



Mastering the Standards for Survey Success: The 2018 HFAP Quality Review



FROM THE BOARD CHAIRS

As physician leaders of the HFAP programs, we know that the laboratories, hospitals, ASCs, and others that choose HFAP are looking for an accreditation experience founded in shared commitment to building people-focused organizations that also function efficiently, effectively, and within a culture of continuous improvement. These goals address and link clinical and business operations. They are interrelated and achievable and this annual report of frequent deficiencies identified in healthcare organizations can help.

Organizations that strive to master the standards get the most benefit from their survey experience. This second annual *HFAP Quality Review* is a resource to help your organization integrate accreditation standards into daily operations. Use it to:

1. Gain insight to how HFAP surveyors work.

HFAP surveyors are evaluating compliance with individual standards in the context of the organization as a whole. They are interested in how the elements of each organization fit together. This report suggests areas for your focused efforts in preparing for a survey and demonstrates how deficiencies occur when disparate aspects of an organization fail to connect.

2. Develop a mindset of expertise.

Read this report in conjunction with the relevant HFAP accreditation manual and/or your most recent deficiency report. This will give confidence that most standards are easily achievable, and suggest solutions for those that provide consistent challenges. If you find that your organization's deficiencies align with the common citations, don't reinvent the wheel. Consider that your peers may have found solutions that will also work for you. Look, too, to HFAP educational offerings (webinars and seminars) for best practices and tools.

3. Achieve continuous readiness.

Assign and perform ongoing audits of policy, process, delivery, and quality assessment. Focus on the feedback loops that ensure a continuous cycle of improvement.

Each of us is committed to HFAP because of its educational philosophy. We believe that accreditation is not intended to be a punitive ordeal but an opportunity to meet regulatory requirements through consultation with experts *who care about the success of each organization* they survey. Our goal as an organization is to point you toward mastery of the standards.



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Introduction

From the c-suite to the custodial staff, an onsite survey can create stress for everyone in a patient care organization. This second annual *HFAP Quality Review* is designed to calm anxiety by giving you advantages:

- Knowledge of the standards most-frequently cited as “not compliant.”
- Knowledge of trends in deficiencies to help you avoid the most common errors.
- Examples of specific citations made by HFAP surveyors.

Using the report

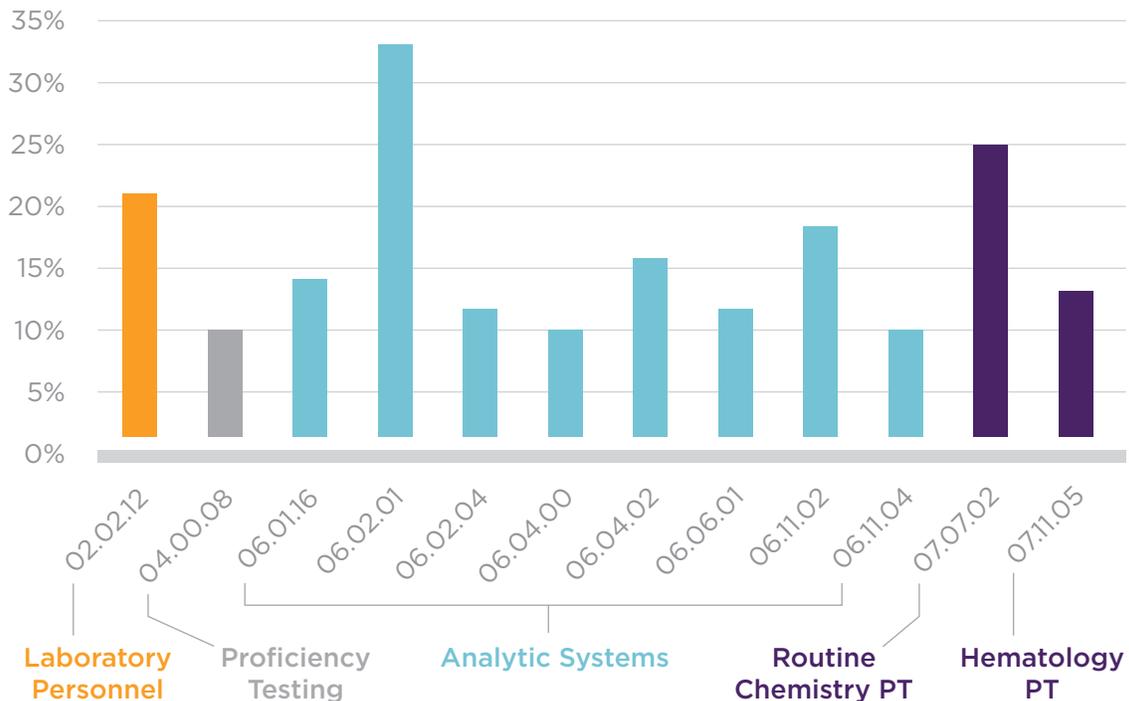
The Deficiency Report that you receive after an onsite survey identifies areas of primary focus for your organization. This document includes data from all surveys conducted in 2017; use it as a guideline for self-assessment and to identify areas of secondary focus when the data differ from findings in your organization.

