.01 Post-Procedure Assessment</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC

The patient's post-procedure condition must be assessed and documented in the healthcare record by a physician, other qualified practitioner, or a registered nurse with, at the minimum, post-procedure care experience in accordance with applicable health and safety laws, standards of practice, and the organization's policies.

Required Elements/Additional Information	Notes
<p>Each post-procedural patient's overall condition must be assessed after the procedure is completed and documented in the healthcare record to determine:</p> <ul style="list-style-type: none"> <li>■ How recovery is proceeding.</li> <li>■ What needs to be done to facilitate recovery.</li> <li>■ Whether the patient is ready for discharge or in need of further</li> </ul>	



treatment or monitoring.

The organization’s clinical policy identifies:

- The criteria for assessment.
- The clinical personnel qualified to perform the assessment.
- Post-procedure recovery care.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- Policies and procedures exist and discuss with staff.
- Through observation of post-procedural patient care and through record review, the organization evaluates each patient after procedure for his/her overall recovery from the procedure and suitability for discharge.
- The post-procedure assessment is performed by a healthcare professional.
- When an RN performs an assessment, there is documentation of the RN’s qualifications to do so.

**Standard 09.02.02  
Post-Anesthesia Evaluation and Care**

Score:  
 C  NC

Before discharge from the setting, each patient must be evaluated by an anesthesia professional or the proceduralist with appropriate anesthesia privileges in accordance with applicable health and safety laws, standards of practice, and the organization’s policies, for proper anesthesia recovery.

**Required Elements/Additional Information**

Notes

**POLICIES**

Organizations develop policies and procedures for transport to the post-anesthesia care area, transfer of care (handoff report), and post-anesthesia care based on nationally recognized standards and guidelines.

**TRANSPORT TO THE POST-ANESTHESIA CARE AREA, IF APPLICABLE**

Policies and procedures identify the level of care required for recovery and hand-off procedures. A patient transported to a level 1\* post-anesthesia care area must be accompanied by the anesthesia provider who administered the anesthesia.

\*Names of area may vary, e.g., Level 1, Stage 1, PACU 1, etc.; however, intent is the area where the patient goes after the procedure.

**HANDOFF REPORT\*\***

The organization identifies the appropriate components of a hand-off report. A joint assessment of the patient (handoff report) is performed at the beginning of the post-anesthesia process by the receiving

licensed nurse and the anesthesia provider and documented in the post-anesthesia care record.

\*\*If the anesthesia professional assumes responsibility for post-anesthesia care, a handoff report is not necessary.

### **POST-ANESTHESIA CARE ASSESSMENT AND MONITORING**

The patient's post-anesthesia condition is continually monitored.

Assessment and monitoring of patients who have received anesthesia includes, at a minimum:

- Respiratory function, including respiratory rate, airway patency, and oxygen saturation.
- Cardiovascular function, including pulse rate and blood pressure.
- Mental status.
- Temperature.
- Pain.
- Nausea and vomiting.
- Postoperative hydration.

An evaluation of the patient's recovery from anesthesia must be completed and documented by an anesthesia professional or the proceduralist with appropriate anesthesia privileges before the patient is discharged from the setting to determine whether the patient is recovering appropriately.

### **Survey Procedure**

#### **Document Review**

Verify:

- Policies and procedures regarding post-anesthesia recovery and evaluation are consistent with the requirement.
- The organization is following its own policy.
- In a sample of patient records for patients who had surgery or a procedure requiring anesthesia, a post-anesthesia evaluation was conducted for each patient.
- The evaluation was conducted by an anesthesia professional or proceduralist with appropriate anesthesia privileges.
- The evaluation was performed prior to the patient's discharge.





<b>Standard 09.02.03 Patient Needs Identification</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization has a policy approved by the professional staff that:

- Identifies the elements related to assessment, care planning, implementation, and evaluation of care from admission through discharge from the organization that are in addition to the assessments related to a procedure.
- Establishes documentation requirements.

Required Elements/Additional Information	Notes
--	-------

Assessment and evaluation of the patient by the healthcare provider(s) and related to a procedure are addressed in separate standards. The intent of this standard is to address other assessments (e.g., nursing).

The organization has a policy that describes:

- The frequency and required elements of the assessments consistent with the complexity of services provided.
- The post-procedure recovery of the patient.
- The assessments and documentation expectations during a patient emergency.
- The healthcare record reflects assessments and reassessments, consistent with policy.

Survey Procedure
------------------

**Document Review**

Verify:

- The current policy describes the required assessments.
- Healthcare records comply with assessments.

<b>Standard 09.02.04 Assessment of Pain</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization leadership has a policy approved by the professional staff that:

- Establishes a standardized tool/scale for the assessment of pain.
- Establishes the frequency and indications for initial assessments and reassessments of pain.
- Establishes the pain management documentation requirements.

Required Elements/Additional Information	Notes
--	-------

The organization has a policy that addresses:

- A standardized tool to assess pain, which uses consistent and quantifiable assessments, such as a visual scale of zero to ten or “FACES” pictures.



- The frequency for pain assessments and reassessments.
- The documentation of pain assessments prior to procedure, post procedure, and after administration of medications or other means for pain control (e.g., TENS, topical creams or ointments, application of cold materials, etc.).

**Survey Procedure**

**Document Review**

Verify:

- The current policy describes the required assessments.
- Healthcare records comply with assessments.

**Standard 09.02.05  
Identification and Response to Patient Deterioration**

Score:  
 C  NC

The organization leadership has a policy approved by the professional staff that:

- Describes staff response upon identification of patients with clinical deterioration.
- Establishes the documentation requirements for the unstable patient including vital signs, treatments, medications, and patient response to treatments.

**Required Elements/Additional Information**

Notes

The organization has a policy that addresses:

- Identification of clinical deterioration.
- Documentation requirements of vital signs, treatments, medications, and patient response to treatments.
- If the assessment determines the need to transfer the patient to another level of care, contact with the receiving organization is documented including the time this contact was made and all other transport policies must be followed.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The current policy describes the required assessments.
- Healthcare records comply with documentation.

**Standard 09.02.06  
Post-Procedure Needs**

Score:  
 C  NC

Post-procedure needs must be addressed and included in the discharge notes.

**Required Elements/Additional Information**

Notes

If the post-procedural assessment identifies patient needs that must be addressed prior to discharge, or patient needs that exceed the organization’s capabilities, the organization must address those patient needs or arrange appropriate and timely transfer to a hospital



for further care.

This must be documented in the discharge notes in the patient's healthcare record.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization identifies patient needs related to safe discharge, or, as applicable, identifies patients who require transfer to a hospital for further treatment that exceeds the organization's capabilities.
- The healthcare records reflect the post-procedural assessment, needs identified, and actions taken by the organization to address those needs in the healthcare record's discharge notes.

**Standard 09.03.01  
Discharge Order**

Score:  
 C  NC

The organization must ensure each patient has a discharge order, signed by the healthcare professional who performed the procedure in accordance with applicable laws or regulations, standards of practice, and the organization's policies.

**Required Elements/Additional Information**

Notes

No patient may be discharged from the organization unless the healthcare professional who performed the procedure signs a discharge order.

The organization must ensure that the healthcare professional follows applicable laws or regulations as well as generally accepted standards of practice and organization policy when determining that a patient has recovered sufficiently from a procedure and may be discharged from the organization, or, as applicable, that the patient must be transferred to another healthcare facility that can provide the ongoing treatment that the patient requires and the organization is unable to provide.

It is permissible for the operating healthcare professional to write a discharge order indicating "the patient may be discharged when stable." In such cases, there must be documentation of when the patient was stable, and the criteria applied for the determination.

**Survey Procedure**

**Document Review**

Verify:

- There is a discharge order signed by the healthcare professional who performed the procedure in the sample of healthcare records being reviewed.



- There is a discharge order signed by the healthcare professional for patients being discharged while the survey takes place.

**Standard 09.03.02  
Discharge Instructions**

Score:  
 C  NC

The organization must:

- Provide each patient with written discharge instructions and essential overnight supplies.
- Ensure that all patients are informed, either in advance of their procedure or prior to leaving the organization, of their prescriptions, postoperative instructions, need for special supplies beyond the first night, fall prevention and healthcare contact information for emergency and follow-up care.

**Required Elements/Additional Information**

Notes

Each patient, or the adult who accompanies the patient upon discharge, must be provided with written discharge instructions.

Either before the procedure or before discharge, each patient must be provided with:

- Prescriptions they will need to fill associated with their recovery from the procedure.
- Written instructions that specify actions the individual will take in the immediate postoperative and post-discharge period to promote their recovery from the procedure; warning signs of complications to be alert for, etc.
- How to contact the healthcare professional who will provide follow-up care to the patient.
- When appropriate, the organization must make an appointment with the healthcare professional for follow-up care.

If the written instructions were provided before the procedures, they are reviewed to ensure they continue to be applicable.

If crutches are required post procedure, the patient must receive instruction on their proper use prior to the procedure.

- The organization must also provide supplies, such as gauze, bandages, etc., sufficient for the patient’s needs through the first night after the procedure.

**Survey Procedure**

**Interview and Document Review**

Verify:

- A copy of the discharge instructions is provided to the patient in the patient’s healthcare record.
- The discharge instructions include postoperative care



instructions for the patient.

- » Do they indicate if the patient was provided prescriptions, if applicable?
- » Do they provide healthcare professional contact information?

Discuss and assess:

- When and how the organization schedules follow-up appointments with the healthcare professional for patients.
- What types of supplies are typically provided to patients upon discharge.

**Standard 09.03.03  
Discharged with a Responsible Adult**

Score:  
 C  NC

The organization must ensure that all patients are discharged in the company of a responsible adult, except those patients exempted by the attending healthcare professional.

**Required Elements/Additional Information**

Notes

Unless the healthcare professional who is responsible for the patient's care in the organization has exempted the patient, the organization may not discharge any patient who is not accompanied by a responsible adult who will go with the patient after discharge.

Exemptions must be specific to individual patients, not blanket exemptions to a whole class of patients.

Organizations must develop policies that address what criteria a healthcare professional will consider when deciding a patient does not need to be discharged in the company of a responsible adult.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The healthcare records identify for each patient the responsible adult who will accompany the patient after discharge or, alternatively, a specific exemption for the patient by the healthcare professional from this requirement.
- The organization ensures an adult accompanies patients discharged, unless the patient has been specifically exempted from this requirement.

**Standard 09.03.04  
Patient Transfers**

Score:  
 C  NC

The organization leadership has a policy approved by the professional staff that:

- Establishes criteria for transferring an unstable patient to a higher level of care.
- Establishes documentation requirements relating to the care of patients being

transferred to a higher level of care.

Required Elements/Additional Information	Notes
<p>In addition to the policy establishing criteria for the transfer of a patient, the organization’s policy addresses:</p> <ul style="list-style-type: none"> <li>■ Information to be communicated to the receiving practitioner and hospital.</li> <li>■ Notification of the patient and family when a transfer is indicated.</li> <li>■ Documentation requirements including:               <ul style="list-style-type: none"> <li>» Acceptance of the patient by the hospital.</li> <li>» Name of accepting practitioner.</li> <li>» A summary of procedures performed, treatments administered, and patient response to treatments.</li> </ul> </li> <li>■ Patient condition at time of departure, including vital signs, level of consciousness, etc.</li> </ul>	
<p><b>Survey Procedure</b></p>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The current policy describes the required assessments.</li> <li>■ Healthcare records comply with documentation.</li> </ul>	



THIS PAGE IS DELIBERATELY BLANK.

—  
10

**SURGICAL  
SERVICES**



**DEFINITION OF SURGICAL, THERAPEUTIC, AND DIAGNOSTIC PROCEDURES**

ACHC has adopted, with minor modification, the definition of surgery developed by the American College of Surgeons, [www.facs.org/fellows\\_info/statements/st-11.html](http://www.facs.org/fellows_info/statements/st-11.html).

Surgical, therapeutic, and diagnostic procedures are performed for the purpose of structurally altering the human body by the incision or destruction of tissues. It 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 includes 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 included. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous (IV), when ordered by a physician.) All of these procedures are invasive, including those that are performed with lasers, and the risks of any procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

**Standard 10.00.01  
Surgical, Therapeutic, and Diagnostic Procedures Performed**

Score:  
 C  NC

Surgical, therapeutic, and diagnostic procedures must be performed in a safe manner by qualified healthcare professionals who have been granted privileges by the governing body of the organization in accordance with approved written policies and procedures of the organization.

**Required Elements/Additional Information**

Notes

“In a safe manner” means primarily that proceduralists and other clinical staff follow acceptable standards of practice in all phases of the procedure, beginning with the pre-procedure preparation of the patient, through to the post-procedure recovery and discharge.

Acceptable standards of practice include maintaining compliance with law and regulations, and consistency with nationally recognized standards and guidelines established by professional organizations such as the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization has written policies and procedures describing appropriate protocols for all surgical, therapeutic, and diagnostic procedures, specific or general in nature, including a list of equipment, materials, and supplies necessary to properly carry out all activities.



<b>Standard 10.00.02 Surgical/Procedural Privileges Roster</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

Surgical/procedural privileges must be delineated for all practitioners performing surgery/procedures in accordance with the competencies of each practitioner.

The surgical/procedural service must maintain a roster of practitioners specifying the surgical/procedural privileges of each.

Required Elements/Additional Information	Notes
<p>A current roster listing each practitioner’s specific surgical/procedural privileges is available in the surgical/procedural suite and where the scheduling of procedures is done. The roster must be updated each time the healthcare professional’s privileges are approved by the governing body.</p> <p>For surgery, if the organization uses RN first assistants, surgical PAs, or other non-MD/DO surgical assistants, the organization must establish criteria, qualifications, and a credentialing process to grant privileges. (Refer to Chapter 3 for credentialing, privileging, and reappraisal requirements.)</p>	

Survey Procedure
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ A roster listing each practitioner’s specific surgical or procedural privileges is current, complete, and available in the surgical/procedural suite and the area where procedures are scheduled.</li> </ul>

<b>Standard 10.01.01 Verification Process</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization adopts written policies and procedures that include the use of standard procedures to ensure proper identification of the patient and procedural site to avoid wrong patient/wrong procedure/wrong site errors.

Required Elements/Additional Information	Notes
<p>Generally accepted procedures to avoid errors require a standardized process including:</p> <ul style="list-style-type: none"> <li>■ A written pre-procedure verification process to ensure all relevant documents (including the patient’s signed informed consent) and related information are available, correctly identified, match the patient, and are consistent with the procedure the patient and the organization’s clinical staff expect to be performed.</li> <li>■ Marking the intended procedure site by the proceduralist who will perform the procedure or another member of the procedural team so that it is unambiguously clear.</li> </ul>	

- A “time out” before starting the procedure to confirm that the correct patient, procedure, and site have been identified, that all required documents, including documentation of allergies, and equipment are available and ready for use, and surgical fire risk mitigation resources are available.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The required policies and procedures delineate the verification process.
- Actual practice follows policy and procedure, by tracking at least one patient during the pre-procedure phase through the beginning of the procedure.

**Standard 10.01.02  
Operative Report**

Score:

C  NC

An operative report describing:

- the techniques used,
- findings, and
- tissues removed or altered

must be completed shortly after the procedure by the surgeon or proceduralist.

Any implants placed during the procedure must be fully identified in the operative report.

**Required Elements/Additional Information**

Notes

The organization requires a full operative report as required in the organization’s professional staff bylaws or policies and procedures. It may also choose to meet the standard using one brief note shortly after the procedure in addition to the full operative report. If a brief note is provided shortly after the procedure, it includes enough detail to facilitate the post-operative care of the patient up through discharge.

The operative report notes any listing of implants, including the manufacturer, model, and serial number when available.

Any device removed includes the manufacturer, model, and serial number when available.

**Survey Procedure**

**Document Review**

Verify:

- Healthcare records include an operative procedure report.
- Any implants or devices are fully identified.



<b>Standard 10.01.03 Tissues Exempt from Pathological Examination</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

The organization has a written policy approved by the professional staff that identifies which tissues removed during a procedure require or are exempt from a pathological examination.

<b>Required Elements/Additional Information</b>	Notes
---	-------

For tissues requiring a pathological examination, the organization policy must address which tissue specimens require:

- Macroscopic examination.
- Both macro- and microscopic examination.

<b>Survey Procedure</b>	
-------------------------	--

**Document Review**

Verify:

- The organization has a written policy for the examination requirements.
- Tissue specimens are examined in accordance with the written policies and tissue reports.

<b>Standard 10.01.04 Removed Specimens</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization has a written policy approved by the professional staff that identifies the storage, labeling, and transportation of specimens removed during a procedure and appropriate follow-up.

<b>Required Elements/Additional Information</b>	Notes
---	-------

The organization’s policy addresses:

- Storage containers appropriate for the type of specimen.
- Required information included in the labeling of the specimen.
- The method of transportation to maintain the integrity of the specimen.
- Communication to the patient’s healthcare provider regarding the results from the pathological examination.

<b>Survey Procedure</b>	
-------------------------	--

**Observation and Document Review**

Verify:

- The organization has a written policy covering storage, labeling, and transportation of specimens.
- The storage, labeling, and transportation of specimens are in accordance with the written policies and tissue reports.

<b>Standard 10.02.01 Adequate Staff</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization ensures:

- Prior to the administration of anesthesia, there is an adequate number of nursing/support staff (other than the anesthesia professionals and surgeon) available to accommodate circulating and other similar duties.
- Staffing includes an adequate number of competent support staff to provide patient care in the post-anesthesia care area.

<b>Required Elements/Additional Information</b>	Notes
<p>The organization has identified adequate support staff roles, including, at a minimum, a nurse and surgical technicians, if appropriate.</p> <p>The procedure must not commence with only the surgeon/proceduralist and anesthesia professional present.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Staffing schedules and policies.</li> </ul>	

<b>Standard 10.02.02 Circulating Professional</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization has a written policy approved by the professional staff that:

- Establishes the qualifications of the circulating professional.
- Establishes the duties of the circulating professional.
- Establishes, at a minimum, one professional dedicated to performing circulating duties, if applicable, for any surgical, therapeutic, or diagnostic procedure.

<b>Required Elements/Additional Information</b>	Notes
<p>The circulating professional must circulate to be free in an emergency.</p> <p>When required by law and regulations, the circulating professional is an RN.</p>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policy requirements are met.</li> <li>■ Competency requirements have been met.</li> <li>■ If a case is circulated by personnel other than an RN, an RN is available.</li> </ul>	



<b>Standard 10.02.03 Staff Training for Emergencies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The governing body is responsible for determining what equipment and medications are necessary for the site of service, but, at a minimum, there is equipment and medication to support respiration, treat acute allergic reactions including anaphylaxis, and provide CPR and defibrillation.

<b>Required Elements/Additional Information</b>	Notes
---	-------

The organization provides a safe environment by maintaining emergency equipment and training staff in the use of it. (See standards 15.02.01 and 15.02.02.)

Based on the patient population and types of procedures performed, appropriate medication supplies are maintained.

<b>Survey Procedure</b>	
-------------------------	--

**Document Review**

Verify:

- The organization has identified the appropriate equipment and medications for the setting and procedures performed.
- The staff is trained in the use of emergency equipment.

<b>Standard 10.03.01 Procedures Performed in the Appropriate Environment</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization has written policies approved by the professional staff that define for each location where procedures are performed:

- Procedures must only be performed in an operating/procedure room.
- The type of procedure(s) that may be performed in each location.
- Limitations on the complexity of procedures to be performed in any given procedure room.
- The level of monitoring required for that procedure/location.
- Minimum personnel requirements for that location/procedure.
- If a room is not designated solely as an operating/procedure room, the policies must define what the room can be used for when surgery or other procedures are not taking place, and the cleaning and preparation required before a procedure can be done in that room and the post-procedure cleaning.
- The process for the periodic review and amendment of procedures offered at the organization.

<b>Required Elements/Additional Information</b>	Notes
---	-------

Surgical, therapeutic, and diagnostic procedures involving various levels of anesthesia and/or sedation should only be performed in locations where adequate equipment, monitoring, and personnel are available.

Each operating/procedure room is designed and equipped for the types of procedures performed. Each operating/procedure room should be free of hazards to patients and staff (e.g., sufficient space, adequate lighting, and necessary furniture).

Single practice healthcare providers should use established professional guidelines or accomplish this review in conjunction with another healthcare provider of similar training and credentials.

- The professional staff contributes to the development, review, and approval of these policies.

**Survey Procedure**

**Document Review**

Verify:

- All required elements are addressed for each procedure location.

**Standard 10.03.02  
Operating or Procedure Room Requirements**

Score:  
 C  NC

The organization ensures that the design of the operating or procedure room and provision of equipment and supplies are consistent with **local, state, or national** operating room/procedure room design and **nationally recognized** equipment guidelines.

**Required Elements/Additional Information**

Notes

The equipment and supplies are sufficient so that the type of procedure conducted can be performed in a manner that will not endanger the health and safety of the patient.

Procedural devices and equipment are monitored, inspected, tested, and maintained by the organization in accordance with applicable laws and regulations, nationally recognized guidelines, and the manufacturer’s recommendations.

Access to the procedural and recovery area is limited to authorized personnel, and the traffic flow pattern adheres to accepted standards of practice.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The organization has sufficient equipment and supplies for the procedures performed.
- The organization monitors, inspects, and tests procedural devices in accordance with applicable laws, regulations, nationally recognized guidelines, and the manufacturer’s recommendations.
- The procedure/operating room and recovery areas are



- designed to limit the traffic flow to authorized personnel.
- There is sufficient space to perform the procedure and, if necessary, initiate emergency procedures such as CPR.

<b>Standard 10.03.03 Designated Post-Procedure Area</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization must have a designated post-procedure area.

Required Elements/Additional Information	Notes
<p>The organization must have adequate space for the recovery of each patient. The space must provide the patient privacy and have adequate supplies to support the patient’s recovery. Staffing provides for appropriate monitoring of each patient.</p> <p>The operating/procedure room may function as the recovery room for as long as no other procedures are being performed in the same room.</p>	
<b>Survey Procedure</b>	
<p><b>Observation</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has a designated post-anesthesia area, or if recovery takes place in the operating/ procedure room, no other procedures are performed until the patient is fully recovered and the room is appropriately cleaned.</li> </ul>	

<b>Standard 10.03.04 Infection Prevention and Control Requirements</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

Operating and procedure rooms are maintained in accordance with nationally recognized guidelines.

Required Elements/Additional Information	Notes
<p>The organization implements infection prevention and control measures according to written policies and procedures, including:</p> <ul style="list-style-type: none"> <li>■ Conformance to aseptic and, when applicable, sterile techniques by all individuals in the surgical area.</li> <li>■ Appropriate cleaning between surgical and procedural cases and appropriate terminal cleaning.</li> <li>■ Operating/procedure room attire is suitable for the kind of case performed.</li> <li>■ Equipment is available for rapid “emergency” high-level disinfection or as applicable, sterilization of operating room/procedure room materials.</li> <li>■ Sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility, including:                             <ul style="list-style-type: none"> <li>» In a moisture- and dust-controlled environment.</li> </ul> </li> </ul>	



- » Written policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
- Temperature and humidity are monitored and maintained within accepted standards of practice.
- As appropriate for the procedures performed or condition of the patient, air flow is negative.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The organization has the required policies and procedures.
- The organization conforms to acceptable infection prevention and control practices.

**Standard 10.03.05  
Prevention of Procedural and Surgical Fires**

Score:  
 C  NC

The organization has written policies and procedures to prevent procedural fires. Measures are taken for the prevention of fires, and all equipment to suppress a fire is present prior to the start of any procedure using laser, light-based, and other energy-emitting technologies.

**Required Elements/Additional Information**

Notes

Conducting procedures in a safe manner requires appropriate use of liquid germicides in the operating or procedure room.

Heat-producing devices are potential ignition sources, while alcohol-based skin preparations provide fuel. Procedures involving electro-surgery, or the use of cautery or lasers involve heat-producing devices.

- An alcohol-based skin preparation, combined with the oxygen-rich environment of an anesthetizing location, could ignite when exposed to a heat-producing device in an operating room. Specifically, if the alcohol-based skin preparation is improperly applied, the solution may wick into the patient's hair and linens or pool on the patient's skin, resulting in prolonged drying time. Then, if the patient is draped before the solution is completely dry, the alcohol vapors can become trapped under the surgical drapes and channeled to the surgical site.

Malfunctioning equipment is inspected and corrected only by appropriately trained technicians. All staff in the procedure room are trained in fire-suppression tactics for each type of device used.

Water, saline, and the appropriate type of fire extinguisher are immediately available.

The physical space is maintained in a manner to reduce the likelihood

of fire.

### ALCOHOL-BASED SKIN PREPARATION

The use of an alcohol-based skin preparation in organizations is acceptable with appropriate fire risk reduction measures taken as part of a systematic approach by the organization to prevent procedure-related fires.

The organization follows fire risk reduction measures for:

- Using skin prep solutions that are:
  - » Packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators; and
  - » Provide clear and explicit manufacturer/supplier instructions and warnings. These instructions for use should be carefully followed.
- Ensuring that the alcohol-based skin prep solution does not soak into the patient's hair or linens. Sterile towels should be placed to absorb drips and runs during application and should then be removed from the anesthetizing location prior to draping the patient.
- Ensuring that the alcohol-based skin prep solution is completely dry prior to draping. This may take a few minutes or more, depending on the amount and location of the solution. The prepped area should be inspected to confirm it is dry prior to draping.
- Verifying that fire mitigation procedures have been identified.
- Verifying that the above has occurred prior to initiating the procedure. This is done, for example, as part of a standardized pre-procedure "time out" used to verify other essential information to minimize the risk of errors during the procedure.

The implementation of these policies and procedures is documented by periodic review as part of the QAPI program.

### Survey Procedure

#### Observation and Document Review

Verify:

- The policies and procedures address all requirements.
- The organization employs appropriate measures to reduce the risk of procedural and surgical fires.
- Follow-up actions are taken to prevent a recurrence of a procedural or surgical fire, if applicable.
- Failure to develop and implement appropriate measures to reduce the risk of fires associated with the use of alcohol-based skin preparations in ORs or procedure rooms is cited.

- The implementation of these policies and procedures is documented by periodic review as part of the QAPI program.

<b>Standard 10.03.06</b> <b>Adequate Instrumentation and Supplies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization has a written policy approved by the professional staff that:

- Establishes sufficient quantities and types of procedural instruments, supplies, and equipment, such as appropriate PAR levels of equipment.
- Addresses the requirement for supplies and equipment to be stored so that movement is minimized during cases.
- Addresses the expectations for processed instruments to be protected from surface/airborne contamination.
- Establishes the process to periodically use the input from staff to evaluate the quantity and quality of equipment available to meet the needs of the patients.

Required Elements/Additional Information	Notes
<p>The design of operating/procedure rooms protects “clean” areas.</p> <p>Instruments, supplies, and equipment must be in sufficient quantity and located so that movement is minimized during cases.</p> <p>Processed instruments are protected from surface/airborne contamination.</p> <p>Opening and closing the door to the operating/procedure room is kept to a minimum to avoid contamination and other infection control breaches.</p>	
<b>Survey Procedure</b>	
<p><b>Observation</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ General and clean areas are clearly identified, and that staff adhere to traffic rules with particular concern regarding decontamination procedures for equipment.</li> </ul>	

<b>Standard 10.03.07</b> <b>Adequate Equipment</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The governing body must determine the necessary supplies and equipment for emergency circumstances. At a minimum, the following equipment is available:

- Communication/call-system.
- Cardiac monitor.
- Defibrillator, manual, or AED.
- Vacuum suction.
- Ventilator or manual ventilation assist device such as an Ambu bag.
- Laryngoscope and endotracheal tubes.



Required Elements/Additional Information	Notes
<p>Systems are available for emergency communication and for patient care crisis.</p> <p>In addition to the equipment listed in the standard, the following must also be available to meet the assessed needs of patients:</p> <ul style="list-style-type: none"> <li>■ Oxygen, humidified.</li> <li>■ Pulse oximetry.</li> <li>■ Patient temperature monitoring.</li> <li>■ Rewarming mechanism.</li> </ul> <p>Age/size-specific resuscitation equipment is required to meet the emergency needs of the patient. If the facility treats pediatric patients, pediatric-sized resuscitation equipment is immediately available.</p>	
Survey Procedure	
<p><b>Observation and Interview</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ All equipment and systems are working and available upon identified need.</li> <li>■ Readiness records for equipment.</li> <li>■ Age-specific resuscitation equipment is readily available.</li> <li>■ Pediatric-sized endotracheal tubes/tracheostomy set are immediately available if the facility treats pediatric patients.</li> </ul>	
Standard 10.03.08 Security of Supplies and Equipment	<p>Score:</p> <p><input type="checkbox"/> C <input type="checkbox"/> NC</p>

The organization must implement adequate provisions to ensure the security of drugs, medical and dental devices, and medical gasses used for procedures.

Required Elements/Additional Information	Notes
<p>The organization has written policies that address the storage of supplies and medications to prevent unauthorized access in the operating/procedure room.</p> <p>When not in use, medication carts are locked and stored with appropriate security. Controlled substances are stored in compliance with governmental laws and regulations.</p>	
Survey Procedure	
<p><b>Observation and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policies address all requirements.</li> <li>■ Medication carts are locked when not in use.</li> </ul>	

<b>Standard 10.04.01 Laser, Light-Based, and Other Energy-Emitting Technologies Officer</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

An individual is designated to oversee education and safety for laser, light-based, and other energy-emitting technologies in use by the organization.

Required Elements/Additional Information	Notes
<p>The officer is designated in writing and appropriately trained in the use of laser, light-based, and other energy-emitting technologies. The position description includes qualifications, supervisory responsibilities, and monitoring and reporting requirements.</p>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Discuss and assess:</p> <ul style="list-style-type: none"> <li>■ Qualifications of the designated individual regarding education and supervision of the services.</li> </ul> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ There is written designation of the responsibility and a position description.</li> </ul>	

<b>Standard 10.04.02 Laser, Light-Based, and Other Energy-Emitting Technologies Policies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
--	--

Policies are written to address the use and storage of laser, light-based, and other energy-emitting technologies in use by the organization.

Required Elements/Additional Information	Notes
<p>Policies are based on nationally recognized guidelines and applicable law and regulations [e.g., OSHA; FDA; National Center for Biotechnology Information (NCBI); International Standards Organization (ISO); American National Standards Institute (ANSI), such as the American National Standard for Safe Use of Lasers and Standards for Safe Use of Lasers in Healthcare Facilities; American Society for Laser Medicine and Surgery, Inc. (ASLMS), etc.]. Policies follow the manufacturer’s instructions and are appropriate for the specific device.</p> <p>The policies emphasize safe operation of the technologies, including protection for patients and staff from hazards associated with the use of the devices.</p> <p>Policies are readily available to staff and implemented.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policies and procedures are based on nationally recognized</li> </ul>	



- guidelines and applicable law and regulations.
- Policies and procedures reflect the manufacturer’s instructions.
- Policies and procedures address identified hazard.

**Standard 10.04.03  
Staffing for the Use of Laser, Light-Based, and Other Energy-Emitting Technologies**

Score:  
 C  NC  NA

Staff must have documentation of training for the use of each device utilized. Non-credentialed staff must have approval to use of each device in their position descriptions.

**Required Elements/Additional Information**

Notes

If required by applicable law or scope of practice, the individual is appropriately certified for each device.

Staff are trained in the use of the device and in the prevention of fires.

Only staff credentialed to use the device are permitted to use the device and must be supervised by a healthcare provider who also is privileged to use the device.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- Staff training for each device.

Verify:

- Documentation of required staff certifications.
- Staff position descriptions include each device used.
- Training documentation for each device used.

**Standard 10.04.04  
Device Use Warning Signs for Laser, Light-Based, and Other Energy-Emitting Technologies**

Score:  
 C  NC  NA

Warning signs are prominently displayed at each entrance to the procedure room only when a device in use may cause combustion.

Signage on the door states admission only by authorized personnel.

**Required Elements/Additional Information**

Notes

The warning sign is used only when the device is in use and throughout the procedure. The sign must be legible and meet national standards and applicable law and regulations. The sign cannot be constantly displayed.

Permanent signage clearly indicates that only authorized personnel are permitted to enter the room. This signage is continuously displayed.

<b>Survey Procedure</b>	
<b>Observation</b>	
<ul style="list-style-type: none"> <li>Verify placement and use of warning signs.</li> </ul>	
<b>Standard 10.04.05</b> <b>Personal Protective Equipment for Laser, Light-Based, and Other Energy-Emitting Technologies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
Personal protective equipment (PPE) is used for patients and staff.	
<b>Required Elements/Additional Information</b>	Notes
<p>The organization has identified the appropriate PPE for use with each device.</p> <p>The equipment includes, at a minimum:</p> <ul style="list-style-type: none"> <li>Eye protection specific to the device being used and available before an individual enters the room.</li> <li>Patients' eyes and airways are protected.</li> </ul>	
<b>Survey Procedure</b>	
<b>Observation and Interview</b>	
Discuss and assess:	
<ul style="list-style-type: none"> <li>Staff use of PPE for each device.</li> </ul>	
Verify:	
<ul style="list-style-type: none"> <li>Use of PPE.</li> </ul>	
<b>Standard 10.04.06</b> <b>Laser Procedures – Safety Features</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
The organization implements safety features for staff, patients, and the facility. A safety manual addressing each laser and light-emitting device is available to staff.	
<b>Required Elements/Additional Information</b>	Notes
<p>A safety manual addresses the features listed for each laser and light-emitting device. There is documentation that all personnel, including physicians and dentists, using lasers or other light-emitting devices have read the safety manual.</p> <p>Safety features include:</p> <ul style="list-style-type: none"> <li>Draping materials are appropriately used for the device, including wet cloths, etc.</li> <li>Flammable prep solutions are not used.</li> <li>Flame-retardant materials are used for draping patients.</li> <li>Warming blankets do not contain flammable coolants.</li> <li>Windows are blocked appropriately for the laser wavelength used.</li> <li>Non-reflective instruments in the operative field, when</li> </ul>	

available.

- Sink and running water in the laser room.
- Peak performance calibration.

### Survey Procedure

#### Observation and Interview

Verify:

- The room used meets the requirements.
- There is a service contract for routine maintenance.

Discuss and assess:

- Safety features with the person responsible for the laser room to evaluate compliance with the standard.





11

# **ANESTHESIA SERVICES**

## DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA

The terms regarding general anesthesia, sedation, and analgesia are defined by the American Society Anesthesiologists in its Continuum of Depth of Sedation, <https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia>.

**Local Anesthesia (“Local Anesthetic”)** is usually a one-time application or injection of medicine that numbs a small area of the body. Patients are able to respond normally to verbal commands and cognitive function as well as physical coordination is not impaired.

**Minimal Sedation (Anxiolysis)** is 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”)** is 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.

*Note:* 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.”<sup>1</sup>

**Deep Sedation/Analgesia** is 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.

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

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue\*\*\* patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue\*\*\* patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue\*\*\* patients who enter a state of General Anesthesia.

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

\*\*\* Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified



practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia, and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

<sup>1</sup> American Society of Anesthesiologists. *Position on Monitored Anesthesia Care*. Last amended on October 17, 2018.

<b>Standard 11.00.01 Anesthesia and Sedation Levels</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization identifies eligible anesthesia and sedation providers in accordance with the governing body’s approved scope of procedures and levels of anesthesia, sedation, and analgesia.

Required Elements/Additional Information	Notes
<p>The organization identifies providers for all anesthesia and sedation levels in accordance with government regulations and scope of practice.</p> <p>Propofol may only be administered by an anesthesia professional.</p> <p>The organization has policies determining the procedures appropriate for moderate sedation.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has identified providers eligible to administer the different levels of sedation and anesthesia.</li> </ul>	

<b>Standard 11.01.01 Director of Anesthesia Services</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization identifies a Director of Anesthesia Services and the responsibilities for the position.

Required Elements/Additional Information	Notes
<p>Policies and procedures outline the criteria for the selection of the Director of Anesthesia Services.</p> <p>The director approves the policies and procedures addressing the administration of the continuum of anesthesia.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The policies and procedures include criteria used to select the Director of Anesthesia Services.</li> </ul>	



- The responsibilities of the position are defined.
- There is evidence that the Director of Anesthesia Services reviews and approves policies pertaining to the administration of anesthesia.

<b>Standard 11.01.02 General Anesthesia, Regional Anesthesia, and Deep Sedation Practitioners</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

Anesthetics must be administered only by:

- A qualified anesthesiologist.
- A physician, podiatrist, or dentist privileged to administer anesthesia.
- A certified registered nurse anesthetist (CRNA).
- A certified anesthesiologist assistant.
- A supervised student registered nurse anesthetist in an approved educational program.
- A supervised anesthesiologist assistant student in an approved educational program.
- A supervised physician in training to be an anesthesiologist in an approved graduate medical program.

Required Elements/Additional Information	Notes
<p>Anesthesia providers are appropriately credentialed and privileged in accordance with the standards in chapter 3: Professional Staff.</p> <p><b>SUPERVISION OF ANESTHESIA TRAINEES</b></p> <p>Supervision is provided in accordance with government regulations and national accreditation standards for education programs for anesthesia trainees and residents.</p>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization’s policy meets the requirements.</li> <li>■ The privilege list for general anesthesia/regional anesthesia/deep sedation/analgesia aligns with privileges granted to providers.</li> </ul>	

<b>Standard 11.01.03 Anesthesia and Sedation Administration</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization has a policy that limits the healthcare professional to performing the procedure and specifically identifies that the proceduralist may not administer any level of anesthesia or sedation.

Required Elements/Additional Information	Notes
The surgeon/proceduralist may supervise a qualified healthcare professional (e.g., RN) although the surgeon/proceduralist cannot	



administer the anesthesia/sedation.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- Whether any procedures have been performed for which the proceduralist also administers anesthesia or sedation.

Verify:

- The policy addresses the role of the proceduralist in compliance with the standard.
- Health records reflect that an anesthesia or sedation provider administered the anesthesia or sedation.

**Standard 11.01.04**

**Non-Anesthesia Professional Supervision of Moderate Sedation**

Score:

C  NC  NA

The organization has policies for credentialing and granting privileges to qualified physicians who supervise moderate sedation by non-anesthesia professionals, in accordance with applicable governmental regulations and professional scope of practice.

**Required Elements/Additional Information**

Notes

The organization establishes policies for competency evaluation of physician (or dentist) supervision of moderate sedation in accordance with applicable government regulations.

The organization's policy includes:

- Requiring successful completion of a moderate sedation examination and annual competency evaluation.
- Credentialing in advanced airway management, including ACLS, PALS if pediatric care is provided, emergency intubation and ability to rescue the patient from unintended deep sedation.
- Selecting medications for moderate sedation.
- If a supervising physician is required, the supervising physician must be physically present in the procedure area during the administration of moderate sedation and immediately available to respond to emergencies, including deeper-than-intended levels of sedation. In addition, the supervising physician selects the agents to be administered.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization's policy meets the requirements.
- Through interviews, training records, and licenses that requirements were met.

**Standard 11.01.05  
Non-Anesthesia Professional Administration of Moderate Sedation**

Score:  C  NC  NA

If the organization permits a registered nurse (RN) or other practitioner who is not an anesthesia professional to administer and monitor moderate sedation under the supervision of a physician with proper privileges, the organization must:

- Ensure that the administration of moderate sedation is in accordance with governmental laws and regulations and the RN or other practitioner’s scope of practice.
- Have a written job description detailing the roles and responsibilities, qualifications, and eligibility criteria for administering and monitoring moderate sedation.
- Ensure the RN or other provider has documented training, experience, and evaluated competencies in administering moderate sedation inclusive of the pre-sedation, monitoring, and post-sedation evaluation of the patient response.

**Required Elements/Additional Information**

Notes

The organization must ensure the RN’s or other provider’s sole responsibility is to administer moderate sedation and continuously monitor the patient’s hemodynamic status and responsiveness.

**COMPETENCY**

The organization verifies the RN or other practitioner has current ACLS certification.

The organization defines the training and its frequency necessary to maintain competency. Training includes, at a minimum, anatomy and physiology related to moderate sedation, medications, and doses appropriate to induce moderate sedation, pharmacological effects, reversal agents, administration techniques, and identification and response and rescue to sedation-related adverse events, including airway management skills to rescue from deeper-than-intended levels of sedation.

- The competency is appropriate to the responsibilities, procedures performed, and patient population.
- The RN or other provider successfully completes an annual competency evaluation related to moderate sedation.
- The RN or other practitioner has current ACLS certification, or PALS if pediatric care is provided.
- Education, training, and competencies to administer and monitor moderate sedation are documented.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization’s policy meets the requirements.
- Through interviews, training records, and licenses that requirements were met.



<b>Standard 11.01.06 Moderate Sedation: Staffing Requirements</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

The organization has a policy approved by the professional staff that establishes:

- The minimum staffing required during moderate sedation procedures.
- A registered nurse (RN) or other practitioner may administer and monitor moderate sedation in accordance with applicable law and standard 11.01.05.
- The roles and responsibilities of the staff assigned to monitor the patient receiving moderate sedation.
- At least one person in the procedure room is ACLS certified.

Required Elements/Additional Information	Notes
<p>The policy addresses each requirement listed in the standard.</p> <p>The patient must be monitored by a qualified RN or other practitioner whose sole responsibility is to monitor the patient, in accordance with applicable laws.</p>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ There is a relevant policy.</li> <li>■ Through interviews, training records, and licenses that the policy requirements were met.</li> </ul>	

<b>Standard 11.02.01 Policies, Procedures, and Protocols for Administration of Moderate Sedation</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

Policies, procedures, and protocols for the administration of moderate sedation include monitoring and evaluation prior to, during, and after the procedure. A post-sedation evaluation prior to discharge is completed and documented.

Required Elements/Additional Information	Notes
<p>The organization's policies, procedures, and protocols approved by the professional staff address all moderate sedation activities, including but not limited to, defining roles and responsibilities for pre-sedation assessment and evaluation, monitoring, patient education and consent, procedural support, and post-sedation recovery and evaluation.</p> <p>If an RN is administering the moderate sedation, protocols specifically address drugs, dosages, routes, and responsibilities for pre-sedation assessment, monitoring, and post-evaluation.</p> <p>Protocols for monitoring the patient address the clinical observation and confirmation of continuous IV access and supplemental oxygen.</p> <p>Monitoring of all moderate sedation cases includes:</p> <ul style="list-style-type: none"> <li>■ Oxygen saturation.</li> </ul>	

- Blood pressure.
- Cardiac rate and rhythm.
- Level of consciousness.
- Respiratory monitoring.

The pre-sedation assessment and evaluation, patient's informed consent to moderate sedation, administration of sedation, monitoring, and evaluation after the procedure are completed and documented.

A post-sedation evaluation is completed and documented prior to discharge.

**Survey Procedure**

**Document Review**

Verify:

- The organization is following its own policy.
- The policies, procedures, and protocols for administration of moderate sedation are consistent with the requirements.
- A sample of patient records for patients who had surgery or a procedure requiring moderate sedation reflects that pre- and post-evaluations were conducted for each patient.
  - » Whether the evaluation was conducted in accordance with the standard.
  - » Whether the evaluation was performed prior to the patient's discharge.

**Standard 11.03.01  
Emergency Training**

Score:  
 C  NC

Anesthesia providers and staff have training in the emergency resuscitation care of the patient.

**Required Elements/Additional Information**

Notes

The organization has identified staff required to have advanced cardiovascular life support training (ACLS) and those required to have basic life support (BLS) training. If pediatric patients receive care, PALS training is also required.

Hands-on training is required to demonstrate airway management skills.

All training is documented—identifying hands-on training—and updated periodically at a minimum of every two years.

**Survey Procedure**

**Document Review**

Verify:

- Staff is trained in emergency resuscitation procedures.





<b>Standard 11.03.02</b> <b>Patient Safety: Malignant Hyperthermia Policy</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
--	--

If the organization stocks malignant hyperthermia triggering agents, the organization leadership has written policies and procedures approved by the professional staff that:

- Addresses recognition and treatment of a patient experiencing malignant hyperthermia.
- Identifies the emergency medication required for treatment of malignant hyperthermia.
- Requires onsite availability of the emergency medications in the amounts required to rescue the patient based on national guidelines.