High-frequency deficiencies are grouped by the type of facility in which they occur most often, but topics related to physical environment and life safety are aggregated to include all organizations because they are commonly cited across both inpatient and outpatient settings. In addition to being central to patient care as they tie to issues of safety, they are often overseen by distinct, non-clinical staff.

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Laboratory Deficiencies



For 2017 accreditation surveys of clinical laboratories, standards for analytic systems (chapter six, *Accreditation Requirements for Clinical Laboratories*, December 2015 update) are the most frequently-cited deficiencies, as shown above. The horizontal axis identifies the specific standard by number and the vertical axis shows the frequency with which that standard was cited as a deficiency.

These standards represent deficiencies cited for more than ten percent of surveys. Additional detail follows.

CHAPTER	STANDARD
Laboratory Personnel	02.02.12 - Competency Evaluation
<i>Overview of the requirement:</i>	The laboratory's technical supervisor is responsible for evaluating the competency of all testing personnel using six elements identified within the standard.
<i>Trending the deficiencies:</i>	Deficiencies were cited when documentation was missing for one or more element of the standard.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> Checkmarks were the only indication of competency evaluation in employee records. There was no further documentation of how skills were assessed. Documentation of competency for personnel did not include all six elements.

CHAPTER

STANDARD

- Documentation of assessment of problem solving skills was missing for seven testing personnel.

Proficiency Testing

04.00.08 - Attestation Statements

Overview of the requirement:

For Moderate Complexity Testing, the laboratory director or a qualified technical consultant to whom this responsibility has been delegated must sign an attestation that samples for proficiency testing are integrated into the regular workload and tested using routine methods.

For High Complexity Testing, the laboratory director or a qualified technical supervisor to whom this responsibility has been delegated must sign an attestation that samples for proficiency testing are integrated into the regular workload and tested using routine methods.

Trending the deficiencies:

Deficiencies were cited when specific testing events lacked signed attestation statements or such statements were signed by non-authorized individuals. Issues arise in immunohematology where a pathologist is typically the only qualified technical supervisor for this high complexity testing.

Examples of surveyor citations:

- Attestation statements are routinely signed by the lab manager but there is no letter of delegation on file from the lab director.
- Attestation statements are routinely signed by the administrative director.
- Attestation statements are missing for:
 - Microbiology, testing event 2017-1
 - Mycology, testing event 2017-2
 - Chemistry, testing event 2017-1
 - Hematology, testing events 2016-2, 2017-1

Analytic Systems

06.01.16 - Procedure Approval

Overview of the requirement:

Approval of all laboratory procedures is the responsibility of the lab director. All procedures, including manuals, manufacturer's instructions for use and package inserts must reflect the director's review and approval, or his/her approved modifications. Periodic review of all procedures should be performed to ensure that they accurately reflect current lab practice.

Trending the deficiencies:

Most deficiencies indicate the lack of a process for either periodic review of standing procedures or missing documentation of approval for changed procedures.