Required Elements/Additional Information	Notes
<p>If the organization stocks medications that are triggering agents for malignant hyperthermia (e.g., inhalation anesthetics, depolarizing muscle relaxants), the organization must:</p> <ul style="list-style-type: none"> <li>■ Provide annual staff training and drills on the recognition and treatment of patients experiencing malignant hyperthermia.</li> <li>■ Have a more extensive supply of emergency equipment, supplies, and medications than an organization that only uses local anesthesia to perform low-risk procedures. If an organization uses triggering agents that carry a risk for malignant hyperthermia, the organization is expected to have the required medications onsite as required to treat this emergency condition based on the recommendations of the Malignant Hyperthermia Association of the U.S. (MHAUS).</li> </ul>	
<b>Survey Procedure</b>	
<p><b>Observation, Interview, and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has policies and procedures regarding the treatment of malignant hyperthermia.</li> <li>■ The setting has the necessary supplies immediately available to treat malignant hyperthermia.</li> <li>■ Clinical staff know where the emergency equipment is located and how to respond to a patient emergency.</li> </ul>	

<b>Standard 11.04.01</b> <b>Adequate Anesthesia Equipment and Supplies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

The organization leadership has a policy approved by the professional staff that:

- Establishes sufficient quantities and types of anesthesia supplies and equipment, such as appropriate PAR levels of equipment.
- Addresses the requirement for anesthesia supplies and equipment to be stored so that movement is minimized during cases.
- Addresses the expectations for processed supplies to be protected from

surface/airborne contamination

- Establishes the process to periodically use staff input to evaluate the quantity and quality of anesthesia equipment available to meet the needs of the patients.

Required Elements/Additional Information	Notes
The policies are reviewed as needed when new equipment is considered, additional procedures are approved, and if there are changes in the patient population.	
Survey Procedure	
<p><b>Observation</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ General and clean areas are clearly identified.</li> <li>■ Staff adhere to traffic rules with particular concern regarding decontamination procedures for equipment.</li> </ul>	
Standard 11.04.02 Maintenance of Anesthesia Equipment	<p>Score:</p> <p><input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA</p>

All anesthesia equipment must be maintained in compliance with all applicable requirements (e.g., Safe Medical Devices/Food & Drug Administration requirements).

Anesthesia machines and related equipment undergo regular, documented, routine preventive maintenance in accordance with manufacturer specifications or nationally recognized standards and guidelines.

Required Elements/Additional Information	Notes
The organization has written policies to address these requirements.	
The healthcare record contains documentation of: <ul style="list-style-type: none"> <li>■ Safety checks completed prior to each patient use.</li> <li>■ The anesthesia machine number. This documentation is necessary in the event of patient injury or any equipment recall.</li> </ul>	
Survey Procedure	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Patient records reflect documentation of the anesthesia machine number and that it was checked prior to use.</li> <li>■ Evidence of equipment maintenance, as required.</li> </ul>	



<p><b>Standard 11.04.03</b>  <b>Security of Supplies and Equipment</b></p>	<p>Score:  <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>The organization must implement adequate provisions to ensure the security of drugs, medical devices, and medical gasses.</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>The organization has policies that address the storage and security of supplies and medications to prevent unauthorized access.</p> <p>When not in use, medication carts are secured in a manner to prevent unauthorized access.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Observation and Document Review</b></p>	
<p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policies address all requirements.</li> <li>■ Medication carts are secured to prevent unauthorized access.</li> </ul>	

12

**PHARMACEUTICAL  
SERVICES**

<b>Standard 12.00.01 Provision of Pharmaceuticals</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

The organization must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice and under the direction of a licensed healthcare professional for pharmaceutical services.

Required Elements/Additional Information	Notes
<p>The organization must designate a specific, licensed healthcare professional to provide direction to the organization’s pharmaceutical service. That individual must be routinely present when the organization is open for business, but continuous presence is not required, particularly when the organization is open for longer periods of time to accommodate the recovery of patients for up to 24 hours.</p> <p>It is recommended that a pharmacist provide oversight or consultation on the organization’s pharmaceutical services.</p> <p>This is required if the organization is performing activities that, under law and regulations, may only be performed by a licensed pharmacist.</p>	

Survey Procedure
<p><b>Interview and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ That a qualified individual has been designated to direct pharmaceutical services in the organization.</li> <li>■ How often and for how long this individual is onsite at the organization.</li> <li>■ Documentation indicates that the individual is providing active direction and oversight to the program.</li> </ul>

<b>Standard 12.00.02 Compliance with Governmental Laws and Regulations</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization demonstrates compliance with requirements of the respective authority (e.g., State Board of Pharmacy) or its equivalent.

The organization’s pharmacy licenses are displayed, as required by law and regulations.

Required Elements/Additional Information	Notes
<p>Organizations must comply with applicable law and regulations that govern the qualifications, certification, or licensure of staff who administer drugs and biologicals and must adhere to accepted standards of practice for medication administration.</p> <p>The pharmacy license and related certificates must be displayed in accordance with any license or certificate requirements. The location of the licenses display minimizes fraudulent activity; for example, the display may be in areas inaccessible to patients and unauthorized staff.</p>	



If the organization uses the healthcare provider’s license in lieu of an organization license, the license is available to authorized individuals.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Through observation, that the facility displays pharmacy licenses, as required.
- The most recent State Board of Pharmacy or other applicable inspection report reflects compliance.

**Standard 12.00.03  
Drug and Biological Orders**

Score:  
 C  NC

Qualified healthcare professionals order and supervise the administration of drugs and biologicals.

**Required Elements/Additional Information**

Notes

Drugs and biologicals used within the organization must be administered to patients in accordance with policies the organization has adopted.

Those policies and the organization’s actual practices are consistent with acceptable standards of practice for medication administration. “Accepted professional practice” and “acceptable standards of practice” mean that drugs and biologicals are handled and administered in the organization in accordance with applicable law and nationally recognized standards for their clinical use.

The organization’s policies and procedures address issues including, but not limited to:

- A healthcare professional acting within their scope of practice must issue an order for all drugs or biologicals administered in the organization.

The administration of the drugs or biologicals must be by, or under the supervision of, healthcare personnel in accordance with applicable laws, standards of practice, and the organization’s policies.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Documents indicate that the requirements are met.
- Medical records reviewed provide evidence that there is an order, signed by a physician or other qualified practitioner, for every drug or biological administered to the patient.
- Drugs or biologicals are administered only by nurses or other qualified individuals, or under the supervision of nurses or

other qualified individuals, as permitted under federal or state law and the organization's policy.

**Standard 12.00.04**  
**Labeling and Storage of Medications**

Score:  
 C  NC

Drugs must be stored and labeled according to established policies and acceptable standards of practice.

**Required Elements/Additional Information**

Notes

The organization must ensure that drugs and biologicals are prepared and managed safely and appropriately,

Organization policies and procedures must address the preparation, storage, and handling of drugs and biologicals.

The policies address, at a minimum:

- The storage and security of drugs and biologicals, including the location of storage areas, medication carts, and dispensing machines.
- Proper environmental conditions.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Policies and procedures reflect safe management of drugs and biologicals.
- Medications are properly labeled, stored, and have not expired.

**Standard 12.00.05**  
**Controlled Substances**

Score:  
 C  NC  NA

The organization has policies and procedures for the receipt, storage, and disposition of all controlled substances used.

**Required Elements/Additional Information**

Notes

Policies and procedures address the following, at a minimum:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
- Requirements for current accurate records of the receipt, storage, and disposition of all scheduled drugs.
- The licensed healthcare professional who has been designated responsible for the organization's pharmaceutical services confirms that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.
- The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the organization to the point of departure, either through administration to the patient, destruction, or return to



the manufacturer.

- » This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
- All drug records are in order and an account of all scheduled drugs is maintained, and any discrepancies in count are reconciled promptly.
- The organization’s system readily identifies loss or diversion of controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

**Survey Procedure**

**Observation and Document Review**

Verify:

- A record system provides information on controlled substances in a readily retrievable manner.
- A system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the organization to the point of departure.
  - » Review the records to determine that they effectively trace the movement of scheduled drugs through the organization.
  - » Confirm that documentation on scheduled drugs is readily retrievable to facilitate reconciliation of the receipt and disposition.
- The individual in charge of the organization’s pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.
- Facility policy and procedures minimize diversion of scheduled drugs.

**Standard 12.00.06  
Blood and Blood Products**

Score:  
 C    NC    NA

Blood and blood products must be administered by only qualified healthcare professionals.

**Required Elements/Additional Information**

Notes

If blood or blood products are administered to patients, administration must be only by a healthcare professional authorized by the organization.

Policies and procedures must specifically address this requirement.

- If the organization does not keep blood or blood products on hand and never administers such products to patients, this is stated by policy.



**Survey Procedure**

**Document Review**

Verify:

- Policies specifically restrict administration of blood and blood products to a qualified healthcare professional.
- A qualified healthcare professional administered the blood or blood product.

**Standard 12.00.07  
Safe Administration Practices**

Score:

C  NC  NA

The organization has policies and procedures supporting safe medication administration practices.

**Required Elements/Additional Information**

Notes

Organization policies and procedures, at a minimum, address:

- Verification prior to administration of the patient, medication, dose, route, and time.
- Safe injection practices based on nationally recognized guidelines, such as the CDC, regarding the use of needles, cannulas that replace needles, and, where applicable, intravenous delivery system.
- Use of fluid infusion and administration sets (i.e., intravenous bags, tubing, and connectors) for one patient only and appropriate disposal after use. (A syringe or needle/cannula is considered contaminated after it has been used to enter or connect to a patient's intravenous infusion bag or administration set.)
- Limiting use of intravenous solution bags or bottles to single patients.
- Limiting use of single-dose vials to only one patient.
- Nationally recognized guidelines for the use of multi-dose vials.
- Aseptic techniques used to avoid contamination of sterile injection equipment.
- Labeling of pre-filled unit dose single-shot medications with the contents, stock dose, and expiration date.
- Labeling of medications drawn up by staff with contents, initials of the person who drew it, dose, date, and time when the medication was drawn. Medications are drawn in advance in accordance with the USP guidelines and manufacturer's instructions.
- Use of surgical masks when placing a catheter or injecting material into the spinal canal or subdural space.
- Measures to eliminate errors regarding look-alike/sound-alike medications and high alert medications (refer to the ISMP



guidelines).

**Survey Procedure**

**Observation and Document Review**

- Verify:
- The organization employs safe injection practices.
  - Documents reflect all requirements.
  - Compliance with standard infection control practices when using injectable medications.
  - Personnel wash their hands prior to providing care to patients.
  - Personnel who prepare injections comply with all pertinent protocols.

**Standard 12.00.08 Preparation Area**

Score:  
 C  NC

There is a designated area free of patients where medications, including multi-dose medications, if used, can be prepared for use on single patients in the pre-op, operative, or recovery areas.

**Required Elements/Additional Information**

Notes

Policies and procedures must address the preparation of medications for administration.

**Survey Procedure**

**Observation and Document Review**

- Verify:
- The area for medication preparation is separate from patient care areas.
  - Policies and procedures for medication preparation address where preparation occurs.

**Standard 12.01.01 Verbal Orders**

Score:  
 C  NC  NA

Orders for drugs and biologicals that are transmitted as verbal communications between the ordering healthcare professional and the organization’s patient care staff, delivered either face-to-face or via telephone, commonly called “verbal orders,” must be followed by a written order that is signed by the ordering healthcare professional.

**Required Elements/Additional Information**

Notes

- The organization must address the following:
- Read-Back Verbal Orders: Policies and procedures for verbal orders include a read-back and verification process, in which the nurse receiving the order repeats it back to the ordering healthcare professional, who verifies that it is correct.

- Documentation of Verbal Order: When administering a drug or biological per a verbal order, the administering staff member must include in the healthcare record entry that the administration of the drug or biological was ordered verbally, indicating the name of the ordering healthcare professional.
  - » Verbal orders must be confirmed in a timely manner by the ordering healthcare professional, noted by signature, date, and time. This should be done as soon as possible after the verbal order is issued.
- Verbal Orders in the Recovery Area: Medications prescribed verbally in the recovery or post-anesthesia area must follow verbal order policy and comply with requirements.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Policies and procedures address verbal orders.
  - » Does the policy require the ordering practitioner to sign, date, and time a written order as soon as possible after issuing the verbal order?
  - » Is there evidence in the medical records that each verbal order was followed by a written order signed by the ordering healthcare professional?
- Do policies and procedures for verbal orders include a "read-back and verify" process?

Discuss and assess:

- How staff handles verbal orders.
  - » Does their practice conform to the regulatory requirements?
  - » Do they use a read-back and verify process?

**Standard 12.01.02  
Adverse Reactions**

Score:

C  NC

Adverse reactions must be reported to the healthcare professional responsible for the patient and must be documented in the record.

**Required Elements/Additional Information**

Notes

Reporting every adverse reaction permits the healthcare professional to assess the patient in a timely manner and determine whether additional treatment is required to counteract the adverse reaction.

The organization must have policies and procedures on adverse reactions to drugs and biologicals that address:

- All adverse reaction(s) experienced by a patient.
- Prompt reporting to the healthcare professional responsible for the patient to assess and determine treatment required.



- Documentation of the adverse reaction on the patient’s healthcare record.
- Staff training on these requirements.
- Mechanisms for monitoring and assessing adverse reaction reports to determine contributing factors, errors, and course of actions effective in addressing identified problems, if any.

**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- Steps clinical staff take if a patient experiences an adverse reaction to a drug.
  - » Are staff aware of the requirement to promptly report this information to the provider responsible for the patient?

Verify:

- Documentation of adverse drug reactions is in the sample of records selected for review.
  - » If no adverse drug reactions are noted, ask organization staff whether they recall any patients having adverse drug reactions, and if so, whether they could pull a medical record containing documentation of an adverse drug reaction.
- Policies and procedures address adverse drug reactions and are consistent with the regulatory requirements.

**Standard 12.01.03 Medication Reconciliation**

Score:  
 C  NC

The organization has a process for medication reconciliation for each patient.

**Required Elements/Additional Information**

Notes

The organization maintains documentation of the patient’s currently prescribed medications prior to arrival for the procedure and confirms the accuracy of the list at the time of admission.

The list includes prescribed and regularly taken over-the-counter drugs, vitamins, herbals, homeopathic, and nutritional supplements.

Whenever possible, the patient (or responsible person) confirms the accuracy of the list.

The list is compared against the pre-admission medication list and any variances are reconciled.

The list of pre-admission medications is readily available for prescribers to review when writing/changing medication orders.

For each medication, documentation includes, at least:

- Drug name.



- Dosage.
- Indications for taking or using.
- Frequency of usage.

There is a reconciliation process to ensure all appropriate medications (including pre-admission medications) are continued following discharge. Post-procedure medications are reconciled with the pre-admission medications, and potential contraindications are identified.

The patient (or responsible person) is informed of medications that need to be discontinued or changed upon discharge.

At time of discharge, a copy of the final medication list is provided to:

- The patient or responsible person.
- The next level of pre-planned care, such as rehabilitation or home health care.

**Survey Procedure**

**Document Review**

Verify:

- Medical records show that the requirements were met.

**Standard 12.02.01  
Disposal of Drugs and Biologicals**

Score:  
 C  NC  NA

The organization has policies and procedures regarding the disposal of unused drugs and biologicals.

**Required Elements/Additional Information**

Notes

Policies and procedures for drug and biological disposal and retention are in accordance with laws, regulations, and guidelines.

Policies address, at a minimum:

- Staff authorized for disposal.
- Documentation and witnessing of disposal.

**Survey Procedure**

**Document Review**

Verify:

- The organization has established the policies and procedures for the disposal of unused drugs and biologicals.

**Standard 12.02.02  
Security of Drugs and Biologicals**

Score:  
 C  NC

Drugs and biologicals must be provided adequate security to prevent unauthorized access.

**Required Elements/Additional Information**

Notes

Drugs and biologicals are stored in areas that are not readily



accessible to unauthorized access. Controls are in place to track drugs and biologicals to ensure their safe storage, handling, and administration.

Medication carts, anesthesia carts, and other nonautomated medication carts containing drugs or biologicals (hereafter, all referred to as “carts”) must be secured (locked) when not in use.

If a cart containing drugs or biologicals is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That individual must monitor the cart and be aware of other people’s activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

**Survey Procedure**

**Observation**

Verify:

- Medications are securely stored.

**Standard 12.02.03  
Emergency Drugs**

Score:  
 C  NC

The organization has a policy approved by the professional staff that:

- Establishes the emergency drugs and quantities to be maintained in the organization.
- Establishes that emergency drugs in the organization must be securely stored.
- Establishes a process to conduct and record an inventory of medications.

**Required Elements/Additional Information**

Notes

During hours of operation, storage units are not required to be locked in order to facilitate emergency access. However, security must be such that breaches are readily evident.

- Written records document the inventory of medications and identified equipment; the inventories are updated at such frequency as to ensure that all emergency medications are available and equipment is in functioning order.
- There are adequate quantities of medications (including oxygen).
- The organization has effective processes to ensure expired medications are removed from the inventory.

**Survey Procedure**

**Document Review**

Verify:

- The organization has established the emergency medications and quantities to be maintained.



- The organization has a process to conduct and record the inventory of medications.
- Medications are securely stored during a tour.



THIS PAGE IS INTENTIONALLY BLANK.



13

**LABORATORY  
SERVICES**

Laboratory testing for humans (excluding research) is regulated in the United States by the Centers for Medicare & Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as defined in 42 CFR 493.

The standards for this chapter reference U.S. CLIA requirements; for surveys in other countries, equivalent laws and regulations will form the basis of the survey.

**Standard 13.00.01  
Laboratory Services**

Score:  C  NC  NA

If the organization performs laboratory services, it must meet the requirements of 42 CFR 493.\*

If the organization does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with 42 CFR 493.\*

\* For non-U.S.-based organizations, laboratory services meet applicable laws and regulations.

**Required Elements/Additional Information**

Notes

The organization's written policies and procedures must identify the kinds of laboratory services that are provided directly by the organization and services that are provided by an external laboratory.

Laboratory services are provided within the appropriate designation as defined by governmental laws and regulations. For example, types of designations in the U.S. states and territories include:

- A Certificate of Waiver is required for organizations performing only waived testing. Waived testing also may be performed under the other certificate types.
- A Certificate of Registration or registration certificate for initial registration with CLIA is required for all laboratories performing moderate or high complexity testing other than those tests categorized as Provider-Performed Microscopy (PPM).
- A Certificate of Compliance is for moderate/high complexity testing.
- A Certificate of Accreditation is for moderate/high complexity testing from an accreditation program with deeming authority under CLIA.
- A CLIA Certificate for Provider-Performed Microscopy (PPM) procedures permits physicians and advanced healthcare practitioners to perform a limited list of moderate complexity microscopic tests, as well as waived tests, as part of a patient's visit.

The organization's written procedures must include the following:

- Laboratory tests that are provided by the organization.
- A well-defined arrangement (need not be contractual) with outside services.
- Routine procedures for requesting lab tests.



- Incorporation of lab reports into the patient’s healthcare records.

When laboratory tests are performed prior to the patient’s procedure, the results are readily available to the healthcare professionals in the organization.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization identifies laboratory testing provided in-house and by an external laboratory.
- If the organization is performing laboratory testing, the laboratory has a CLIA Certificate of Compliance (if the laboratory is surveyed by the state agency) or a CLIA Certificate of Accreditation (if the laboratory is surveyed by an approved accreditation organization).
- If testing is done through an external laboratory, the organization has proof that the external laboratory has a current CLIA Certificate covering the services provided.

**Standard 13.01.01  
Laboratory Director**

Score:  
 C  NC

All laboratory testing must be under the supervision of the current director, noted on the CLIA certificate(s), and must adhere to all governmental laws and regulations.

**Required Elements/Additional Information**

Notes

All CLIA certificates must state the name of a current director. In the event of a CLIA-named healthcare provider leaving the organization, the CLIA certificate must be updated with a new director’s name.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of testing.

**Survey Procedure**

**Document Review**

Verify:

- Laboratory testing is under the supervision of a current director, accurately identified on the CLIA certificate.
- Adherence to laws and regulations is documented.

**Standard 13.02.01**  
**Waived Testing** Score:  
 C  NC

Laboratories performing waived testing must have a current, valid CLIA Certificate of Waiver to perform waived testing.

**Required Elements/Additional Information** Notes

Waived testing may be performed under a CLIA Certificate of Waiver or other CLIA certificates, including a Certificate for PPM procedures, a Certificate of Registration, a Certificate of Compliance, or a Certificate of Accreditation.

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and tests approved for waiver under CLIA criteria. The FDA list of waived tests is continuously revised as new tests are waived. The most current information on FDA-cleared, waived tests can be found on the FDA website.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The organization holds at least a Certificate of Waiver.
  - » For a Certificate of Waiver, verify the tests performed by the laboratory are limited to those categorized as waived.
  - » **The Certificate of Waiver is in good standing.**

**Standard 13.02.02**  
**Waived Testing Personnel** Score:  
 C  NC

All personnel performing waived testing must have appropriate training and demonstrate satisfactory levels of competence.

**Required Elements/Additional Information** Notes

The organization has a process to ensure that personnel performing waived tests are appropriately trained before performing the test. Evidence of training is maintained. Competency for each waived test is documented.

Personnel performing waived testing meet qualifications specified by law and regulations. For example, personnel with high school diplomas or associate degrees must meet training requirements.

**Survey Procedure**

**Observation and Document Review**

Verify:

- All personnel performing waived testing have received appropriate training.
- Training activities and competency are documented for each



person performing testing.

Identify:

- Mechanism(s) used to ensure that testing personnel are following the laboratory's written policies and procedures.

**Standard 13.02.03  
Manufacturer's Instructions for Waived Testing**

Score:  
 C  NC  NA

The laboratory maintains a current copy of the manufacturer's instructions for the tests performed and follows the current manufacturer's instructions.

**Required Elements/Additional Information**

Notes

The current manufacturer's instructions are available to personnel performing waived tests. The organization has a written process ensuring each shipment of tests is reviewed for changes in the manufacturer's instructions and training personnel on the changes.

The manufacturer's instructions are followed for:

- Using the appropriate specimen.
- Adding the required reagents in the prescribed order and amount.
- Adhering to the manufacturer's storage and handling instructions.
- Using the proper expiration date for the storage method.
- Performing the quality control, if required.
- Performing function checks or calibration, if required.
- Adhering to the manufacturer's instructions for confirmatory testing.
- Reporting the results as required by the manufacturer.
- Performing instrument maintenance, if required.
- Adhering to timing requirements for test incubation, result interpretation, or other procedural steps.

*Note:* If a test is modified by the testing organization **in any way**, it is no longer considered waived and cannot be used under a CLIA Certificate of Waiver. Examples of modifications (any changes) include:

- Altering the timing of the test.
- Diluting a reagent.
- Physically modifying a component, such as cutting test cards or strips to increase the number of samples tested per kit.
- Testing a sample that is not indicated as an approved sample type or not collected using the appropriate device, kit, or container per the manufacturer's instructions.
- Any change or modification to the manufacturer's instructions results in a test that is **no longer waived**, and the test automatically defaults to a high complexity test, which means

the laboratory is subject to the CLIA requirements for high complexity testing.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The laboratory routinely reviews incoming package inserts for changes in the manufacturer’s instructions.
  - » If changes have been made, verify that the organization provides information or training to staff on the change(s).
- The organization documents the name of the test, lot number, and expiration date. *Note:* This may be documented in the patient chart or in a separate log.
- There is a written policy or procedure for how to report test results.

Review:

- Documentation supporting the organization’s monitoring of room and/or refrigerator temperature to ensure kits, reagents, etc., are stored according to the manufacturer’s instructions.

**Standard 13.02.04  
Quality Control for Waived Tests**

Score:  C  NC  NA

The laboratory follows the manufacturer’s instructions for quality control (QC) and reviews the results to determine if results are acceptable prior to reporting patient results.

The laboratory documents corrective actions when QC results do not meet acceptable limits.

**Required Elements/Additional Information**

Notes

Controls must be treated and tested in the same way as patient samples and by the same personnel who routinely perform patient testing. At a minimum, the organization must follow the manufacturer’s instructions and test controls with:

- Each new shipment of kits/reagents.
- A change in lot number.
- Each new operator.

To detect problems and evaluate trends, testing personnel or supervisory staff must review QC data prior to reporting patient results on days when controls are run. The laboratory director or supervisor must review QC data at least monthly or more frequently if so-specified in the laboratory QC policy.

With respect to internal controls, acceptable control results must be recorded, at a minimum, once per day of patient testing for each device. Acceptable internal control results need not be recorded if an unacceptable instrument control automatically locks the instrument



and prevents release of patient results.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The frequency of QC performance.
- QC results are reviewed at least monthly or more frequently as determined by the organization.

Interview:

- Staff to confirm they are able to verbalize what actions to take in the event of unacceptable QC results.

**Standard 13.03.01  
Provider-Performed Microscopy (PPM) Procedures**

Score:

C  NC  NA

A valid Provider-Performed Microscopy Procedures CLIA certificate is required for testing, and the organization or testing site must meet all applicable CLIA regulations including quality standards for moderate complexity testing.

**Required Elements/Additional Information**

Notes

Procedures currently approved under CLIA as PPM are limited to the following nine specific microscopic examinations using bright-field or phase-contrast microscopy procedures:

- All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.
- All potassium hydroxide (KOH) preparations.
- Pinworm examinations.
- Fern tests.
- Post-coital direct, qualitative examinations of vaginal or cervical mucous.
- Urine sediment examinations.
- Nasal smears for granulocytes.
- Fecal leukocyte examinations.
- Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

If the organization has more than one location, a separate PPM certificate is obtained for each location.

Tests categorized as waived may also be performed by laboratories with a PPM CLIA certificate.

Information on obtaining a PPM certificate may be found in the CLIA regulations.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The CLIA certificate is the correct certificate type for the testing performed.
- The certificate is current.

Interview:

- Staff to determine if there have been any changes in ownership, director, address, or test menu since the last on-site inspection or issued date of certificate.
  - » If so, review documentation that the appropriate agencies have been notified.

**Standard 13.03.02  
Provider-Performed Microscopy (PPM) Director**

Score:

C  NC  NA

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of Provider-Performed Microscopy (PPM) procedures.

**Required Elements/Additional Information**

Notes

If the laboratory is performing PPM, the laboratory director must:

- Be a physician, advanced healthcare practitioner, or dentist.
- Possess a current license as a laboratory director issued by the state in which the laboratory is located if licensing is required.
- Be eligible to be an operator of a laboratory or testing site within the requirements of CLIA.
- Be authorized to practice independently in the state in which the laboratory or testing site is located.

The laboratory director must ensure applicable CLIA requirements for PPM procedures are met, including, but not limited to:

- Current procedure manual with evidence of laboratory director approval and review.
- Appropriate physical environment for testing.
- Equipment maintenance procedures and documentation of compliance.
- Quality control policy/procedure to include number, type, and frequency with evidence of compliance.
- Test report criteria.
- Proficiency testing (PT) or method of evaluating accuracy of testing twice yearly.
- Policies/procedures for a quality assessment system that covers all phases of the testing process.
- Retention of all records including test requests, specimen information, patient results, quality control records, PT records,





and quality assessment records for at least two years.

*Note:* PT is not specifically required for PPM procedures. However, PPM testing sites must verify the accuracy of their testing at least twice a year. Participation in a voluntary PT program will satisfy that requirement. All CLIA-approved PT programs offer a clinical microscopy module with at least two testing events per year.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The qualifications of the laboratory director to ensure they have not owned or operated a laboratory that has had its certificate revoked.
- Compliance with applicable CLIA requirements regarding laboratory director responsibilities.
- PPM testing is confined to CLIA-approved PPM procedures or waived tests and no others.

Discuss and assess:

- How the director fulfills the assigned responsibilities.
  - » Are there deficiencies that reflect a lack of director involvement or oversight?

**Standard 13.03.03  
Provider-Performed Microscopy (PPM) Procedure Criteria**

Score:  
 C  NC  NA

Provider-Performed Microscopy (PPM) procedures must meet the following criteria:

- The examination must be personally performed by a practitioner as defined by CLIA.
- The procedure must be categorized as moderately complex.
- The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.
- The specimen is labile or delays in performing the test could compromise the accuracy of the test result.
- Control materials are not available to monitor the entire testing process.
- Limited specimen handling or processing is required.

**Required Elements/Additional Information**

Notes

Practitioners approved by CLIA to perform PPM are:

- A physician during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.
- An advanced healthcare practitioner, practicing in accordance with applicable laws, during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a

clinic, group medical practice, or other healthcare provider of which the advanced healthcare practitioner is a member or an employee.

- A dentist during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

The [FDA website](#) provides information on the tests categorized as waived or non-waived (i.e., moderate or high complexity tests). Test systems, assays, and examinations not yet classified are considered high complexity.

*Note:* A modified waived or moderate complexity test (including modifications in its intended use) is considered uncategorized for CLIA purposes and therefore becomes a high complexity test. As such, the test may not be performed under a PPM certificate.

Information on best practices for PPM testing may be found in the [CDC website](#).

**Survey Procedure**

**Interview and Document Review**

Verify:

- The testing performed meets the criteria for PPM procedures or is categorized as waived testing.

**Standard 13.03.04  
Provider-Performed Microscopy (PPM) Personnel**

Score:  
 C  NC  NA

The organization must have a sufficient number of individuals who meet the qualification requirements to perform the functions specified in this section for the volume and complexity of testing performed.

There is a written program to ensure that each individual conducting provider-performed microscopy (PPM) procedures maintains satisfactory levels of competence.

**Required Elements/Additional Information**

Notes

Each individual performing PPM procedures must meet the qualifications defined by CLIA and possess a current license issued by the state in which the organization is located if licensing is required.

PPM testing personnel are required to undergo competency assessment to ensure accurate and reliable testing and reporting. If the laboratory director is the only individual testing and reporting test results, a minimum level of proficiency must be established and documented in order to ensure that the required competency for accurate and reliable testing and reporting is maintained.

*Note:* A common method to establish competency is to participate in external assessment activities such as proficiency testing (PT). The requirements for performing the assessment and its frequency are determined by the laboratory or testing site’s policies and procedures

and must be performed for testing personnel for each test that the individual is approved to perform.

Competency assessments must include all six elements described below for each test system during each assessment period unless an element is not applicable to the test system. Elements of competency assessment include, but are not limited to:

1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing.
2. Monitoring the recording and reporting of test results.
3. Review of intermediate test results or worksheets, QC records, PT results, and preventive maintenance records.
4. Direct observation of instrument maintenance and function checks.
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples.
6. Assessment of problem-solving skills.

### Survey Procedure

#### Interview and Document Review

Verify:

- A written policy defines the process for competency assessment and states the frequency of such assessment.
- Documentation reflects ongoing competency assessment for each individual performing PPM procedures.

Discuss and assess:

- Any significant pervasive issues that may be directly linked to insufficient testing personnel and/or to the management of those personnel.

#### Standard 13.03.05

#### Provider-Performed Microscopy (PPM) Policies and Procedures

Score:

C  NC  NA

The organization must have written policies/procedures for provider-performed microscopy (PPM) procedures, as applicable, for:

- Each test performed including specimen handling, performance, and reporting.
- Quality control (QC) for stains and reagents.
- Storage of reagents, test kits, and controls.
- Instrument maintenance and function checks (e.g., microscopes, centrifuges, etc.).
- Safety rules and regulations including, but not limited to, the use of personal protective equipment and adherence to universal precautions.
- Corrective action for QC failures.
- Quality assessment.

Required Elements/Additional Information	Notes
<p>The organization must document and maintain records of:</p> <ul style="list-style-type: none"> <li>■ Test results.</li> <li>■ QC, including lot numbers and expiration dates for stains and reagents.</li> <li>■ Temperature logs of storage (room temp or refrigeration), as applicable.</li> <li>■ Instrument maintenance and function checks (e.g., microscopes, centrifuges, etc.).</li> </ul>	
Survey Procedure	
Observation, Interview, and Document Review	
<p>Verify:</p> <ul style="list-style-type: none"> <li>■ Required records are maintained by the organization.</li> <li>■ Records reflect compliance with the policies and procedures.</li> <li>■ Reagents, test kits, and controls are stored appropriately.</li> <li>■ Staff can demonstrate retrieving a patient test result.</li> </ul>	

Standard 13.04.01 Moderate or High Complexity Testing	Score:
	<input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
<p>Organizations performing moderate or high complexity testing comply with laws and regulations.</p>	

Required Elements/Additional Information	Notes
<p>Organizations performing moderate or high complexity testing have adequate space, equipment, and personnel. The organization must have policies and procedures ensuring compliance with law and regulations.</p>	
Survey Procedure	
Observation, Interview, and Document Review	
<p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization performing tests at the moderate or high complexity level under CLIA meets applicable law and regulations.</li> </ul>	

Standard 13.05.01 Contract Laboratory Services	Score:
	<input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA

<p>If the organization contracts with a laboratory for testing, it must:</p> <ul style="list-style-type: none"> <li>■ Ensure the contracted laboratory is certified.</li> <li>■ Have specimen collection and processing procedures from the external laboratory.</li> <li>■ Be responsible for tracking and monitoring the quality of services provided by the</li> </ul>	
---	--



laboratory.

Required Elements/Additional Information	Notes
<p>The organization has written procedures that describe:</p> <ul style="list-style-type: none"> <li>■ Internal specimen collection and processing to support the contract requirements.</li> <li>■ Processes to monitor the adequacy and timeliness of services provided by the external laboratory.</li> </ul>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has specimen collection and processing procedures from the external laboratory.</li> <li>■ The organization tracks and monitors the quality of services provided by the external service.</li> </ul>	
<b>Standard 13.06.01</b> <b>Expired Supplies</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA

The organization does not have expired laboratory testing supplies, including:

- Specimen collection equipment.
- Test kits.
- Reagents.
- Other materials associated with laboratory testing.

Required Elements/Additional Information	Notes
<p>The organization has systems to identify items with upcoming expiration dates, such as rotating supplies using a "first in, first out" approach.</p>	
<b>Survey Procedure</b>	
<p><b>Observation</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The organization has no expired testing equipment, supplies, or other materials.</li> </ul>	
<b>Standard 13.06.02</b> <b>Work Areas</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA

The work area for testing must be constructed, arranged, and maintained to ensure the following:

- The space, ventilation, and utilities necessary for conducting all phases of the testing process.
- Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

**Required Elements/Additional Information**

Eating, drinking, smoking, handling contact lenses, and applying cosmetics (including lip products) is prohibited in all technical work areas when testing is performed.

Written safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards and biohazardous materials.

**Survey Procedure**

**Observation**

Verify:

- Employees do not perform the prohibited activities in the work area for testing.
- Glucose solutions are stored appropriately.
- The organization follows safety procedures for the disposal of radiological, chemical, and biological wastes (including blood drawing equipment).
- Safety protocols for transporting waste, including liquid waste containment.

Discuss and assess:

- Which safety protocols are observed and practiced by staff in the test work area.
- Spill clean-up procedures (chemical, biological, and radiological).

Notes



THIS PAGE IS INTENTIONALLY BLANK.

14

**RADIOLOGICAL  
SERVICES**





This chapter is applicable when image-guided procedures are performed. It is not applicable to diagnostic radiological services.

**Standard 14.00.01  
Radiologic Services**

Score:  
 C  NC

Radiology services are provided directly by a credentialed healthcare provider and must meet applicable laws and regulations.

**Required Elements/Additional Information**

Notes

The scope and complexity of radiological services provided as an integral part of the organization’s procedures, either directly or under arrangement, must be specified in writing and approved by the governing body. The scope of services identifies the radiopharmaceuticals used in the facility.

Radiological services integral to the procedure itself are imaging services performed immediately before, during, or after the procedure that are necessary to the completion of the procedure.

If the organization does not provide these radiological services directly (i.e., using its own staff), then it must obtain them via a contract or other formal arrangement.

The organization must ensure that the provision of radiological services in the organization complies with national standards and laws and regulations.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The scope of the radiology services.
- If the organization provides radiologic services, either directly or under arrangement, the only radiologic services performed are integral to its approved procedures.

Discuss and assess:

- Documentation related to how these responsibilities for radiological services have been implemented in the organization.

**Standard 14.01.01  
Person Responsible for Radiologic Services**

Score:  
 C  NC

The governing body must appoint a qualified individual, in accordance with laws and regulations and organization policies, to be responsible for all radiologic services.

**Required Elements/Additional Information**

Notes

The organization must establish in writing the eligibility criteria, including education and experience, that must be met by this



individual. The individual appointed may be a healthcare professional; however, this is not required.

The individual is qualified, through training and/or experience, to oversee all aspects of the service.

**Survey Procedure**

**Interview and Document Review**

Verify:

- The individual responsible for ensuring all radiologic services are provided in accordance with the standards:
  - » Is qualified for this role in accordance with governmental laws and regulations and organization policies.
  - » Was appointed by the organization’s governing body.
- The individual has the authority to remedy noncompliance with any of the requirements.

**Standard 14.01.02  
Orders for Radiologic Services**

Score:  
 C  NC

Radiology services must be provided directly by a credentialed healthcare provider with clinical privileges or, consistent with law and regulations, other practitioners authorized by the professional staff and the governing body to order the services.

**Required Elements/Additional Information**

Notes

The professional staff and the governing body determine the necessary qualifications and clinical privileges that practitioners must have to order diagnostic radiologic studies or therapeutic procedures.

The order must include information about the study that the qualified staff member performing the procedure, who is designated in accordance with Standard 14.01.04, is expected to review prior to implementing the order.

**Survey Procedure**

**Observation and Document Review**

Verify:

- A qualified staff member confirms that there is an order from an authorized practitioner and reviews information included in the order prior to beginning a study or procedure.
- Healthcare records of patients that received radiology services document that the order was provided by an authorized practitioner prior to the radiology image being completed.

**Standard 14.01.03  
Retention of Records**

Score:  
 C  NC

The organization must maintain the following for at least five years or the time period specified in law and regulations, whichever is longer.

- Copies of reports and printouts, including readily accessible electronic or digital records, separate from or included in the medical record.
- Films, scans, image records, digital files, reports, and printouts, as appropriate.

**Required Elements/Additional Information**

Notes

The organization must maintain records for all radiologic procedures performed.

The organization must adopt and implement written policies and procedures for maintaining records, including, at a minimum:

- The orders for the services, copies of reports and printouts, and any films, scans, digital or other image records, as appropriate.
- Storage format as original or hard copies or in readily accessible digital/electronic format, separate from or included in the medical record.
- The length of time records (radiology films, image records, scans, digital files, reports, and printouts) are stored..
- Signatures of all reports of studies by the radiologist or other authorized practitioner (in the case of studies not designated as requiring a radiologist to interpret them) who reads and evaluates the findings of the study.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The organization maintains radiologic records for at least five years or in accordance with law and regulations, whichever is longer.
- Radiology records are maintained in the manner as required in the Healthcare Records chapter. Sufficient record retention space, organization, retrievability, and security are available.
- A written policy is in place regarding the retention of diagnostic imaging studies and radiation therapy reports. Practice is consistent with policy.



<b>Standard 14.01.04 Qualified Personnel</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

Only personnel designated as qualified by the professional staff, whether employed or contracted, may use the radiological equipment and administer procedures.

Personnel are appropriately trained in the use of the equipment, adverse events, and safety measures.

Required Elements/Additional Information	Notes
--	-------

The professional staff must develop written policies, consistent with governmental laws and regulations, that govern the designation of all personnel who are qualified to use the radiologic equipment and perform diagnostic or therapeutic studies or procedures.

Job descriptions, approved by the designated individual overseeing the services, define the qualifications, training, and functions for each imaging and therapy staff member.

Qualifications must include appropriate training and demonstrated competence in the use of equipment and administration of procedures prior to being designated as qualified.

Training of personnel includes, at a minimum:

- How to respond to adverse events that may occur during a radiologic study or procedure.
- Proper operation of equipment per manufacturer’s instructions and organization policy.
- Assessment and reassessment of staff competency of staff skills.
- Safety measures for the use and operation of the equipment to protect themselves, patients, and the facility.
- Documentation of training completion dates and evidence of satisfactory competence. Staff that complete training but cannot demonstrate satisfactory competence must not be permitted to use radiologic equipment and/or administer procedures.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- The professional staff established written criteria for personnel who use radiologic services equipment and perform studies or procedures.
- Radiologic services staff are periodically trained and reassessed for competence for each modality they perform to ensure that they are operating the equipment according to the manufacturer’s instructions and the organization’s policy and know how to respond to adverse events related to their use of

the equipment.

- Any staff using different pieces of radiological equipment and/or administering patient procedures meet the qualifications established by the professional staff for the tasks they perform as documented in personnel files.

**Standard 14.02.01  
Safety for Patients and Personnel**

Score:  
 C  NC

Proper safety precautions must be maintained against radiation hazards for patients, personnel, and facilities.

**Required Elements/Additional Information**

Notes

The organization must adopt and implement written policies and procedures that provide safety for patients and personnel and are consistent with accepted professional standards for radiologic services.

The organization must implement and ensure compliance with its established safety standards.

Areas where radiologic services are provided must be equipped with the necessary equipment or materials to immediately respond to potential adverse events. This could include, but is not limited to, things like a crash cart, emergency stop mechanisms, and cleaning and decontamination agents, if applicable.

**PROTOCOLS**

Protocols are designed to minimize the amount of radiation while maximizing the yield and producing diagnostically acceptable image quality.

Written protocols developed or approved by the individual providing oversight for the radiologic services, in conjunction with other qualified radiologic services personnel, are designed to ensure that diagnostic studies and therapeutic procedures are routinely performed in a safe manner, utilizing parameters and specifications that are appropriate to the ordered study/procedure.

Existing protocols must be reviewed periodically and updated as needed.

**WRITTEN SAFETY POLICIES**

The policies must contain safety standards for at least:

- Identification of patients at high risk for adverse events for whom the radiologic study or procedure might be contraindicated (e.g., pregnant women, individuals with known allergies to contrast agents, individuals with implanted devices, etc.). Policies would address the steps to be taken, and by which personnel, if an order is written for a radiologic study or procedure for an individual identified in the radiologic services policies as potentially at high risk (e.g., notify the ordering

- healthcare professional, canceling the procedure, etc.).
- Clear and easily recognizable signage identifying hazardous radiation areas.
  - Limitations on access to areas containing radiologic services equipment.
  - Adequate shielding for patients, personnel, and facilities.
  - Types of personal protective shielding (e.g., lead aprons, lead gloves, protective eyewear, thyroid shields, portable individualized lead panels, stationary barriers) to be used.
  - Identification of circumstances, for patients, including high-risk patients as identified in radiologic services policies and procedures, that patient family members or support persons may be with the patient during a study or procedure.
  - Lead and concrete barriers built into the walls and other structures of the imaging areas.
  - Labeling of radioactive materials, waste, and hazardous areas.
  - Transportation of radioactive materials within the organization.
  - Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials.
  - Testing of equipment for radiation hazards.
  - Maintenance of personal radiation monitoring devices.
  - Proper storage of radiation monitoring badges when not in use.
  - Storage of radionuclides and radiopharmaceuticals as well as radioactive waste.
  - Identification and use of appropriate containers to be used for various radioactive materials, if applicable, when stored, in transport between locations within the organization, in use, and during/after disposal.
  - Disposal of radionuclides and unused radio pharmaceuticals.

### Survey Procedure

#### Observation, Interview, and Document Review

Verify:

- The policies and procedures are followed when radiologic services are delivered to patients.
- The protocol(s) for one or more studies/procedures(s) were followed.
- Hazardous materials are stored properly in a safe manner.
- There are written policies and procedures for specific radiological service modalities that are based on identified, professionally approved standards and which address the ALARA principle as well as other safety and risk-reduction

measures discussed in the guidance.

- There is evidence that safety protocols are reviewed periodically and, if applicable, updated.
- Staff are familiar with the policies and procedures related to safety in general and to specific clinical protocols.
- Staff are trained at appropriate intervals to ensure they are operating the equipment according to the manufacturer's instructions and the organization's policy.
- Staff know how to respond to adverse events.
- Areas where radiologic services are provided are equipped with the equipment or materials to immediately respond to an adverse event.
- Adverse events are analyzed for their causes, and preventive actions are taken. Note: Deficiency to be cited both here and under the applicable QAPI standard.
- Criteria have been developed for identifying patients who are vulnerable to radiation.

Discuss and assess:

- How the organization monitors the quality and safety of the services.

**Standard 14.02.02  
Radiation Exposure Monitoring**

Score:  
 C  NC

All personnel exposed to radiation sources must be monitored on an ongoing basis and checked periodically with all results reviewed by a qualified professional and stored as required by governmental laws and regulations.

**Required Elements/Additional Information**

Notes

This requirement applies to radiologic services personnel, as well as other organization employees who may be regularly exposed to radiation due to working near radiation sources (e.g., certain nursing and maintenance staff).

The organization must adopt and implement policies and procedures to ensure safety from radiation hazards, to include, at least:

- The types or locations of personnel who require monitoring for radiation exposure must be identified in the policies and procedures developed or approved by the individual who oversees the services, in conjunction with the appropriately qualified radiation safety personnel.
- The documentation of monitoring of staff exposure by qualified personnel.

The organization is expected to proactively monitor the staff's cumulative dosage and take appropriate steps if an individual staff member's cumulative dosage level exceeds parameters specified per policy, (e.g., reassignment to areas or roles without radiation



exposure).