Examples of surveyor citations:

- Manuals included many changes written as annotations or attached without date or signature.
- Lab manuals included procedures that did not reflect approval by the current medical director.
- Procedures added in January 2017 were unsigned as of March 2017.

CHAPTER	STANDARD
Analytic Systems	06.02.01 – Essential Conditions
<i>Overview of the requirement:</i>	The lab must define criteria consistent with manufacturer’s instructions for water quality, temperature, humidity, and protection of equipment and instruments from electrical fluctuations that are could adversely affect results.
<i>Trending the deficiencies:</i>	Citations reflect one or more missing element of the standard.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ Lab manager reported in interview that the same water type should be used for all dilutions and reconstitutions but this was not included in the water quality policy. ▪ Neither temperature nor humidity were monitored with a certified instrument. ▪ Thermometer and humidistat were past their certification expiration dates. ▪ The lab manager could not produce a water policy.
Analytic Systems	06.02.04 – Reagent Kit Components
<i>Overview of the requirement:</i>	Components of reagent kits must be used together and components from kits with different lot numbers may not be interchanged (unless approved by manufacturer).
<i>Trending the deficiencies:</i>	Deficiencies relate to missing policy/procedure to consistently address this standard in some lab departments.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ Pathology department does not have a procedure to avoid mixing stain kit components. ▪ Policy for each kit procedure does not include prohibition on interchanging the reagent of differing kit lots. ▪ Histology department does not have a procedure prohibiting interchange of stain kit components.
Analytic Systems	06.04.00/06.04.02 – Maintenance Checks/Modified System Maintenance Checks
<i>Overview of the requirement:</i>	The lab must comply with the manufacturer’s maintenance recommendations for each unmodified piece of equipment and instrument. Similarly, for equipment, instruments, or test systems developed internally, a maintenance protocol must be established and followed for performing scheduled preventive maintenance and unscheduled repairs when needed. Documentation is required.
<i>Trending the deficiencies:</i>	Deficiencies reflect missing documentation of preventive maintenance performed.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ Daily cleaning and maintenance on the microtome, embedding center, and tissue processor are performed but not logged. No yearly preventive maintenance occurred for these instruments per interview.

CHAPTER

STANDARD

- No preventive maintenance on microscopes or cryostat in past two years.
- Water system monthly sanitation is inconsistently performed by the biomed department with documentation missing for 2 months in each of 2015, 2016, and 2017 (as of survey date).
- No policy for maintenance of centrifuge timers.

Analytic Systems

06.06.01 - Control Procedures

Overview of the requirement:

CMS permits laboratories to develop and customize quality control for some testing using an Individualized Quality Control Plan (IQCP) comprised of a risk assessment (RA), a quality control plan (QCP), and a quality assessment plan (QA). The RA identifies the questions to ask, the QCP addresses data collection and the QA closes the loop by analyzing the data to confirm that quality benchmarks are achieved or to identify a need for improvement. This is a voluntary process. If the lab opts NOT to apply IQCPs, then it must perform QC testing procedures as specified by manufacturer’s instruction or CLIA requirements, whichever is more stringent.

Trending the deficiencies:

If the laboratory chooses to deviate from the more stringent of manufacturer’s or CLIA requirements, then an IQCP including all elements must be developed, implemented, and documented.

Examples of surveyor citations:

- QC procedures for Oxicom use for oximeter testing were less stringent than the CLIA regulatory requirement for QC each day of patient testing but no IQCP had been developed to modify the CLIA regulation.
- Review of the technical procedures for Rapid Strep and RSV, and review of the QC/patient logs revealed that the currently approved procedure is to perform QC on each new lot number and shipment of kits, and every 30 days. For Strep, the 30 day QC was not performed June – Nov. 2016. For RSV the 30 day QC was not performed in Sep., Oct., or Nov. 2016 or Jan. 2017.
- Laboratory policy and manufacturer’s instructions call for quality control testing on each kit for Rapid Streptococcal Antigen but testing practice revealed external controls were tested only on every new lot number.