Organizations must educate staff members who are monitored for radiation exposure regarding:

- Appropriate use of the monitoring meters or badges (or through use of a “personal radiation monitoring device,” which employs current technology for the same measurement purpose).
- The importance of tracking their radiation exposure over various timeframes, such as the most recent month and year, as well as their cumulative exposure through work.
- Appropriate storage of the meters and/or badges as well as the procedures to follow if the exposure device exceeds cumulative dosage parameters specified per the organization’s policy, and that in such case corrective action is taken and documented.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- The organization requires periodic checks on all radiology personnel and any other staff exposed to radiation, and that the personnel are knowledgeable about radiation exposure for month, year, and cumulative/entire working life.
- Personal shielding, supplies, and equipment are properly maintained and routinely inspected by the organization.
- Records document periodic tests of radiology personnel via exposure meters or test badges and that corrective action is taken if an over-exposure occurs.
- The proper shielding is applied to a patient who is undergoing a procedure using ionizing radiation.
- Staff members appropriately extricate themselves from the immediate exposure field while performing a study or procedure using ionizing radiation.
- The appropriate staff have a radiation-detecting device wear it correctly.

**Standard 14.02.03  
Periodic Inspection of Equipment**

Score:  
 C  NC

Periodic inspections of equipment must be made, and hazards identified must be promptly corrected.

**Required Elements/Additional Information**

Notes

The organization must ensure that equipment is inspected in accordance with the manufacturer’s instructions, governmental laws and regulations, guidelines, and the organization’s written policies and procedures.



Policies and procedures address equipment, including:

- Devices used to deliver diagnostic or therapeutic radiologic services.
- Exposure meters, badges, or personal radiation monitoring devices used by staff.
- Inspection or calibration devices used to deliver diagnostic or therapeutic radiologic services.

Inspections and maintenance, including correction of identified hazards, must be performed by qualified employees (e.g., medical physicists, qualified biomedical technicians, etc.) or through contractual arrangements with vendors with appropriate expertise.

The organization must be able to demonstrate current inspection and proper correction of all hazards.

- Documentation of preventive maintenance, quality control tests, service records, and major software/hardware upgrades must be maintained and readily available for inspection.
- Organizations must have a system to track all modifications made to the equipment that would significantly impact the accuracy of the dosage delivered.

### Survey Procedure

#### Observation and Document Review

Verify:

- The inspection records (logs) show that periodic inspections are conducted in accordance with the manufacturer's instructions, laws and regulations, and the organization's written policies and procedures.
- The inspection schedule and the mechanism for identifying hazards, including accurate dosimetry determinations with phantom patients, as applicable.
- Any problems identified are properly corrected in a timely manner.
- Inspection and maintenance activities are performed by qualified individuals.
- The maintenance logs show documentation of the calibration upon installation and after major upgrades or servicing.
- Aprons and other shields are checked at least annually for cracks.

#### Standard 14.02.04 Radioactive Materials

Score:

C  NC  NA

The organization has written policies and procedures in place for receipt, storage, containment, and disposal of all radioactive materials including dyes, pharmaceuticals, and seeds.



Required Elements/Additional Information	Notes
<p>The organization’s policies and procedures address the waste management of hazardous radiation materials and incorporate national guidelines (e.g., Nuclear Regulatory Commission) to safeguard patients, visitors, and employees from potential exposure. The written policies and procedures address at least:</p> <ul style="list-style-type: none"> <li>■ Identification of applicable governmental laws and regulations.</li> <li>■ Use and accessibility of Material Safety Data Sheets.</li> <li>■ Identification of low-level waste generated by the organization (e.g., radioactively contaminated protective clothing, tools, filters, rags, medical tubes).</li> <li>■ Separate, identifiable, storage areas.</li> <li>■ Use of appropriate storage and transport containers.</li> <li>■ How to handle emergencies, such as leakage and spillage.</li> <li>■ Receipt, storage, transportation, and disposition of radioactive materials throughout the facility.</li> </ul>	
<p><b>Survey Procedure</b></p>	
<p><b>Interview and Document Review</b></p> <p>Discuss and assess:</p> <ul style="list-style-type: none"> <li>■ Staff knowledge and compliance with the policies and procedures.</li> </ul> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policies and procedures address the required elements.</li> <li>■ Any hazardous radiation materials are clearly labeled, properly stored in a safe manner in the requisite containers and disposed of in the appropriate manner.</li> <li>■ Inspection records (logs) reflect disposal practices that comply with the policies and procedures.</li> </ul>	

  
15

**PHYSICAL  
ENVIRONMENT**

GENERAL REQUIREMENTS		
<b>Standard 15.00.01</b> <b>Environment</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC	
<p>The organization must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.</p>		
<b>Required Elements/Additional Information</b>	Notes	
<p>The organization must comply with requirements governing the construction and maintenance of a safe and sanitary physical plant, safety from fire, emergency equipment, and emergency personnel.</p>		
<b>Survey Procedure</b>		
<p><b>Observation</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The facility is adequately designed and equipped, clean and orderly, and free of hazards.</li> </ul>		
<b>Standard 15.00.02</b> <b>Physical Environment</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC	
<p>The organization must provide a functional and sanitary environment that is adequate for the provision of procedures.</p>		
<b>Required Elements/Additional Information</b>	Notes	
<p>The organization must be designed and equipped to provide safe, efficient, and respectful, high quality ambulatory healthcare services.</p> <p>The physical premises of the organization and those areas of its surrounding physical structure that are used by patients (including at least all stairwells, corridors, and passageways) must meet the requirements of this chapter.</p> <p>There must be adequate space for all clinical and administrative functions. If space in areas is inadequate, there are long and/or short-term goals and plans to address space concerns.</p> <p>When possible, guidelines from the Facilities Guideline Institute (FGI) are used.</p>		
<b>Survey Procedure</b>		
<p><b>Observation</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Each operating room is appropriate for the types of surgery performed.</li> <li>■ A hazard-free environment for patients and staff (e.g., sufficient space, adequate lighting, and necessary furniture).</li> <li>■ There are no signs of overcrowding or insufficient cleanliness.</li> </ul>		



Discuss and assess:

- Staff perception regarding sufficient space to accomplish tasks.

**DESIGN OF THE ENVIRONMENT**

**Standard 15.01.01  
Procedure Room Design**

Score:

C  NC

Each procedure room must be designed and equipped so that the types of procedures conducted can be performed in a manner that protects the lives and ensures the physical safety of all individuals in the area.

**Required Elements/Additional Information**

Notes

The use of the term “procedure room” includes operating rooms and minor procedure rooms.

Procedure rooms must be designed in accordance with industry standards for the types of procedures performed in the room, including whether the room is used for sterile and/or non-sterile procedures.

Existing procedure rooms must meet the standards in force at the time they were constructed, whereas new or reconstructed procedure rooms must meet current standards. Although the term “procedure room” includes both traditional operating rooms (ORs) and minor procedure rooms, this does not mean that procedure rooms must meet the same design and equipment standards as traditional ORs. In all cases, the procedure room design and equipment must be appropriate to the types of surgical procedures performed in it.

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

Procedure rooms must be appropriately equipped for the types of procedures performed. Equipment includes both:

- Facility equipment (e.g., lighting, generators or other back-up power, air handlers, medical gas systems, air compressors, vacuum systems, etc.).
- Medical equipment (e.g., biomedical equipment, radiological equipment, if applicable, OR tables, stretchers, IV infusion equipment, ventilators, etc.).

Procedure room equipment must be inspected, tested, and maintained by the organization in accordance with the manufacturer’s recommendations, consistent with federal and state law (including regulations).

**Survey Procedure**

**Observation**

Verify:

- Compliance with all aspects of the standard.
- There is an unrestricted area, a semi-restricted area, and a restricted area.
  - » What is the traffic pattern?
  - » Where are the scrub-sinks?
  - » Is there a clock to time scrubs?
- The procedure rooms meet applicable design standards.
- The procedure rooms are appropriately equipped for the types of surgery performed.
- There is enough equipment, including surgical instrument sets, for the volume of procedures typically performed.
- There is evidence, such as logs on each piece of electrical or mechanical equipment, indicating routine inspection, testing, and maintenance of the equipment.
- Considering the size of the procedure rooms and the amount and size of procedure room equipment, is there sufficient space for the unobstructed movement of patients and staff, including the ability to provide care in an emergency (e.g., “code”)?
- Responsibility for equipment testing and maintenance within the organization.

**Standard 15.01.02  
Temperature, Humidity, and Air-Flow Requirements**

Score:  
 C  NC

Temperature, humidity, air-pressure relationships, and air exchange rates in ORs must be maintained within acceptable standards and applicable governmental laws and regulations to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort.

**Required Elements/Additional Information**

Notes

Organizations must maintain records that demonstrate that acceptable standards are met.

The frequency of recording temperature, humidity, and air pressure is determined by organizational policy but must be conducted at least once per OR/procedure room on days of operation.

An organization must also ensure that the procedure room humidity level is appropriate for all of its surgical and anesthesia equipment, and that supplies that require a different level of humidity than that in the OR/procedure room are appropriately stored until used.

The Facility Guidelines Institute (FGI) 2014 Guidelines for Design and

Construction of Health Care Facilities and the American Society for Heating, Refrigerating, and Air Conditioning (ASHRAE) Standard 170, Ventilation of Health Care Facilities, provide examples of acceptable temperature, humidity, and air-flow standards for procedure rooms.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The temperature, humidity, and air-pressure records for ORs reflect that appropriate levels are maintained and recorded daily.
  - » If monitored temperature, humidity levels, and air-pressure relationships were not within acceptable parameters, there is evidence that corrective actions are performed in a timely manner to achieve acceptable levels.

**Standard 15.01.03  
Separate Recovery Area and Waiting Area**

Score:  
 C  NC

A designated area for the recovery of patients following a procedure must be adequately designed for that use.

**Required Elements/Additional Information**

Notes

The area designated within the facility where patients recover immediately after the procedure does not need to be reserved for recovery use exclusively but must meet all requirements for a recovery area when used as such.

- The recovery area must be equipped to allow appropriate monitoring of the patient’s recovery.
- The type of equipment required depends on the type(s) of procedures performed in the organization.
- The size of the recovery area must be commensurate with the number of procedure rooms in the facility and the expected volume of patients who will be in recovery simultaneously.

The recovery area may be used for preoperative preparation of patients as well as for postoperative recovery, consistent with accepted standards of practice.

- Under no circumstances may the recovery area be used as a general waiting area for patients awaiting preoperative preparation or for people who accompany patients.
- Likewise, patients recovering from procedures may not be placed in a waiting room or area, unless they have already been medically discharged from the organization and are, for example, waiting briefly while the adult who accompanied them brings a car to the facility’s entrance for physical discharge.

- Consistent with accepted standards of practice, including infection control standards and protection of patients' rights to privacy and confidentiality of their clinical information, the organization may permit individuals who accompany patients to be present in the space used for recovery of patients.

**Survey Procedure**

**Observation**

Verify:

- There is a separate room in which patients recover from their surgery.
  - » Is it appropriately equipped?
  - » Does it ensure patient privacy relative to the nature of anesthesia used?
- There is a separate waiting area for visitors and patients who have not yet begun preoperative preparation.

**EQUIPMENT**

**Standard 15.02.01  
Emergency Equipment and Supplies**

Score:  
 C  NC

The professional staff and governing body of the organization coordinate, develop, and revise organization policies and procedures to specify the types of emergency equipment and supplies required for use in the procedure room. The equipment must meet the following requirements:

- Be immediately available for use during emergency situations.
- Be appropriate for the organization's patient population.
- Be maintained by appropriate personnel.

**Required Elements/Additional Information**

Notes

The organization must provide the appropriate emergency equipment and supplies necessary to meet the emergency needs of the entire patient population in accordance with acceptable standards of practice in the industry. Acceptable standards of practice include adhering to relevant laws as well as standards or guidelines issued by nationally recognized professional organizations, etc.

In the case of an organization with more than one procedure room, the policy addresses:

- The type and quantity of emergency equipment and supplies that must be present in each procedure room.
- For equipment not maintained within each procedure room, the organization determines how many items must be available and where they are located so that the equipment is immediately available when needed in each procedure room.
- The type and quantity of equipment and supplies that are



present in the patient recovery space.

The organization is expected to maintain a comprehensive, current, and appropriate set of emergency equipment, supplies, and medications that meet current standards of practice and are necessary to respond to a patient emergency in the organization.

The organization must use qualified personnel to maintain emergency equipment, supplies, and medications. Contracted personnel may perform these functions.

The organization must conduct periodic assessments of its policies and procedures in order to anticipate the emergency equipment, supplies, and medications that may be needed to address any likely emergencies, taking into consideration the types of patients it serves and the types of procedures performed.

### Survey Procedure

#### Observation, Interview, and Document Review

Verify:

- Policies and procedures address emergency equipment and supplies.
  - » Has the organization identified supplies and equipment that are likely to be needed in emergency situations?
  - » For organizations with multiple ORs, does the policy clearly identify the quantity of equipment, supplies, and medications required and their location?
- The designated emergency equipment is immediately available to the procedure rooms, if needed.
- There are sufficient clinical personnel qualified to use the emergency equipment, medications, and supplies.

Discuss and assess:

- How the specified 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.
- Staff knowledge of where the emergency equipment is located.
- How simultaneous emergencies (e.g., an emergency in more than one procedure room, or an emergency in the procedure room and another one in the recovery area) would be handled.

**Standard 15.02.02  
Emergency Personnel**

Score:  
 C  NC

Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the organization.

**Required Elements/Additional Information**

Notes

The organization must provide qualified personnel necessary to meet the emergency needs of the entire patient population in accordance with acceptable standards of practice. The organization has written policies and procedures for resuscitative techniques and personnel training.

Whenever there is a patient who has been registered in the reception area and not yet discharged from the organization, including patients in the waiting area, in preoperative preparation, undergoing a procedure, or in the recovery space, the organization must also have personnel present who have appropriate training and competence in the use of the required emergency equipment and supplies.

It is not necessary for the organization to have one person who knows how to use all the equipment/supplies, so long as for each type of equipment/supply there is always some staff member present who is competent to use it.

**Survey Procedure**

**Interview and Document Review**

Verify:

- Through documentation that the organization has staff with the requisite training and competence to use all required emergency equipment and supplies, and to perform cardiopulmonary resuscitation.
- There is evidence that someone trained in the use of the emergency equipment/supplies is available whenever there is a patient in the organization.

Discuss and assess:

- Whether staff identified as having emergency responsibilities are aware of their role in handling an emergency.
  - » Do they know where the emergency equipment/supplies are kept?
- What type of back-up system is available when a staff member designated to handle emergencies is participating in a procedure on another patient.



**FACILITIES**

<b>Standard 15.03.01 Required Facilities</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization must have adequate provisions for:

- Reception/waiting/toilet areas for patients, family/companions.
- Patient registration.
- Private interview area(s) for discussion of anticipated procedures and accomplishing preadmission testing/teaching.
- Private dressing space for patients.
- Provision for safekeeping of patient clothing and a mechanism for protecting valuables.
- Patient preparation/holding.
- The patient's right to privacy (visual and auditory), which may include segregation of pre- and post-procedure patients.
- Post-procedure observation/holding.

Required Elements/Additional Information	Notes
--	-------

The organization provides for patient privacy during the patient's stay in the facility. To the extent possible, auditory privacy is provided during interviews and pre- and post-procedural teaching.

Survey Procedure
------------------

**Observation**

Verify:

- All areas meet the standard's requirements.
- All areas where patients disrobe for signage and privacy.

<b>Standard 15.03.02 Facility Maintained Clean and Orderly</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The interior of the facility, the exterior of the physical structure housing the organization, and the exterior walkways and parking areas must be clean and orderly, and maintained free of any defects that are a hazard to patients, personnel, and the public.

Required Elements/Additional Information	Notes
--	-------

Cleanliness and orderliness are the responsibility of the organization. Organizations located in multiple-use buildings are responsible for communicating problems to the management of the building.

There must be policies and procedures relating to the description and scope of practice of housekeeping services.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- The interior and exterior of the facility reflect adequate maintenance and general upkeep.
- Compliance with housekeeping policies.
  - » Are the policies adequate to ensure ongoing cleanliness?

Discuss and assess:

- Leadership communication with building management when problems are identified.

**Standard 15.03.03  
Accessibility Compliance**

Score:

C  NC

The organization’s physical space must be barrier free and in compliance with all applicable requirements of the Americans with Disabilities Act (ADA) and other applicable accessibility regulations.

**Required Elements/Additional Information**

Notes

Doorways, stairwells, corridors, and passageways are of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), and in case of stairwells, equipped with firmly attached handrails on at least one side.

There is at least one toilet in the organization, which is accessible and constructed to allow use by ambulatory and non-ambulatory individuals.

At least one entrance is usable by individuals in wheelchairs. In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the organization.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Exemptions or other documents that may relate to this standard.
- Compliance throughout the facility.

<b>Standard 15.03.04</b> <b>Lighting and Room Temperature</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
Lighting must be sufficient to carry out services safely. Room temperature and ventilation must be maintained at comfortable levels.	
<b>Required Elements/Additional Information</b>	Notes
Environmental controls are adequate and provide for an efficient, comfortable, and therapeutic environment.  See 15.01.02 for temperature, humidity, and air-pressure requirements.	
<b>Survey Procedure</b>	
<b>Observation</b> Verify: <ul style="list-style-type: none"> <li>■ The environmental controls and the physical environment.</li> </ul>	
<b>Standard 15.03.05</b> <b>Security</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
The organization provides for the physical security of staff, patients, and visitors, and their possessions.	
<b>Required Elements/Additional Information</b>	Notes
Security is appropriate for the type of services and physical environment in which the organization(s) is located.	
<b>Survey Procedure</b>	
<b>Observation and Interview</b> Discuss and assess: <ul style="list-style-type: none"> <li>■ Security incidents.</li> </ul> Verify: <ul style="list-style-type: none"> <li>■ Security during walk-arounds.</li> </ul>	
<b>Standard 15.03.06</b> <b>Adequate Signage</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
Adequate signage is available inside and outside to identify areas and to facilitate the easy movement of patients and visitors from one area to another.	
All signage meets applicable regulations, and when there are a significant number of non-English speaking patients, instructions reflect the relevant language(s).	
<b>Required Elements/Additional Information</b>	Notes
No additional information.	

<b>Survey Procedure</b>	
<b>Observation and Interview</b>	
Verify: <ul style="list-style-type: none"> <li>■ Patient demographics with staff are reflected in signage throughout the facility.</li> <li>■ Braille and other signage is used, as appropriate.</li> </ul>	
<b>Standard 15.03.07 Patient Areas Identified</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
Rooms that patients may be expected to enter must be clearly identified, including instructions for access.	
<b>Required Elements/Additional Information</b>	Notes
Instructions may indicate: enter, knock before entering, ring bell for access, etc. Attire is appropriate to the room's use.	
<b>Survey Procedure</b>	
<b>Observation</b>	
Verify: <ul style="list-style-type: none"> <li>■ Signage is on rooms, and if the door is usually closed, instructions for entering are present.</li> </ul>	
<b>Standard 15.03.08 Limited Access to Patient Areas</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
The general public, including other patients and visitors, must have restricted access to areas where patients are expected to wait or transit in other than their own clothes.	
<b>Required Elements/Additional Information</b>	Notes
There must be walls, screens, or other devices that protect these waiting/holding areas from public view.	
<b>Survey Procedure</b>	
<b>Observation</b>	
Verify: <ul style="list-style-type: none"> <li>■ Traffic patterns and privacy protection in these areas.</li> </ul>	



<p><b>Standard 15.03.09</b>  <b>Facility Free of Rodent and Insect Infestation</b></p>	<p>Score:  <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>Provisions must be in effect to ensure that the organization’s premises are maintained to be free of rodent and insect infestation.</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>Services may be contracted. When contracts are used, the organization is responsible for quality control.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Observation and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Policies or contracts for service.</li> <li>■ There is no evidence of rat or mouse droppings or the presence of flies, ants, or other insects.</li> </ul>	
<p><b>HAZARDOUS AREAS, MATERIALS, AND WASTE</b></p>	
<p><b>Standard 15.04.01</b>  <b>Elimination or Isolation of Hazards</b></p>	<p>Score:  <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>Hazards that might lead to injury are eliminated or, when not eliminated (e.g., wet floors during house cleaning), are isolated by a barrier and clearly identified.</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>The organization has appropriate supplies to address potential hazards.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Observation and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Housekeeping and safety policies address hazards.</li> <li>■ Housekeeping practices are compliance with policies.</li> <li>■ Cords and other objects do not create hazards.</li> </ul>	
<p><b>Standard 15.04.02</b>  <b>Hazardous Materials Identified</b></p>	<p>Score:  <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>All hazardous materials must be identified, labeled, and accompanied by a Safety Data Sheet (SDS).</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>Current SDS are always available to the staff for every potential hazardous material contact. SDS may be in printed or electronic forms.</p>	

<b>Survey Procedure</b>	
<b>Observation and Interview</b>	
Discuss and assess:	
<ul style="list-style-type: none"> <li>■ Areas requiring SDS and how chemicals and SDS are used.</li> </ul>	
Verify:	
<ul style="list-style-type: none"> <li>■ Specific SDS are readily available for all hazardous chemicals in use.</li> </ul>	
<b>Standard 15.04.03 Hazardous Areas Identified</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
The doors of all areas where there are hazardous materials must be clearly identified with the nature of the hazard, and access is limited.	
<b>Required Elements/Additional Information</b>	Notes
Regulated medical waste and sharps are restricted from public access. All waste is stored per appropriate directives.	
<b>Survey Procedure</b>	
<b>Observation and Document Review</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Storage areas for medical waste, nuclear waste, etc. are designated.</li> <li>■ Policies address handling of hazardous materials.</li> </ul>	
<b>Standard 15.04.04 Hazardous Areas Equipped for Handling Spills</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
All areas where there are hazardous materials have kits or materials to limit and control the spread of the material and, as applicable, facilitate the clean-up of any spills.	
<b>Required Elements/Additional Information</b>	Notes
Spill kits are based upon applicable Safety Data Sheets (SDS) or as directed, by applicable Occupational Health and Safety Administration (OSHA) and/or National Fire Protection Association (NFPA) directives, or the manufacturers' instructions.	
<b>Survey Procedure</b>	
<b>Interview</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Staff knowledge of the location and use of spill kits based on the appropriate SDS.</li> </ul>	





<b>Standard 15.04.05 OSHA Compliance</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
--	--

The organization must provide, as per OSHA requirements, emergency measures as needed to prevent or limit injury in case of accidental exposure to hazardous chemicals.

Required Elements/Additional Information	Notes
For eye wash and emergency showers, the plumbing and temperature controls are appropriately checked.	
<b>Survey Procedure</b>	
<p><b>Observation, Interview, and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Copies of SDS and OSHA requirements are kept in high-risk areas.</li> <li>■ Items needed for potential emergencies are located and accessible in high-risk areas.</li> </ul> <p>Discuss and assess:</p> <ul style="list-style-type: none"> <li>■ Staff use of identified emergency items.</li> </ul>	

<b>Standard 15.04.06 Emergency Eye Wash Stations</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
--	--

All locations where caustic or corrosive chemicals are used and could be splashed into the eyes must have emergency eye wash stations available. Stations comply with ANSI Z358.1-2014 and offer continuous temperature control eye flushing.

Required Elements/Additional Information	Notes
As required by OSHA, organizations must conduct a risk assessment to determine the need for approved eye wash stations where injurious corrosive materials exist.	
ANSI Z358.1-2014 is the standard that must be followed for the proper design, installation, and maintenance of emergency eye wash stations, including non-plumbed eye wash stations. Mixer valves are required to ensure the correct water temperature.	
Weekly water-flow tests and annual inspections are required for each eye wash station, per ANSI Z358.1-2014.	
Eye wash kits that have squeeze bottles are not prohibited, but they do not meet the ANSI standard to function as an eye wash station when one is required by OSHA.	
<b>Survey Procedure</b>	
<p><b>Observation and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Continuous flow eye wash stations are in all locations</li> </ul>	

recommended or required by SDS or OSHA.

- Weekly water-flow logs and annual inspection reports are maintained.

**Standard 15.04.07**  
**Storage of Compressed Medical Gas Cylinders**

Score:  
 C  NC  NA

Compressed gas cylinders must be stored in an approved manner with valve protective caps (when supplied) in place, and when in use, placed in holders that prevent their being knocked over.

**Required Elements/Additional Information**

Notes

Large tanks should be stored in areas specifically designed for hazardous materials and secured to prevent their falling.

Small tanks may be stored as indicated above or in single or multiple tank stands designed to prevent falling over or lying on their sides.

Empty cylinders cannot be stored with full cylinders and must comply with section 11.3 of the NFPA 99-2012.

**Survey Procedure**

**Observation**

Verify:

- Gas storage areas in all locations demonstrates compliance.

**Standard 15.04.08**  
**Personal Protective Equipment (PPE)**

Score:  
 C  NC

Appropriate personal protective equipment (PPE) is provided to ensure against possible exposure to hazardous materials and wastes.

**Required Elements/Additional Information**

Notes

The types of protective equipment may range from self-contained breathing apparatuses to negative flow hoods to gloves and other personal protective coverings.

Use of the protective equipment follows nationally recognized guidelines and applicable regulations, including OSHA and relevant SDS.

**Survey Procedure**

**Observation and Interview**

Discuss and assess:

- Staff knowledge of protective equipment requirements.

Verify:

- The availability and proper use of equipment.



<p><b>Standard 15.04.09</b>  <b>Cleaning and Repair of Protective Equipment</b></p>	<p>Score:  <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>The organization must provide, clean, and repair all personnel protective equipment at no cost to the employee.</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>For the purposes of this standard, smocks, outer clothing, etc., worn by surgical or dental technicians are included.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Observation and Interview</b>                  Discuss and assess:</p> <ul style="list-style-type: none"> <li>■ Cleaning and replacement policies.</li> </ul>	
<p><b>Standard 15.04.10</b>  <b>Regulated Medical Waste Properly Controlled</b></p>	<p>Score:  <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>All areas where regulated medical waste is generated must contain properly identified and colored containers for containment prior to disposal.</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>Refer to OSHA Standard 1910.1030 (d) through (h) Bloodborne pathogens.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Observation</b>                  Verify:</p> <ul style="list-style-type: none"> <li>■ Hazardous waste containers are maintained in all appropriate places.</li> </ul>	
<p><b>Standard 15.04.11</b>  <b>Proper Disposal of Non-Reusable Sharps</b></p>	<p>Score:  <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>Contaminated, non-reusable sharps must be discarded in a puncture-resistant, approved container, located as near as possible to the point of use.</p>	
<p><b>Required Elements/Additional Information</b></p>	<p>Notes</p>
<p>Refer to OSHA Standard 1910.1030 (d) through (h) Bloodborne pathogens, subpart Z.                  Containers are wall mounted and located out of reach of children.</p>	
<p><b>Survey Procedure</b></p>	
<p><b>Observation</b>                  Verify:</p> <ul style="list-style-type: none"> <li>■ Sharps containers are adequately maintained, located off the</li> </ul>	

floor, and out of the reach of children.

**Standard 15.04.12  
Hazardous Waste Properly Controlled**

Score:  
 C  NC

Hazardous materials such as regulated medical waste, sharps, radioactive waste, etc., must be stored in a controlled location and disposed of in accordance with local, state, and federal regulations.

**Required Elements/Additional Information**

Notes

The organization has policies and procedures for disposal, including transport of waste.

Applicable permits and inspections reports are maintained.

**Survey Procedure**

**Observation, Interview, and Document Review**

Verify:

- There are policies and records for the disposal of waste.
- Storage and disposal areas are controlled.

Discuss and assess:

- Waste storage and how it is accounted for between pick-ups, etc.

**MEANS OF EGRESS**

**Standard 15.05.01  
Doors**

Score:  
 C  NC

Doors in the path of egress must be side-hinged or pivot-swing type.

Doors must open to a minimum of 90 degrees from its closed position and extend no more than 7 inches into the corridor when opened to its fullest extent.

**Required Elements/Additional Information**

Notes

Doors complying with NFPA 7.2.12 are permitted.

Doors in the path of egress are required to swing in the direction of egress when serving a room or area with an occupant load of 50 or more persons.

A level landing surface is required and must be maintained on each side of the door's threshold. The depth of the landing is to be at least equal to the width of the widest door leaf.

**Survey Procedure**

**Observation**

Verify:

- Doors in the path of egress during building tour for compliance.



- » Side-hinged or pivot-swing type open to at least 90 degrees and extend no more than seven inches into the corridor when fully opened.
- » Horizontal sliding doors are also side-hinged and capable of “breaking away” and swinging from the side hinges unless the door serves a room with an occupant load of less than 10 persons.

**Standard 15.05.01  
Door Locks**

Score:  
 C    NC    NA

Doors in the means of egress must be operable with not more than one releasing operation.

Doors within the means of egress must not be equipped with a latch or lock that requires the use of a tool or key from the egress side. Locks complying with 7.2.1.5.5 shall be permitted only on principal entrance/exit doors.

Doors in the means of egress are permitted to be equipped with delayed egress locks, provided the entire facility (not just the organization, if multiple tenants) is protected with automatic sprinklers or fully detected with smoke detectors, provided all of the provisions of 7.2.1.6.1 of the 2012 Life Safety Code are met.

Doors in the means of egress are permitted to be equipped with access-control locks, provided all of the provisions of 7.2.1.6.2 of the 2012 Life Safety Code are met.

Doors separating elevator lobbies from exit access corridors are permitted to be locked with electrical locks, provided all of the provisions of 7.2.1.6.3 of the 2012 Life Safety Code are met.

**Required Elements/Additional Information**

Notes

Occupants accessing doors in the path of egress are not permitted to operate more than one device to open the door.

A door is not permitted to have a lock separate from the latching mechanism that would require the occupant to operate two devices to open the door. (Note: Pulling on a handle or pushing on the door is not considered an operation.) However, two releasing operations are permitted for existing hardware on a door leaf serving an area with an occupant load not exceeding three, provided that releasing does not require simultaneous operations.

**Survey Procedure**

**Observation**

Verify:

- How doors are locked and if they comply with the provisions listed.
- Delayed egress locks to ensure that they are only installed in fully sprinklered or fully detected buildings.
- Access-control locks to determine they have motion sensors mounted on the egress side to automatically unlock the door

when someone approaches, and a “Push to Exit” button mounted on the egress side within five feet of the door that unlocks the door when depressed.

- Elevator lobby locks and ensure the elevator lobby is smoke detected and the entire building is sprinklered.

**Standard 15.05.03  
Exit Discharge**

Score:

C  NC  NA

The walking surface on the exit discharge must be level, having no more than a quarter inch of abrupt change in elevation, and be free from snow and ice accumulation.

The exit discharge shall be illuminated under both the normal and emergency lighting mode, all the way to the public way.

**Required Elements/Additional Information**

Notes

The exit discharge is the portion of means of egress from the exit door to the public way. Typically, this is from an exterior door to a sidewalk or street.

The walking surface must be free of cracks causing unevenness. Note that steps are permitted.

An exit discharge across an unimproved area, such as a lawn or gravel, is not considered compliant with this standard because of the uneven walking surface.

Illumination of exit discharge must be by lighting fixtures with more than one lamp, or multiple lighting fixtures to ensure path is illuminated if one lamp fails.

**Survey Procedure**

**Observation**

Verify:

- All exit discharges have level walking surfaces and illumination all the way to the public way.

**Standard 15.05.04  
Corridors**

Score:

C  NC  NA

Items attached to the wall of the corridor cannot project more than four inches into the corridor.

Dead-end corridors are limited to 50 feet in an existing organization, and 50 feet in a new organization located in a building that is protected throughout by automatic sprinklers.

For a new organization located in a building that is not fully protected with automatic sprinklers, the maximum dead-end corridor is 20 feet.

The corridors must be maintained to the full required width.



<p><b>Required Elements/Additional Information</b></p> <p>Projection examples include drinking fountains, flip-down desks for wall charting stations, evacuation chairs, hand-rub dispensers, and any other item attached to the wall surface.</p> <p>This limitation on projections applies to new and existing conditions, regardless of how long they have been installed.</p> <p>Existing compliant corridors (20 feet or less) in buildings that are not fully protected with automatic sprinklers cannot be remodeled or changed to use the 50-foot requirement.</p> <p>All corridors have a minimum required width that is to be maintained as free and clear. The minimum width is as determined per NFPA 101 section 7.3, and corridors or passageways serving 50 or more occupants are a minimum of 44 inches.</p> <p>If the corridor is wider than the required width, then non-combustible items may be left unattended if they do not obstruct the required width.</p>	<p>Notes</p>
<p><b>Survey Procedure</b></p> <p><b>Observation</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Wall-mounted items in the corridor do not project more than four inches.</li> <li>■ Items left unattended in corridors do not obstruct the required width of the corridor.</li> </ul> <p>Observe:</p> <ul style="list-style-type: none"> <li>■ Dead-end corridors, remembering that locked doors in the path of egress may create an unexpected dead-end corridor.             <ul style="list-style-type: none"> <li>» Do they exceed 50 feet for an existing organization; 50 feet for a new organization in buildings that are fully sprinklered; or 20 feet in a new organization in a building that is not fully sprinklered?</li> </ul> </li> </ul>	
<p><b>Standard 15.05.05</b> <b>Path of Egress Obstructions</b></p>	<p>Score: <input type="checkbox"/> C <input type="checkbox"/> NC</p>
<p>The path of egress must be free and clear of all obstructions or impediments all the way to the public way.</p>	
<p><b>Required Elements/Additional Information</b></p> <p>This standard applies to items and objects that would impede travel along the path of egress, including stairwells, passageways, and exit discharges, all the way to the public way.</p>	<p>Notes</p>

<b>Survey Procedure</b>	
<b>Observation</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Each path of egress all the way to the public way to ensure there are no objects that would impede access.</li> </ul>	
<b>Standard 15.05.06 Travel Distance to Exits</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>The maximum travel distance between any point in a building and the exit shall not exceed 200 feet for buildings not fully protected with automatic sprinklers.</p> <p>For buildings that are fully protected with automatic sprinklers, the maximum travel distance from any point in a building to an exit is 300 feet.</p>	
<b>Required Elements/Additional Information</b>	Notes
<p>The travel distance to an exit is measured along the normal walking path, around objects in rooms, and no closer than 12 inches to walls.</p>	
<b>Survey Procedure</b>	
<b>Observation</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Travel distances to exits are within the allowable amount.</li> </ul>	
<b>Standard 15.05.07 Exit Enclosures</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>Stairwells and exit passageways must have the required fire resistive rating separation for the number of stories they serve.</p> <p>Stairwells and exit passageways must be constructed and maintained in accordance with section 7.1 of the 2012 Life Safety Code.</p>	
<b>Required Elements/Additional Information</b>	Notes
<p>Openings in stairwells that are exit enclosures (fire rated) are limited to those necessary for access from normally occupied spaces and corridors.</p> <p>Existing openings to mechanical equipment spaces protected by fire-rated door assemblies are permitted, provided:</p> <ul style="list-style-type: none"> <li>■ The space is used solely for non-fuel-fired mechanical equipment.</li> <li>■ The space contains no storage of combustibles materials.</li> <li>■ The building is protected throughout by an automatic sprinkler system.</li> </ul> <p>New construction exit enclosures are prohibited from penetrations, with the exception of:</p>	





- Electrical conduits serving the exit enclosure.
- Required exit doors.
- Ductwork and equipment necessary for independent stair pressurization.
- Water or steam piping necessary for heating or cooling of the exit enclosure.
- Sprinkler piping and standpipes.
- Penetrations for fire alarm circuits when the circuits are installed in a metal conduit.

Items that have the potential to interfere with its use as an exit are not permitted to be stored in an exit enclosure.

Minimum headroom in exit enclosures must be at least seven foot six inches, unless existing conditions, which is permitted to be seven foot zero inches.

Stairs and ramps that continue more than half a story beyond the level of exit discharge must be provided with an interruption gate to prevent occupants from traveling past the level of exit discharge during building evacuation.

**Survey Procedure**

**Observation**

Verify:

- Exit enclosures do not have openings to unoccupied rooms.
- If existing mechanical spaces open directly to exit enclosure, the space is not used for fuel-fired equipment, the space contains no storage of combustibles, and the building is fully sprinklered.

**Standard 15.05.08  
Emergency Lighting**

Score:  
 C  NC

All means of egress must be continuously illuminated when the building is occupied. Illumination must be such that the failure of a single unit or other device will not leave the area in darkness.

If equipped with battery-powered emergency lighting, this lighting must be tested for at least 30 seconds every month and for 1 ½ hours annually.

**Required Elements/Additional Information**

Notes

The illumination of the means of egress must be equipped to operate under emergency power conditions.

Emergency lighting should be available where required by specific life safety or program requirements. If equipment is self-testing, monthly testing is not required.

Note: Section 38.2.9.1 of the 2012 Life Safety Code addresses

emergency lighting.

**Survey Procedure**

**Observation and Document Review**

Verify:

- The means of egress is equipped with emergency lighting.
- Emergency lighting is available where required. Ask to see the lighting tested.
- Policies and records of compliance.

**OPERATING FEATURES**

**Standard 15.06.01  
Portable Heaters**

Score:

C  NC  NA

Portable heaters with elements that exceed 212°F are not permitted inside an organization.

Portable electric heaters with elements that do not exceed 212°F are only permitted in nonsleeping staff and employee areas.

**Required Elements/Additional Information**

Notes

No additional information.

**Survey Procedure**

**Observation**

Verify:

- Portable space heaters are not observed under workstations, in storage rooms, or in patient treatment rooms.

**Standard 15.06.02  
Smoke-Free Policy**

Score:

C  NC

All organizations in which patients are seen or transact business must have a smoke-free policy.

**Required Elements/Additional Information**

Notes

“NO SMOKING” signs or similar such signs are posted on all primary entrance doors and in other locations as appropriate.

Smoke should only be allowed for patients for medical reasons and with the healthcare provider’s orders.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Non-smoking policies.
- Conspicuously placed “NO SMOKING” or “THIS IS A SMOKE-FREE SPACE” signs indicate compliance.



<b>Standard 15.06.03 Records of Inspections are Maintained</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

Records must be maintained of inspections by local, state, and federal authorities, and documentation of corrective action when required.

<b>Required Elements/Additional Information</b>	Notes
No additional information.	
<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ Results of inspections and evidence of corrective actions.</li> </ul>	

**FIRE PROTECTION SYSTEM**

<b>Standard 15.07.01 Fire Protection Systems - Inspection, Testing, and Maintenance</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

**If present, all fire protection systems, including attached devices, must be inspected, tested, and maintained. All testing results are documented.**

<b>Required Elements/Additional Information</b>	Notes
<p><b>This standard does not require the organization to have all components listed, but if installed, they must be maintained, inspected, and tested according to the methods and frequencies identified in Appendix A - Life Safety Code.</b></p> <p><b>The reliability of the fire protection systems is critical for the safety of the facility's occupants. In OBS locations that are leased and/or within a multi-occupancy building, it is the responsibility of the OBS to obtain maintenance records from the lessor, building manager or building owner.</b></p> <p><b>The organization must determine a minimum schedule for inspection, testing and maintenance of fire protection systems. The frequency of the testing may be determined by local law, local authority having jurisdiction, or other local codes and regulations. In the absence of local law, fire protection systems are to be maintained and tested according to the original manufacturer recommendations. The organization must follow the more stringent requirement when local codes, law, or regulation conflicts with manufacturers' recommendations. In lieu of local requirements and unknown manufacturer recommendations, the systems described must meet the minimum requirements for inspection, testing and maintenance of the NFPA 101 <i>Life Safety Code</i>, 2012 edition.</b></p> <p><b>The <i>Life Safety Code</i> references include:</b></p> <ul style="list-style-type: none"> <li>■ Fire Alarm Systems – NFPA 72, National Fire Alarm and Signaling Code, 2010 Edition</li> </ul>	

- Portable Fire Extinguishers – NFPA 10, Standard for Portable Fire Extinguishers, 2010 Edition
- Clean Agent Fire Suppression System – NFPA 2001, Standard on Clean Agent Fire Extinguishing Systems, 2012 Edition
- Fire Sprinkler Systems – NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, 2011 Edition
- Emergency Power Generators – NFPA 110, Standard for Emergency and Standby Power Systems, 2010 Edition
- Medical Gas and Vacuum Systems – NFPA 99, Health Care Facilities Code, 2012 Edition
- Fire and Smoke Dampers – NFPA 80, Standard for Fire Doors and Other Opening Protectives, 2010 Edition

See Appendix Chapter 16 for additional information and clarification.

Any deficiencies identified during inspection, testing and maintenance activities must be corrected and retested. Deficiencies that cannot be corrected on the same day as discovered, must have a documented risk assessment according to 16.00.02 Alternative Life Safety Measures to ensure the safety of patients, staff, and visitors. The correction and retest are documented.

### Survey Procedure

#### Observation and Document Review

##### Verify:

- During the building tour, installed systems and devices are accessible.
- Documentation reflects appropriate testing and inspection frequencies are achieved.
- Documentation of corrective actions for devise(s) that failed during inspection, testing and maintenance activities.
- Routine reporting of results and activities to an oversight committee.

THIS PAGE IS INTENTIONALLY BLANK.



# APPENDIX

  
16

# **LIFE SAFETY**

**This chapter will only be applicable to OBS organizations that operate in buildings that have fire detection, fire suppression, fire safety, and building services.** The standards in this chapter are based on the 2012 edition of the NFPA 101 *Life Safety Code* and the 2012 edition of the NFPA 99 *Health Care Facilities Code*. Compliance with the *Life Safety Code* is based on Business Occupancy chapters within the code. (2012 *Life Safety Code*, NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.).

If the authority having jurisdiction (AHJ) requires an organization to meet a different edition of the NFPA *Life Safety Code*, only comparable requirements to these standards will be assessed.

### LEASED SPACE

Organizations leasing space are required to meet the requirements. Evidence of compliance may be provided by the building management or the organization to demonstrate compliance with the requirements.

### TESTING AND INSPECTION DOCUMENTATION

Unless otherwise stated, testing, inspection, and maintenance documentation must include, at the minimum, the following:

- Name of the individual performing the activity.
- Affiliation of the individual performing the activity.
- The signature of the individual performing the activity.
- Activity name.
- Date(s) (month/day/year) that activity was performed.
- The frequency that is required of the activity.
- The NFPA code or standard that requires the activity to be performed, as applicable.
- The results of the activity, such as “Pass” or “Fail.”

### DEFINITION OF TIME

ACHC defines the intervals between testing and inspection activities identified in this chapter. Because NFPA standards and codes are written by different technical committees, they often do not agree on the definition of a specified period of time, such as “quarterly” or “annually.” ACHC has reviewed all the NFPA standards and developed guidance that everyone can follow and still meet the intent of the respective NFPA technical committee.

Testing and inspection activity cannot exceed the allowable amount of time permitted by the applicable standard or regulation as defined below.

The completion of the weekly and monthly activities is to be performed during the designated calendar period.

The completion of the quarterly, semi-annually, annually, three-year, five-year, and six-year activities is to be performed during the last calendar month of that period.

During document review, Surveyors will:



- Assess through review of documentation, that testing, inspection, or maintenance activity is performed within the limits of this standard.
- Score non-compliance with the respective standard that requires the testing/inspection activity if the activity was not conducted within the specified time frame.

---

#### TESTING AND INSPECTION DEFINITIONS OF TIMES

---

Unless otherwise stated, the periods of time for testing, inspection, and maintenance activities specified within this chapter are defined as follows:

Weekly or “every 7 days”:

The activity is performed and completed anytime during the calendar week.

Monthly or “every 30 days”:

The activity is performed and completed anytime during the calendar month.

Quarterly or “every 3 months”:

The activity is performed and completed quarterly, during the third month of the quarterly period.

Semi-annually or “every 6 months”:

The activity is performed and completed semi-annually, during the sixth month of the semi-annual period.

Annually or “every 12 months”:

The activity is performed and completed annually, during the twelfth month of the annual period.

3-Years:

The activity is performed and completed once every 3 years, during the 36th month of the 3-year period.

5-Years:

The activity is performed and completed once every 5 years, during the 60th month of the 5-year period.

6-Years:

The activity is performed and completed once every 6 years, during the 72nd month of the 6-year period.