Analytic Systems

06.11.02 - IQCP Risk Assessment

Overview of the requirement:

For each regulatory quality control requirement that is replaced by an IQCP, a risk assessment (RA) evaluates potential failures and sources of error relating to specimen, test system, reagent, environment, and testing personnel. The RA must encompass preanalytic, analytic, and postanalytic phases.

Trending the deficiencies:

Deficiencies are cited when multi-site laboratories opting to use an IQCP, base the risk assessment on a single lab location, and when some test are omitted from the RA.

CHAPTER

STANDARD

<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ No documentation was available to support RA for the following tests: RSV, Fly A7B, Bactec, C diff, Grp B Strep, MRSA, Crypto/Gia, EPOC, Istat Troponin, Microscan, Strep A, Fetal Fibronectin, H pylori, Serum HCG, Mono, TOX drug screen, D-Dimer, BNP, RV, and Microbiology Media. ▪ The IQCP for strep testing at this location is based on the hospital's main lab IQCP and does not address potential failures and errors <i>specific to this testing site</i>. ▪ While reviewing documentation it was difficult to determine whether all five components were included in the RA. Twelve tests had no documentation supporting risk assessment for the use of an IQCP.
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Analytic Systems

06.11.04 – IQCP Quality Assessment

<i>Overview of the requirement:</i>	The lab establishes and follows a policy for on-going review of the IQCP.
<i>Trending the deficiencies:</i>	Collecting data is not sufficient for a compliant IQCP. The laboratory must analyze the data it collects to ensure that the QCP is adequate and effective.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ While the IQCP written detail includes monitoring on a weekly, monthly, and annual basis, there is no evidence that the data is further evaluated in a QA report. ▪ The lab hasn't incorporated QA in its IQCP. ▪ No system has been established to verify effectiveness of the IQCP written for serum HCG, Triage Meter, exempt media and AST/ID.

Specialty-Subspecialty Specific (Routine Chemistry)

07.07.02 – Routine Chemistry Proficiency Testing

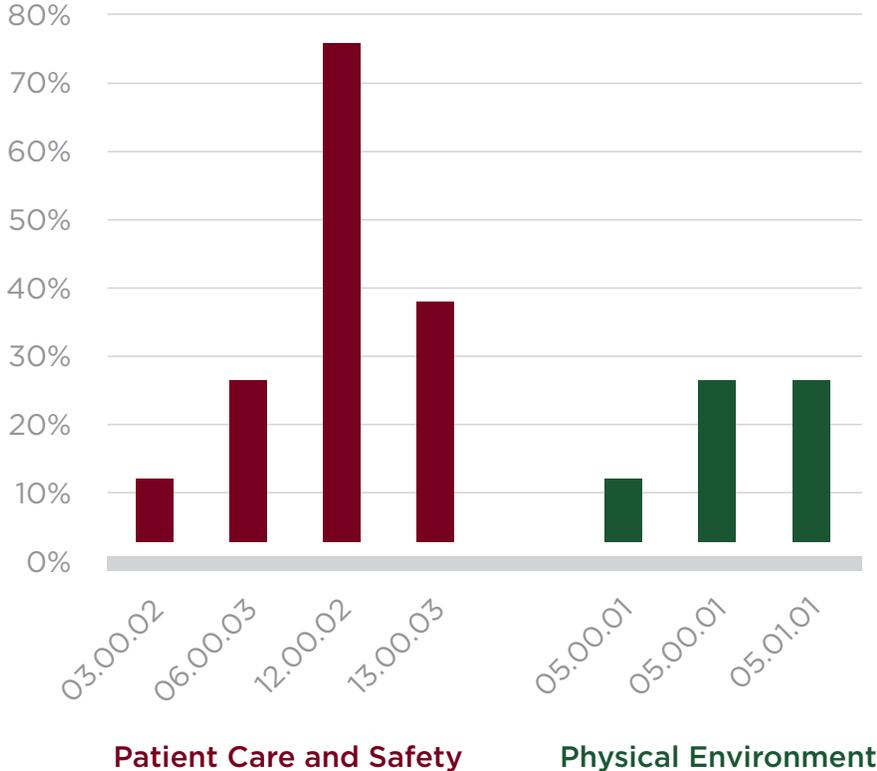
<i>Overview of the requirement:</i>	PT for each analyte must attain a score of at least 80% for each testing event.
<i>Requirement for addressing deficiencies:</i>	When the lab scores under 80% for an individual analyte, it must document its investigation and remedial action.