---

## CHAPTER TABLE OF CONTENTS

<b>GENERAL REQUIREMENTS</b>	
<i>Life Safety Code Compliance</i>	16.00.01
Alternative Life Safety Measures – Policy	16.00.02
Fire Alarm and Automatic Sprinkler system Outages	16.00.03
Life Safety Drawings	16.00.04
Interior Finish	16.00.05
<b>FIRE DETECTION SYSTEMS</b>	
Fire Alarm System – Installation and Maintenance	16.01.01
Fire Alarm System – Testing	16.01.02
Fire Alarm System – Transmitting Signal	16.01.03
<b>FIRE SUPPRESSION SYSTEMS</b>	
Water Based Fire Suppression System – Installation and Maintenance	16.02.01
Water Based Fire Suppression System – Inspection and Testing	16.02.02
Water Based Fire Protection – Control Valves, Piping and Hangers	16.02.03
Fire Pumps Monthly Test	16.02.04
Fire Pumps Annual Test	16.02.05
Alternative Fire Suppression Systems Installation and Testing	16.02.06
Water Based Standpipe and Hoses Inspection and Testing	16.02.07
Water Based Fire Department Connections	16.02.08
Portable Fire Extinguishers – Installation, Inspection, and Maintenance	16.02.09
Fire Hose Valves	16.02.10
Internal Inspection of Piping	16.02.11
<b>FIRE SAFETY</b>	
Fire-Rated Barriers	16.03.01
Fire and Smoke Dampers	16.03.02
Overhead-Rolling/Horizontal-Sliding Doors	16.03.03
Fire Rated Door Assemblies	16.03.04
Hazardous Areas	16.03.05
<b>BUILDING SERVICES</b>	
Elevator Recall	16.04.01
Generator Inspection	16.04.02
Monthly Generator Load Test	16.04.03
Automatic Transfer Switch Test	16.04.04
Medical Gas Shutoff Valves	16.04.05
Utility Systems	16.04.06
Medical Gas Systems and Equipment – Maintenance	16.04.07



GENERAL REQUIREMENTS	
<b>Standard 16.00.01</b> <i>Life Safety Code Compliance</i>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
An organization must meet the provisions applicable to business occupancies.	
Required Elements/Additional Information	Notes
<p>All organizations, regardless of size, must comply with the applicable NFPA 101 <i>Life Safety Code</i> (2012 edition) requirements for all locations. All buildings and spaces owned, leased, or rented that are used for organization business must comply with the <i>Life Safety Code</i>.</p> <p>The organization is responsible for developing a systematic process for assessing the compliance with the <i>Life Safety Code</i> of each building under its control.</p> <p>Although ACHC does not specify what processes the organization should use to achieve <i>Life Safety Code</i> compliance, the results must show that the facilities are in full compliance with the <i>Life Safety Code</i>, and other applicable standards.</p>	
Survey Procedure	
Observation and Document Review	
Verify: <ul style="list-style-type: none"> <li>■ Buildings comply with the <i>Life Safety Code</i>, as applicable to business occupancies.</li> </ul>	
<b>Standard 16.00.02</b> <i>Alternative Life Safety Measures – Policy</i>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
When the <i>Life Safety Code</i> cannot be met and corrections cannot be made on the same day as discovered, the organization conducts an assessment and implements appropriate measures to mitigate for impairments to the <i>Life Safety Code</i> ; such measures are written in an Alternative Life Safety Measures (ALSM) policy.	
Required Elements/Additional Information	Notes
<p>Features of life safety may be compromised or impaired during periods of construction, maintenance, or emergency repairs. During these periods, the ASC must perform a documented risk assessment of the deficiency and implement compensating measures based on the criteria of their ALSM policy. The organization’s ALSM policy addresses assessment of the deficiency to determine what, if any, alternative measures are needed.</p> <p>When alternative measures are implemented, they must be continued until such time as the deficiency is resolved.</p> <p>The assessment is documented. This is typically accomplished by a template form or checklist within the policy.</p>	

**Survey Procedure**

**Observation and Document Review**

Verify:

- The organization's ALSM policy clearly identifies that it applies to all conditions when impairments to features of life safety exist, including during periods of construction, maintenance, and emergency repairs.
- There is evidence of ALSM for areas in the organization where a feature of life safety may be compromised, such as construction areas and areas under maintenance.
- Documentation indicates the organization has conducted ALSM assessment for known life safety deficiencies.
- The ALSM policy clearly identifies what compensating measures will be taken when certain deficiencies are discovered.

**Standard 16.00.03**

**Fire Alarm and Automatic Sprinkler System Outages**

Score:

C  NC

The organization notifies the local emergency response force (fire department) when:

- A fire alarm system, or a part thereof, is out of service for more than four hours in a 24-hour period.
- An automatic sprinkler system, or a part thereof, is out of service for more than 10 hours in a 24-hour period.

The notification of the local emergency response force is documented.

The organization evacuates the building during the outage.

**Required Elements/Additional Information**

Notes

The phrase "or parts thereof" refers to circuits or branches of the systems, not a single device.

The organization has a policy to evacuate the building when notification is required to the local emergency response force.

**Survey Procedure**

**Document Review**

Verify:

- Notification of local fire departments is documented.
- The organization has a policy to evacuate the building.



<b>Standard 16.00.04 Life Safety Drawings</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
---	--

Basic drawings of the facility indicating the following features are required:

- Rated walls and barriers, including their fire rating.
- Exit, exit enclosure, horizontal exit, and exit discharge.
- Hazardous rooms.
- The farthest travel distance to the closest exit.
- Areas of the facility that are and are not protected with sprinklers.
- Smoke partitions.

Required Elements/Additional Information	Notes
<p>Basic life safety drawings are critical to the maintenance of life safety features in the organization.</p> <p>Life safety drawings must include the basic information identified in the standard and may include additional information that is pertinent to the life safety features.</p> <p>The organization must have provisions to answer all questions concerning the life safety drawings.</p>	
<b>Survey Procedure</b>	
<p><b>Interview and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Before starting the building tour, the adequacy of the life safety drawings.</li> <li>■ The representatives are able to interpret the drawings and answer questions that may arise.</li> </ul>	

<b>Standard 16.00.05 Interior Finish</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The interior finish on walls and ceilings in exits and exit access corridors must be Class A or Class B.

The interior finish on walls and ceilings in areas other than exits and exit access corridors (i.e., rooms), must be Class A, Class B, or Class C.

Required Elements/Additional Information	Notes
<p>Class A interior wall and ceiling finishes have a flame spread rating of 0 – 25, and a smoke development rating of 0 – 450.</p> <p>Class B interior wall and ceiling finishes have a flame spread rating of 26 – 75, and a smoke development rating of 0 – 450.</p> <p>Class C interior wall and ceiling finishes have a flame spread rating of 76 – 200, and a smoke development rating of 0 – 450.</p>	

### Survey Procedure

#### Observation and Document Review

Review:

- The flame spread rating of selected interior finishes to determine if it meets the proper classification rating.
  - » Plywood used as interior finish in utility or equipment rooms would be permitted provided it met the required flame spread for that classification

### FIRE DETECTION SYSTEMS

#### Standard 16.01.01

#### Fire Alarm System: Installation and Maintenance

Score:

C  NC  NA

A fire alarm system is required when the building is three or more stories in height, the occupancy is subject to 100 or more occupants above or below the level of exit discharge, or the occupancy is subject to 1,000 or more total occupants.

A fire alarm system required for life safety shall be installed and maintained in accordance with sections 38/39.3.4 of the *Life Safety Code* (2012 edition), and in accordance with NFPA 72, 2010 edition, National Fire Alarm Code.

#### Required Elements/Additional Information

Notes

The NFPA *Life Safety Code* describes the basic installation requirements and the NFPA *National Fire Alarm Code* provides specific installation details.

Once installed, fire alarm systems must be maintained to the original installation requirements.

Personnel performing inspections, testing, and maintenance on fire alarm systems must have proper certification, license, and/or training to do so.

### Survey Procedure

#### Observation and Document Review

Verify:

- Components of the fire alarm system are installed according to the codes and standards identified.
- The fire alarm system is maintained in accordance with the original installation requirements.
- Documentation for the individual(s) performing testing, inspection, or maintenance of fire alarm system, and its components, is on file for review or required in the vendor contract.



<b>Standard 16.01.02 Fire Alarm System: Testing</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

Fire alarm systems, and all their components, shall be tested according to NFPA 72 National Fire Alarm Code (2010 edition), Table 14.4.2.2 Test Methods, and Table 14.4.5 Testing Frequencies.

All testing results are documented.

<b>Required Elements/Additional Information</b>	Notes
---	-------

Reliability of the fire alarm system is critical for the safety of the facility's occupants.

This standard does not require all of the components identified in NFPA 72 (2010 edition) and Tables 14.4.2.2 and 14.4.5, but if installed, they must be maintained and tested according to the methods and frequencies identified.

The overall fire alarm system consists of multiple connected and inter-connected components and systems that together create a detection and notification system.

Basic components include power supplies, control panels, initiating devices, notification devices, and interface devices, which require specific testing procedures at specified frequencies. Secondary components that are controlled by the fire alarm system such as air-handlers, smoke dampers, smoke or fire doors held open, and access-control, or delayed egress locks, must be tested through their normal range of control when activated (or de-activated) by the fire alarm system.

<b>Survey Procedure</b>
-------------------------

**Interview and Document Review**

Verify:

- Documentation demonstrating compliance with NFPA 72 (2010 edition) and Tables 14.4.2.2 and 14.4.5 must be maintained for a minimum of three years.
- Documentation must demonstrate that each and every individual device connected to the fire alarm system is inventoried, its location identified, and whether it passed (or failed) its test.
- The fire alarm test report fully complies with the frequencies identified in Table 14.4.5 of NFPA 72 (2010 edition).
- The organization annually tests the interface devices (relays) between the fire alarm systems and the locks used on the delayed egress and access-control locks.

Discuss and assess:

- Whether test methods used on the fire alarm system components are consistent with Table 14.4.2.2 of NFPA 72.

**Standard 16.01.03**  
**Fire Alarm System: Transmitting Signal**

Score:

 C  NC  NA

The fire alarm system shall transmit an appropriate signal to an offsite monitoring station, or directly to the emergency response force.

This signal shall be tested annually from the alarm panel in the protected premises to the emergency response force.

All results of the tests are documented.

**Required Elements/Additional Information**

Notes

This standard does not require the fire alarm system to transmit all three signals, but when the fire alarm system activates an alarm signal, supervisory signal, or a trouble signal, it must be transmitted to an approved location, such as an auxiliary fire alarm system, a central station, a proprietary system, or a remote supervising station. Manual reporting systems and methods are not permitted.

Annually, the off-premises monitoring transmission equipment must be tested to ensure the local fire-responding agency received an alarm signal, even if the transmission of that signal is through a third-party entity.

NFPA 72 (2010 edition) Table 14.4.2.2 (18) (a) through (e), and Table 14.4.5 (22) describes in detail the methods and procedures to follow for each type of system.

**Survey Procedure**
**Document Review**

Verify:

- The fire alarm system signal is transmitted as an annual test from the fire alarm panel to the emergency response force.

**FIRE SUPPRESSION SYSTEMS**
**Standard 16.02.01**  
**Water-Based Fire Protection System Installation and Maintenance**

Score:

 C  NC  NA

If present, the water-based fire protection system must be installed and maintained in accordance with section 9.7 of the *Life Safety Code* (2012 edition), NFPA 13-2010, and NFPA 25-2011.

Ceilings that are required to limit the passage of smoke, such as ceilings containing smoke or heat detectors, and sprinklers are free from cracks, holes, or missing tiles.

**Required Elements/Additional Information**

Notes

This standard does not require the installation of sprinklers unless required by the construction type or other codes, standards, and regulations.

All sprinkler systems installed must comply with NFPA 13 *Standard for*



*the Installation of Sprinkler Systems*, (2010 edition), regardless of whether sprinkler systems are required or not.

Once installed, sprinkler systems must be maintained to the original installation requirements.

Where ceilings are expected to resist the passage of smoke, gaps or cracks exceeding an eighth of an inch constitutes non-compliance with this standard.

Suspended grid and acoustical tile type of ceiling, when properly installed and maintained, can limit the passage of smoke.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Whether the construction type requires sprinklers.
- Components of the sprinkler system are installed and maintained in accordance with NFPA 13.
- Ceilings have no missing tiles, cracks, or holes. There are no missing escutcheon plates around sprinklers or communication wires penetrating the ceiling.

**Standard 16.02.02**

**Water-Based Fire Protection System Testing and Inspection**

Score:

C  NC  NA

If provided, water-based fire protection systems and all their components must be tested, inspected, and maintained in accordance with NFPA 25 *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, 2011 edition.

All results of testing, inspection, and maintenance activities are documented.

**Required Elements/Additional Information**

Notes

Water-based sprinkler systems, including pre-action and dry-pipe systems, are included in this standard.

This standard does not require automatic sprinkler systems or their components to be installed, but if it does, the sprinkler systems must be tested, inspected, and maintained according to NFPA 25 *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems* (2011 edition).

Water-based fire protection systems and components, include, but are not limited to:

- Sprinklers.
- Piping and hangers.
- Control valves, valve components, and trim.
- Water-flow devices.
- Standpipe and hoses.
- Dry-pipe, deluge, and pre-action valves.

- Service mains.
- Storage tanks.

Control valves are required to be visually inspected monthly to confirm they are still in their designated position. This inspection must be documented.

**Survey Procedure**

**Document Review**

Verify:

- Documentation demonstrating compliance with NFPA 25 (2011 edition) must be maintained for a minimum of three years. Documentation demonstrates that each and every device connected to the water-based fire protection system is accounted for and passed or failed its test.
- The water-based fire protection system documentation fully complies with the frequencies identified in NFPA 25 (2011 edition). Each individual sprinkler system device that is tested is identified as to its location, and whether or not it passed or failed its test.
- The sprinkler control valves are inspected monthly.

**Standard 16.02.03**

**Water-Based Fire Protection System Control Valves, Piping, and Hangers**

Score:

C  NC  NA

If provided, control valves used in water-based fire protection systems must be electronically supervised with tamper switches and connected to the building fire alarm system to send electronic supervisory signals. Tamper switches must be tested at intervals according to 143.02.02.

Sprinkler piping and hangers shall be free of all material, including wire, cable, conduit, HVAC duct, or any other objects, and shall not be used to support any other item or system.

**Required Elements/Additional Information**

Notes

Chains and locks on control valves, while permitted, do not demonstrate compliance with this standard.

Nothing is permitted to be attached to sprinkler piping and hangers, including wire and cable.

**Survey Procedure**

**Observation**

Verify:

- Sprinkler control valves are electronically monitored.
- Sprinkler piping and hangers have nothing suspended or attached to them.



<b>Standard 16.02.04 Fire Pumps Monthly Test</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
--	--

If so equipped, electric-motor-driven fire pumps must be tested monthly at no-flow conditions in accordance with NFPA 25 *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, 2011 edition.

If so equipped, engine-driven fire pumps must be tested weekly at no-flow conditions in accordance with NFPA 25, 2011 edition.

The results of all testing activities are documented.

Required Elements/Additional Information	Notes
<p>This standard does not require the installation of fire pumps in the facility.</p> <p>If so equipped, the organization performs monthly fire pump tests at no-flow (or churn) conditions for a minimum of ten minutes for electric-motor-driven pumps and a minimum of 30 minutes for engine-driven pumps.</p> <p>No-flow test must begin by reducing water pressure at the start switch.</p> <p>Suction pressure readings and discharge pressure readings are recorded.</p>	
<b>Survey Procedure</b>	
<p><b>Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ The fire pump is tested in accordance with NFPA 25.</li> </ul>	

<b>Standard 16.02.05 Fire Pumps Annual Test</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

If so equipped, fire pumps must be tested annually at specified flow conditions in accordance with NFPA 25 *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, 2011 edition.

The results of all testing activities are documented.

Required Elements/Additional Information	Notes
<p>This standard does not require a fire pump to be installed, but if it is, the fire pump must be tested according to NFPA 25 <i>Standard for the Testing, Inspection and Maintenance of Water-Based Fire Protection Systems</i> (2011 edition).</p> <p>An annual water-flow test is required for all fire pumps, consisting of:</p> <ul style="list-style-type: none"> <li>■ A churn test.</li> <li>■ The pump operated at design flow (100% nameplate capacity).</li> <li>■ The pump operated at peak flow (150% nameplate capacity).</li> </ul>	

- During peak flow, a power failure is simulated on electric-motor-driven pumps equipped with automatic transfer switches to ensure emergency power supply is connected, and confirmation of peak flow continues.
- After peak flow has been confirmed and documented, normal power is restored to ensure circuit protection devices have not opened.
- Additional readings and measurements are required during this annual flow test. If peak flow is not attainable due to limitations in water supply, that shall not constitute an unsuccessful test.

**Survey Procedure**

**Document Review**

Verify:

- The fire pump is tested annually in accordance with NFPA 25 (2011 edition) and this standard.

**Standard 16.02.06  
Alternative Fire Suppression Systems Installation and Testing**

Score:  
 C    NC    NA

Approved fire suppression systems that are installed, tested, and maintained to their respective NFPA standard are permitted to be an alternative to water-based fire protection systems without the facility being classified as non-sprinklered.

All such alternative fire suppression systems shall be connected to the building fire alarm system and initiate an alarm when activated.

If so equipped, the cooking hood fire suppression system must be inspected monthly and maintained semi-annually, and cooking hoods are required to meet NFPA 96, *Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations*, 2011 edition.

The results of all testing activities are documented.

**Required Elements/Additional Information**

Notes

This standard does not require the installation of an alternative fire suppression system.

If so equipped, alternative fire suppression systems must be installed, tested, and maintained in accordance with their respective NFPA standard.

Examples of alternative fire suppression systems are:

- Halon systems.
- FM-200 systems.
- Inergen systems.
- CO<sub>2</sub> systems.
- Cooking hood suppression systems.



**Survey Procedure**

**Interview and Document Review**

Discuss and assess:

- With the facility manager, what areas contain alternative fire suppression systems.

Verify:

- Documentation reflects appropriate testing and inspection frequencies are achieved.

**Standard 16.02.07  
Water-Based Standpipes and Hoses Inspection and Test**

Score:

C  NC  NA

If so equipped, water-based automatic (wet) standpipes must be tested once every five years at flow conditions equal to original acceptance requirements at the hydraulically most-remote location.

If so equipped, manual (dry) standpipes must be hydrostatic tested at not less than 200 psi pressure for two hours, or at 50 psi in excess of the maximum pressure, whichever is greater, at least once every five years.

If so equipped, occupant-use fire hoses must be unracked annually and inspected for abnormal wear conditions.

Occupant-use fire hoses must be hydraulically pressure tested in accordance with NFPA 1962, *Standard for the Inspection, Care, and Use of Fire Hose, Couplings, and Nozzles and the Service Testing of Fire Hose*, (2008 edition) five years after initial installation and every three years thereafter.

The results of all testing and inspection activities are documented.

**Required Elements/Additional Information**

Notes

This standard does not require the installation of standpipes or occupant-use fire hoses.

If the hydraulically most-remote location (e.g., inaccessible roof) is not attainable, then the local fire authority having jurisdiction (AHJ) must be consulted for an acceptable alternate location.

If the original acceptance requirements for the water-flow test are not known, then the water-flow must achieve 500 gallons per minute.

The testing for dry standpipes includes the piping in the fire department connection.

This standard does not require the installation of occupant-use fire hoses, but if so equipped, then they must be unracked annually and inspected for abnormal wear and re-racked without using the same folds.

Organizations that remove occupant-use fire hoses must have the approval of the local or state authority on fire prevention.

<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Wet standpipe systems are water-flow tested at least once every five years in accordance with NFPA 25.</li> <li>■ Dry standpipe systems, including the piping for the fire department connections, are hydrostatic tested at least once every five years in accordance with NFPA 25.</li> <li>■ Annual fire hose inspection and when it was last pressure tested or replaced.</li> <li>■ Local or state authority having jurisdiction (AHJ) permission to remove occupant-use fire hoses from the facility.</li> </ul>	

<b>Standard 16.02.08 Water-Based Fire Department Connections</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
--	--

If so equipped, fire department connections must be maintained in accordance with NFPA 13 (2010 edition) and inspected quarterly in accordance with NFPA 25 (2011 edition).  
The results of all inspection activities are documented.

<b>Required Elements/Additional Information</b>	Notes
<p>The fire department connections may be known as Siamese connections. This standard includes those connections where a fire department would hook-up and pump water into the buildings.</p> <p>Fire department connections must be properly maintained for immediate use, and not be obstructed by vehicles, vegetation, or anything else preventing its view from the street.</p>	

<b>Survey Procedure</b>	
<b>Observation and Document Review</b>	
Verify:	
<ul style="list-style-type: none"> <li>■ Documentation to ensure fire department connections are inspected at least once per quarter in accordance with NFPA 25, 2011 edition.</li> <li>■ Fire department connections are not obscured and are visible from the street.</li> </ul>	

<b>Standard 16.02.09 Portable Fire Extinguishers Installation, Inspection, and Maintenance</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

Portable fire extinguishers must be installed, inspected, and maintained in accordance with *NFPA 10 Standard for Portable Fire Extinguishers*, 2010 edition.  
Fire extinguishers shall be inspected monthly and maintained annually.  
The results of all inspection and maintenance activities are documented.



<p><b>Required Elements/Additional Information</b></p> <p>Portable fire extinguishers are not permitted to sit on the floor but are required to be mounted on brackets or placed in cabinets at least four inches above the floor and no higher than 60 inches above the floor.</p> <p>Access to extinguishers must not be obstructed. In large rooms and in certain locations where visual obstructions cannot be completely avoided, means must be provided to indicate the extinguisher location.</p> <p>Fire extinguishers may be electronically monitored through the building's fire alarm system, provided it meets all of the requirements in chapter seven of NFPA 10-2010.</p> <p>The selection of portable fire extinguishers is based on the hazard it is designated to protect.</p> <p>The travel distance required to get to a fire extinguisher is based on the level of the hazard and the capacity and type of the extinguisher, as identified in NFPA 10.</p> <p>The monthly inspection documentation must identify the date (month/day/year) and signature (or initials) of individual performing the inspection. Electronic documentation is acceptable provided it contains all required data and is retrievable at the time of survey.</p>	<p>Notes</p>
<p><b>Survey Procedure</b></p> <p><b>Observation and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Monthly inspection documentation for portable fire extinguishers during the building tour.</li> <li>■ The fire extinguisher installation is at least four inches above the floor and the handle is no more than 60 inches above the floor.</li> </ul>	
<p><b>Standard 16.02.10</b> <b>Fire Hose Valves</b></p> <p>If so equipped, all fire hose valves must be inspected quarterly.</p> <p>Class I and Class III standpipe hose valves (two and a half-inch hose valves) must be tested annually.</p> <p>Hose valves on hose stations attached to sprinkler systems, and Class II standpipe hose valves (one and a half-inch hose valves), must be tested once every three years.</p> <p>Inspections and tests are documented.</p>	<p>Score:</p> <p><input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA</p>
<p><b>Required Elements/Additional Information</b></p> <p>Quarterly inspection ensures:</p> <ul style="list-style-type: none"> <li>■ Hose caps are in place and not damaged.</li> </ul>	<p>Notes</p>

- Hose threads are not damaged.
- Valve handles are present and not damaged.
- Gaskets are inspected for damage or deterioration.
- Hose valves are not leaking.
- There are no obstructions to hose valves.
- If required, restricting devices are present.

Class I and Class III (two and a half inch) hose valves must be tested annually by opening and closing the valve. *Note:* Full flow of water is not required.

Class II and one and a half-inch hose valves must be tested once every three years by opening and closing the valve. *NOTE:* Full flow of water is not required.

**Survey Procedure**

**Document Review**

Verify:

- Quarterly inspection documentation indicates all fire hose valves are inventoried, their location identified, and whether they passed or failed their inspection is documented.
- Annual tests of two and a half-inch hose valves and three-year test of Class II and one and a half-inch hose valves document that the valve was opened.
- Test and inspection records document whether any damaged equipment or failed test/inspection was followed up with appropriate repairs.

**Standard 16.02.11  
Internal Inspection of Piping**

Score:  
 C    NC    NA

An internal inspection of water-based fire protection system piping and branch line conditions must be conducted once every five years.

**Required Elements/Additional Information**

Notes

The internal inspection must be conducted by opening a flushing connection at the end of one main and by removing a sprinkler toward the end of one branch line for the purpose of inspecting for the presence of foreign material.

Tubercules or slime, if found, must be tested for indications of Microbiological Influenced Corrosion (MIC).

Non-metallic piping is not required to be inspected internally.





<b>Survey Procedure</b>
<p><b>Observation and Document Review</b></p> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Documentation shows the internal inspection was conducted on the sprinkler piping.</li> <li>■ Documentation reflects testing of MIC, if slime was found.</li> <li>■ Documentation of corrective actions to eliminate MIC, if MIC was determined to be present.</li> </ul>

**FIRE SAFETY**

<b>Standard 16.03.01 Fire-Rated Barriers</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
--	--

The organization shall ensure that fire-rated barriers are properly rated, appropriate for their purpose, do not contain unsealed penetrations, and have the appropriate fire-rated opening protectives.

<b>Required Elements/Additional Information</b>	Notes
---	-------

Not all fire-rated barriers are rated the same. The 2012 edition of the *Life Safety Code* specifies which fire-rated barrier receives what fire rating.

Opening protectives are fire-rated door assemblies, windows, and fire dampers. Not all fire-rated barriers are required to have fire dampers.

**Survey Procedure**

<p><b>Observation and Document Review</b></p> <p>Review:</p> <ul style="list-style-type: none"> <li>■ The life safety drawings to understand what rating each fire barrier is required to have.</li> </ul> <p>Verify:</p> <ul style="list-style-type: none"> <li>■ Fire-rated barriers above and below the ceiling, looking for unsealed penetrations.</li> <li>■ Door assemblies in fire-rated barriers to ensure they are properly fire rated, self-closing, and positive latching.</li> </ul>
--

<b>Standard 16.03.02 Fire and Smoke Dampers</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
---	--

An internal inspection of water-based fire protection system piping and branch line conditions must be conducted once every five years.

<b>Required Elements/Additional Information</b>	Notes
---	-------

Fire dampers are required to be installed, maintained, and tested in accordance with NFPA 80 *Standard for Fire Doors and Other Opening Protectives* (2010 edition), and smoke dampers are required to be

installed, maintained, and tested in accordance with NFPA 105 *Standard for Smoke Door Assemblies and Other Opening Protectives* (2010 edition).

Dampers installed in the facility must be documented identifying the following:

- Type of damper.
- Location of damper (i.e., floor, unit, room, area, etc.).
- Orientation of damper (i.e., horizontal or vertical).
- Date of installation (if known).
- Last test date and results (Pass/Fail).

*Note:* There are no provisions in the NFPA codes or standards that permit inaccessible dampers to remain inaccessible and untested.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Documentation demonstrating compliance with NFPA 80 (2010 edition) and NFPA 105 (2010 edition) is maintained for a minimum of four years.
- Each fire and smoke damper is documented, identified as to its location, and whether the damper passed or failed its test.

**Standard 16.03.03  
Overhead-Rolling/Horizontal-Sliding Doors**

Score:

C  NC  NA

If so equipped, overhead-rolling and horizontal-sliding fire doors are required to be tested once per year for proper operation and closure, in accordance with NFPA 80 *Standard for Fire Doors and Fire Windows* (2010 edition).

The results of all testing and inspection activities are documented.

**Required Elements/Additional Information**

Notes

This standard does not require an organization to have overhead-rolling or horizontal-sliding fire doors, but if they do, the doors must be installed, maintained, and tested in accordance with NFPA 80 *Standard for Fire Doors and Fire Windows* (2010 edition) to ensure proper operation.

The test of the fire door assembly must be initiated by all devices associated with the control of the door, such as smoke detector and interface, thermal link, etc.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Documentation demonstrating compliance with NFPA 80

(2010 edition) is maintained for a minimum of three years.

- Each overhead-rolling or horizontal-sliding fire door was tested at least annually, and the test was initiated by the safety device that controls the door.

**Standard 16.03.04  
Fire-Rated Door Assemblies**

Score:  
 C  NC

Fire door assemblies must meet the provisions of NFPA 80 *Standard for Fire Doors and Fire Windows*, 2010 edition.

All fire-rated door assemblies must be tested and inspected on an annual basis according to NFPA 80, 2010 edition.

The test and inspection are documented.

**Required Elements/Additional Information**

Notes

Doors in fire-rated door assemblies must have a legible label that identifies its fire rating. Frames in fire-rated door assemblies must have a legible label that identifies it as a fire-rated frame. Note that frames are not required to be labeled with an hourly rating, unless the assembly rating is for three or more hours.

Fire-rated door assemblies must have self-closing devices, positive latching hardware, gaps between meeting edges of door pairs are no more than an eighth of an inch, and the space between the bottom of the door and the floor is no more than three quarters of an inch.

All after-market hardware installed on fire-rated door assemblies must be listed for use on fire-rated door assemblies.

All fire-rated door assemblies throughout the facility must be inventoried, then tested and inspected on an annual basis.

**Survey Procedure**

**Observation and Documentation Review**

Verify:

- Fire door labels indicate the door is properly rated for the fire barrier designation. If the label is not legible, then the door is not compliant.
- The gap between meeting edges of door pairs and the undercut of the door is within measured limits.
- After-market hardware installed on fire-rated doors (astragals, coordinators, closers, etc.) are listed for use on fire-rated door assemblies.
- There is documentation to demonstrate that each individual fire-rated door assembly is tested and inspected on an annual basis.

**Standard 16.03.05  
Hazardous Areas**

Score:

 C  NC  NA

Hazardous areas must be protected by enclosing the area with a fire barrier without windows that has a one-hour fire resistance rating or protecting the area with an automatic extinguishing system.

**Required Elements/Additional Information**

Notes

Hazardous areas must be identified on the organization's Life Safety Drawings. Hazardous areas include, but are not limited to:

- Areas used for general storage.
- Boiler or furnace rooms.
- Maintenance shops that include woodworking and painting areas.

In a new organization construction, hazardous areas that are provided with automatic extinguishing systems must also be protected with smoke partitions.

**Survey Procedure**
**Observation and Document Review**

Verify:

- The life safety drawings identify hazardous areas and the hazardous area meets the requirements listed.

**BUILDING SERVICES**
**Standard 16.04.01  
Elevator Recall**

Score:

 C  NC  NA

All elevators, new or existing, that have a travel distance of 25 feet or more above or below the level that best serves the needs of the local emergency fire response force must be equipped with elevator recall, also known as Firefighter's Service, Phase 1.

**Required Elements/Additional Information**

Notes

Elevator recall is designed to capture the control of the car, return it to a previously designated floor, and open its door when a smoke detector located in the elevator lobby, elevator shaft, or elevator mechanical room is in alarm.

Elevator recall is required to be tested monthly in accordance with the *Life Safety Code*, regardless of what the Elevator Safety Code requires. If the organization leases space in a building that requires an elevator recall, the organization must provide evidence that the building management meets this requirement.



**Survey Procedure**

**Document Review**

Verify:

- Documents reflect monthly elevator recall testing.

**Standard 16.04.02  
Generator Inspection**

Score:

C  NC  NA

Where general anesthesia or life-support equipment is used, each organization must be provided with an emergency electrical system (i.e., emergency power) in accordance with NFPA 99).

Emergency power generators, when provided, and all appurtenant components must be inspected weekly.

Generators located indoors must be separated from the rest of the facility with two-hour, fire-rated barriers.

Batteries used in connection with the generator shall be inspected weekly and maintained in full compliance with the manufacturer’s recommendations, and electrolyte-specific gravity levels on lead-acid batteries shall be recorded.

Sealed lead-acid batteries must have an electrical conductive test performed.

Results of the inspection shall be documented.

**Required Elements/Additional Information**

Notes

Routine inspection for generators must be accomplished in accordance with NFPA 110 (2010 edition).

If located outside the building, the generator shall be located in an enclosure capable of resisting the entrance of snow and rain.

No other equipment except that which serves the space is permitted to be stored in these rooms.

Where sealed lead-acid batteries are used, electrolyte-specific gravity levels are not required to be recorded; however, conductance testing will be required, with the results documented.

A fuel quality test shall be performed at least annually\* using tests approved by ASTM D 975-2 standards. Fuel samples are often collected and tested by a third-party lab.

A remote, manual-stop station must be located outside the room housing the generator or elsewhere on the premises when the generator is located outside the building.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Generators located indoors are separated with two-hour fire-rated barriers, and no other items are stored in the room.



- Weekly inspection log confirms battery electrolyte-specific gravity readings or conductive readings are recorded.
- Annual fuel quality test has been conducted.

**Standard 16.04.03  
Generator Monthly Load Test**

Score:  
 C  NC  NA

If present, emergency power generators shall be tested 12 times a year with a dynamic load of at least 30 percent of nameplate rating, with testing intervals not less than 20 days and not more than 40 days, for a minimum of 30 minutes.

In lieu of meeting 30-percent nameplate rating during each monthly load test, generators may be operated to meet the manufacturer’s recommended prime mover’s exhaust gas temperature.

If the organization cannot meet the 30-percent nameplate rating or the exhaust gas temperature for any of the monthly load tests, then a supplemental annual load test must be conducted with connected loads of 50 percent of nameplate rating for 30 minutes, followed by 75 percent of nameplate rating for 60 minutes, for a total of 90 continuous minutes. The monthly load tests must still be conducted at the appropriate intervals even if they do not meet the load requirements.

Results of tests shall be documented.

**Required Elements/Additional Information**

Notes

Emergency power generator sets shall be tested in accordance with NFPA 110, (2010 edition).

**Survey Procedure**

**Document Review**

Verify:

- Testing is performed as required. Check monthly test dates to ensure no tests are accomplished sooner than 20 days and no later than 40 days from the previous test.
- Designated loads are met, and the annual load test was for at least 90 continuous minutes, if applicable.

**Standard 16.04.04  
Automatic Transfer Switch Test**

Score:  
 C  NC  NA

If a generator is present, automatic transfer switches shall be tested 12 times a year, with testing intervals not less than 20 days and not more than 40 days.

Results of tests shall be documented.

**Required Elements/Additional Information**

Notes

All automatic transfer switches must be tested monthly, operating the transfer switch from the standard position to the alternate position and then return to the standard position. Tests shall be in accordance with NFPA 110 (2010 edition).



<b>Survey Procedure</b>	
<b>Document Review</b>	
Verify: <ul style="list-style-type: none"> <li>■ Testing is performed as required.</li> </ul>	
<b>Standard 16.04.05 Medical Gas Shutoff Valves</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC <input type="checkbox"/> NA
<p>If present, medical gas shutoff valves shall be labeled to reflect the rooms that are controlled by such valves.</p> <p>Medical gas shutoff valves must be accessible from a standing position in the corridor on the floor served by the shut-off valves, and not located behind doors or other building appurtenances.</p> <p>Medical gas shutoff valves must be placed such that a wall intervenes between the valve and the outlets/inlets that it controls.</p> <p>The medical gas shutoff valve must not be located in a room with a station outlet/inlet that it controls.</p> <p>Access to medical gas shutoff valves must not be obstructed.</p>	
<b>Required Elements/Additional Information</b>	Notes
Medical gas shutoff valves must be accessible and properly labeled to assist in proper routine adjustment of systems and during emergencies.	
<b>Survey Procedure</b>	
<b>Observation</b>	
Verify: <ul style="list-style-type: none"> <li>■ Medical gas shutoff valves are accessible and labeled.</li> <li>■ Medical gas shutoff valves are located in the corridor on the same story as the area served.</li> <li>■ Medical gas shutoff valves are located outside of the room with outlets/inlets that they control.</li> </ul>	
<b>Standard 16.04.06 Utility Systems</b>	Score: <input type="checkbox"/> C <input type="checkbox"/> NC
<p>Utility systems are properly installed and maintained to a fire-safe condition.</p> <p>If provided, kitchen cooking exhaust hoods and associated equipment are inspected and cleaned on a semi-annual basis.</p>	
<b>Required Elements/Additional Information</b>	Notes
<p>Access to electrical control panels must not be obstructed.</p> <p>Circuits in electrical control panels must be properly labeled as to their use.</p>	

Electrical junction box covers must be properly installed.

Electrical wires and cables are not permitted to be tied to conduits.

The filters, traps, hoods, exhaust duct, and exhaust fans of cooking hoods capture air-borne grease and are required to be inspected and cleaned in accordance with NFPA 96 (2011 edition). Fusible links must be replaced with new ones during every semi-annual cleaning and used links destroyed.

Listed cooking hoods containing mechanically operated devices shall be inspected and tested by properly trained, qualified, and certified persons every six months or as recommended by the manufacturer's listings.

**Survey Procedure**

**Observation and Document Review**

Verify:

- Electrical control panels have proper clearance and all circuits are labeled.
- Electrical junction boxes are properly covered.
- Electrical conduits are free of attached wires and cables.
- Documentation for cooking hood inspection/cleaning, if provided.

**Standard 16.04.07  
Medical Gas Systems and Equipment Maintenance**

Score:  
 C  NC  NA

If present, there is a routine monitoring and maintenance system for oxygen, compressed air, and vacuum systems and equipment. Medical gas systems and equipment must be installed, inspected, tested, and maintained in accordance with NFPA 99 (2012 edition) chapter 5 and chapter 11.

Storage of all medical compressed gas cylinders must comply with NFPA 99, *Standard for Health Care Facilities*, 2012 edition.

**Required Elements/Additional Information**

Notes

Storage of compressed medical gas cylinders is limited as follows:

- Up to 300 cubic feet per smoke compartment is permitted to be stored outside of a designated room provided the cylinders are properly secured.
- For quantities over 300 cubic feet but less than 3,000 cubic feet per smoke compartment, cylinders must be stored outside the facility or within an interior room with limited combustible construction with a door that can be secured against unauthorized entry.
- Oxidizing gases must be separated from combustibles a minimum of 20 feet in non-sprinklered areas; or 5 feet in sprinklered areas; or in an enclosed cabinet of non-



- combustible construction having a minimum fire protection rating of half an hour.
- For rooms containing gas manifold systems, or storage rooms of compressed gas cylinders in total quantities of 3,000 cubic feet or greater, the room must meet the following conditions:
    - » Walls having a minimum of one-hour fire-resistive rating.
    - » Door assemblies having a minimum of one-hour fire-resistive rating.
    - » Doors must be self-closing, positive latching, and be secured.
    - » All electrical devices must be protected from physical damage or located a minimum of 60 inches above the floor.
    - » If heated, must be by indirect means.
    - » Racks and chains or other fastening devices must be present to secure all cylinders and are non-combustible.
    - » A constant mechanical ventilation system with its inlet no more than 12 inches above the floor; or where natural ventilation is used in lieu of mechanical ventilation, it must consist of two louvered openings, each having a minimum free area of 72 square inches, with one located within 12 inches above the floor and the other located within 12 inches of the ceiling.
    - » Mechanical ventilation must be at the rate of 1 cubic foot per minute/5 cubic feet of designed stored gas, but no less than 50 cubic feet per minute and no more than 500 cubic feet per minute.
  - Flammable liquids, gases, and vapors are not permitted to be stored with oxidizing gases.
  - Rooms containing gas manifold systems are not permitted to be used for any other purpose.
  - The gas content of medical piping systems must be readily identifiable with appropriate labeling with the name of the gas contained. Labels must appear on piping at intervals of not more than 20 feet, and at least once in each room and each story traversed by the piping system.
  - Medical gas systems, including master alarm panels and branch alarm panels must be inspected, tested, and maintained according to the organization's policy, which is consistent with NFPA 99 (2012 edition) chapter 5. For inspection and testing frequency intervals greater than one year, a risk assessment must demonstrate no adverse implications based on historical evidence.

## Survey Procedure

### Observation and Document Review

Verify:

- Storage areas for compressed medical gas cylinders meet the requirements.
- There is a policy on inspection, testing, and maintenance of medical gas systems, including alarm panels.
- Testing and inspection records provide evidence of routine inspections and documentation of the organization's monitoring and maintenance program.

### Resources

National Fire Protection Association

1 Batterymarch Park

Quincy, MA 02169

Tel. (617) 770-3000

[www.nfpa.org](http://www.nfpa.org)

- NFPA 99, *Standards for Health Care Facilities Code* of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.
- TIA 12-2 to NFPA 99, issued August 11, 2011.
- TIA 12-3 to NFPA 99, issued August 9, 2012.
- TIA 12-4 to NFPA 99, issued March 7, 2013.
- TIA 12-5 to NFPA 99, issued August 1, 2013.
- TIA 12-6 to NFPA 99, issued March 3, 2014.
- NFPA 101, *Life Safety Code*, 2012 edition, issued August 11, 2011.
- TIA 12-1 to NFPA 101, issued August 11, 2011.
- TIA 12-2 to NFPA 101, issued October 30, 2012.
- TIA 12-3 to NFPA 101, issued October 22, 2013.
- TIA 12-4 to NFPA 101, issued October 22, 2013.



THIS PAGE IS INTENTIONALLY BLANK.

# Glossary

<b>Adverse event</b>	<p>ACHC's Office-Based Surgery Accreditation program references events related to patient safety using descriptions developed by the Institute of Medicine:</p> <ul style="list-style-type: none"><li>■ “An <b>error</b> is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).”</li><li>■ “An <b>adverse event</b> is an injury caused by medical management rather than the underlying condition of the patient.”</li><li>■ “An adverse event attributable to error is a <b>preventable adverse event</b>.”</li></ul>
<b>Anesthesia provider</b>	<p>An individual administering analgesia/anesthesia; may be a physician anesthesiologist, certified registered nurse anesthetist, or other healthcare professional trained in the delivery of analgesia/anesthesia.</p>
<b>Anesthesiologist assistant</b>	<p>A healthcare professional working under the direction of licensed anesthesiologist.</p>
<b>Credentialing</b>	<p>The formal process for reviewing and verifying the professional credentials of a healthcare provider prior to granting privileges for the provider to deliver services.</p>
<b>Exposure incident</b>	<p>An incident in which a patient, visitor, or staff member is exposed to an infectious agent; which may include specific eye, mouth, other mucus membrane, nonintact skin, or parenteral contact with blood or other potentially infectious materials.</p>
<b>Materiel</b>	<p>The materials and equipment of an organization. Medical materiel include, for example, pharmaceuticals, gloves, masks, and ventilators.</p>
<b>Organization</b>	<p>A legal entity or defined subcomponent of a larger legally organized entity. If a subcomponent, it is not required to be legally organized, but must be defined.</p>
<b>Physician</b>	<p>A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, or a doctor of podiatric medicine (defined in accordance with §1861(r) of the Social Security Act).</p>
<b>Privileging</b>	<p>The formal process for determining the scope of practice a healthcare provider may undertake within an individual organization after review of training, experience, and past performance. Privileges are based on the organization's and provider's abilities to support the practice.</p>

---

<b>Surrogate (Patient Rights)</b>	An individual designated by the patient, in accordance with applicable government laws and regulations, to make healthcare decisions on behalf of the patient or to otherwise assist the during their treatment by the organization.
<b>Procedure</b>	An established process for doing something; a surgical operation.
<b>Personnel</b>	People working in the organization including both those directly employed and those employed by contract. Used interchangeably with "staff."
<b>Professional Staff</b>	A formal organization of licensed healthcare personnel delegated with the authority and responsibility to maintain proper standards of care and/or health-related service and to plan for continuance and improvement of that care.

---

# Acronyms

The following is a list of acronyms frequently seen in materials related to requirements for surgical settings. Not all of these items appear in ACHC Standards in this edition of the *Accreditation Requirements for Office-Based Surgery*.

<b>AAMI</b>	Association for the Advancement of Medical Instrumentation
<b>ABMS</b>	American Board of Medical Specialties
<b>ADA</b>	American Dental Association
<b>AHJ</b>	Authority having jurisdiction
<b>AHP</b>	Allied Health Personnel
<b>ALM</b>	Association for Linen Management
<b>ALSM</b>	Alternative Life Safety Measures
<b>AMA</b>	American Medical Association
<b>ANSI</b>	American National Standards Institute
<b>AOA</b>	American Osteopathic Association
<b>AORN</b>	Association of periOperative Registered Nurses
<b>APIC</b>	Association for Professionals in Infection Control and Epidemiology
<b>APSF</b>	Anesthesia Patient Safety Foundation
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CIBC</b>	Certification Board of Infection Control and Epidemiology, Inc.
<b>CLIA</b>	Clinical Laboratory Improvement Amendments
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>CPR</b>	Cardiopulmonary resuscitation
<b>CRNA</b>	Certified Registered Nurse Anesthetist
<b>DEA</b>	Drug Enforcement Administration
<b>ECFMG</b>	Educational Commission for Foreign Medical Graduates
<b>EPA</b>	Environmental Protection Agency
<b>HAI</b>	Healthcare-associated infection

<b>HLAC</b>	Healthcare Laundry Accreditation Council
<b>IUSS</b>	Immediate use steam sterilization
<b>LSC</b>	Life Safety Code® (published by the National Fire Protection Association®)
<b>NBCRNA</b>	National Board of Certification and Recertification for Nurse Anesthetists
<b>NPDB</b>	National Practitioner Data Bank
<b>NFPA</b>	National Fire Protection Association®
<b>OIG</b>	Office of Inspector General
<b>OSHA</b>	Occupational Safety and Health Administration
<b>PSV</b>	Primary source verification
<b>QAPI</b>	Quality Assurance and Performance Improvement
<b>RN</b>	Registered nurse
<b>SDS</b>	Safety Data Sheet
<b>SHEA</b>	Society for Healthcare Epidemiology of America
<b>SSI</b>	Surgical site infection
<b>WHO</b>	World Health Organization