Specialty-Subspecialty Specific (Hematology)

07.11.05 – Hematology Proficiency Testing

<i>Overview of the requirement:</i>	PT for each analyte must attain a score of at least 80% for each testing event.
<i>Requirement for addressing deficiencies:</i>	When the lab scores under 80% for an individual analyte, it must document its investigation and remedial action.

Ambulatory Surgery Center Deficiencies



For 2017 surveys of ASCs, the most frequently-cited deficiencies fall into two broad areas: patient care and safety and the environment, as shown above. The horizontal axis identifies the specific standard by number (see *Accreditation Requirements for Ambulatory Surgical Centers*, 2017 edition) and the vertical axis shows the frequency with which that standard was cited as a deficiency.

CHAPTER	STANDARD
Surgical Services	03.00.02 – Surgical Procedures Performed Safely
<i>Overview of the requirement:</i>	This CMS Condition for Coverage requires that surgical procedures are performed by qualified physicians who have been granted privileges by the governing body.
<i>Trending the deficiencies:</i>	This condition-level standard frequently correlates with 06.00.03 on the next page. Absent a reappraisal process, it may be that procedures are performed by physicians who do not have current peer review and an application for reappointment in their credentialing file. Without this documentation, it is difficult to be confirmed as compliant with this standard.

CHAPTER

STANDARD

Examples of surveyor citations:

- The last reapplication with approval had expired July 2016. The facility was unable to provide documentation of a reapplication request by or a peer review of the physician. The facility lacked evidence of reappointment approval, based on review of governing body meeting minutes from 2014, 2015, 2016 and 2017.
- During review of credentialing files and Governing Board meeting minutes it was identified that five of the six providers requiring recredentialing were not documented as being approved or discussed at the Governing Board meetings.

Medical Staff

06.00.03 - Reappraisals

Overview of the requirement: Medical staff privileges are granted by the governing body and a reappointment process is followed at least every 24 months.

Trending the deficiencies: This is a time-driven standard and deficiencies reflect a failure to develop an on-going, cyclical process.

Examples of surveyor citations:

- Initial appraisals and reappraisal dates could not be determined from credentialing files.
- Credentialing files did not contain evidence that the board reviewed and granted privileges.
- One of two physicians performing procedures did not have current privileges. There was no reapplication request or peer review on file and no reappointment approval in governing body minutes from the past four years.

Infection Control

12.00.02 - Sanitary Environment

Overview of the requirement: A functional and sanitary environment for surgical services is maintained to avoid sources and transmission of infections and communicable diseases. This extends to all areas of the facility with the expectation that nationally-recognized infection control guidelines are the basis for related policies and procedures.

Trending the deficiencies: A significant number of deficiencies related to monitored safety factors (ventilation, air exchange, temperature and humidity control) not being reported to the Infection Control or Quality committee.

Other citations related to work flow (access to non-sterile functional areas through clean storage), housekeeping, condition of equipment related to patient care, and hand hygiene.

Examples of surveyor citations:

- Hand hygiene practice as observed was inconsistent with ASC policy.
- Procedure table frames showed large areas of rust.
- Visible accumulations of dust were apparent on exhaust vents in OR and procedure rooms.
- Dust and dead insects were present on gas valves.

CHAPTER

STANDARD

Patient Admission, Assessment, and Discharge **13.00.03 - Admitting History and Physical Update**

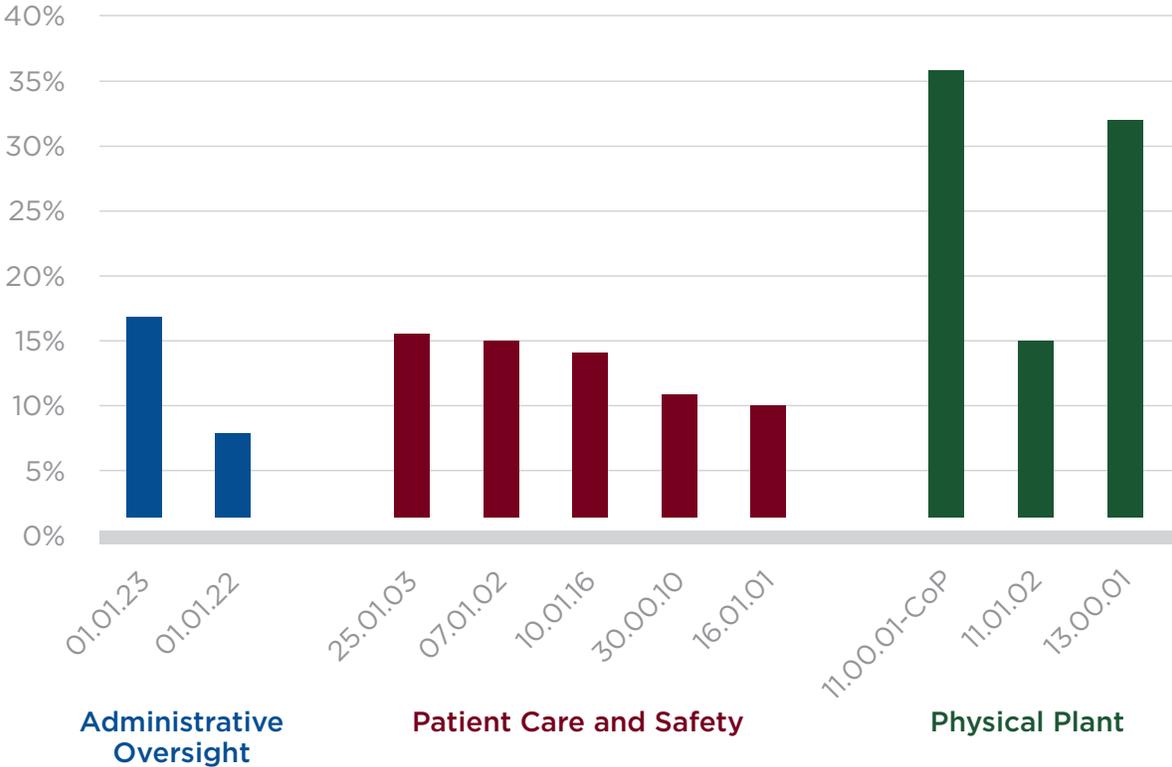
Overview of the requirement: The patient’s medical record must include documentation that a pre-surgical assessment was completed by a physician with regard to the risk of anesthesia and the procedure. This assessment should consider any changes in the most recent H&P and address allergies or reactions to drugs or biologicals.

Trending the deficiencies: Deficiencies reflected missing elements. These may be defined within the standard, e.g. allergy documentation, or within the organization’s policies for anesthesia risk assessment.

- Examples of surveyor citations:*
- No documentation of allergies noted.
 - H&P performed within 30 days of admission and pre-surgical update was noted in record, but 4 of 5 charts were missing date and time of update as required by facility policy.
 - Updates were signed off more than a week after the procedure.
-

For Physical Environment deficiencies, see page 19.

Acute Care Hospital Deficiencies



For 2017 surveys of acute care hospitals, the most frequently-cited deficiencies fall into three broad areas: administrative oversight, patient care and safety, and the physical plant, as shown above. The horizontal axis identifies the specific standard by number (see *Accreditation Requirements for Acute Care Hospitals*, 2017 edition) and the vertical axis shows the frequency with which that standard was cited as a deficiency.

The most frequently identified deficiency (36% of surveys) is a condition-level finding for Physical Environment. Until CMS issued new Emergency Management regulations (effective November 15, 2017), CMS Condition of Participation §482.41 included three expectations to ensure the safety of the patient: (1) Emergency Management, (2) Physical Environment, and (3) Life Safety. HFAP surveyors cited non-compliance with this CoP as a result of total deficiencies for Chapter 9, Chapter 11, and Chapter 13. (See pages 19–25 for additional detail on these related deficiencies.) This failure to meet a CMS Condition of Participation will trigger a second survey event to insure that the Plan of Correction submitted by the hospital has been fully implemented and the deficiency corrected.

Specific examples of surveyor findings related to deficiencies in administrative oversight and patient care and safety standards are described on the following pages.

CHAPTER

STANDARD

Administration

01.01.22 and 01.01.23 - Contracted Services and Contractor Quality Monitoring

Overview of the requirement:

A hospital's governing body is responsible for all services provided by the hospital regardless of whether they are provided directly by hospital employees or indirectly through contractual relationships (including joint ventures and shared services). Services provided must be assessed to ensure that the hospital, as a whole, is in compliance with Conditions of Participation and standards.

An annual Quality Plan, approved by the governing body, includes performance measures for every hospital department and service, including those services furnished under contract. The governing body maintains a list of all contracted services to ensure that the quality of these services is subject to the same assessment as those provided directly by the hospital.

Trending the deficiencies:

These closely related standards are often deficient in tandem. If the overall Quality Plan does not include all services, the omission will be noted as non-compliance with standard 01.01.22. If an individual contract fails to stipulate performance indicators and reporting requirements, this often signals a failure to report quality data to the Quality Committee, and to communicate upward to the governing body. In the event a facility lacks evidence of monitoring the quality of any single contracted service, non-compliance will be noted. Conversely, if the governing body does not maintain a list of current contracts, it is a missed opportunity to question omitted data.

When only one of these standards is cited, it is often because a link in the chain of reporting has been broken.

Examples of surveyor citations:

- Contracted services submit quality reports to the Quality Committee, but these are not advanced to the governing body for review.
- Governing body meeting minutes do not reflect review of clinical services provided under contract.
- There is no evidence of a system to address the standard.
- The hospital is part of a system that provides some services at the corporate level but there is no reporting that allows the hospital governing body to assess services for quality.

**Pharmacy Services/
Medication Use**

25.01.03 - Security of Medications

Overview of the requirement:

All drugs and biologicals are stored so as to prevent unmonitored access by unauthorized individuals. Areas restricted to authorized personnel only would generally be considered "secure." This includes areas in which staff are actively providing care to patients or setting up for procedures prior to a patient's arrival.

CHAPTER

STANDARD

A unit in which care is active around the clock is considered secure when hospital policies limit entry and exit to appropriate staff, patients, and visitors. A unit that is not currently in use, e.g., an inactive surgical suite, is not considered secure. Under this circumstance, the hospital may choose to lock the entire suite, to lock non-mobile carts containing drugs and biologicals, or to move mobile carts to a locked room. All Schedule II, III, IV, and V drugs must be kept locked within a secured area.

Patient self-administration of non-controlled drugs and biologicals must be addressed in hospital policy.

Trending the deficiencies:

Most deficiencies result from inconsistent adherence to hospital policy for securing medications that creates risk of access by unauthorized individuals. Often housekeeping and engineering staff have access to secure areas via master keys and access to Schedule II, III, IV and V drugs is not further controlled.

When using a lock and key process for crash carts, there is risk of delayed access for patient care if staff are unable to immediately locate the key to open the cart. Locating the crash/mobile/med carts in a visible, staff high traffic area can be helpful in preventing unauthorized access.

Many organization use plastic numbered lock tags. These plastic tags must themselves be secured and a crash cart log used to demonstrate that carts and equipment have been checked daily (or more frequently, as per hospital policy).

Examples of surveyor citations:

- Drugs are delivered from the pharmacy to open bins in medication rooms accessed by non-licensed personnel (housekeeping, patient care techs).
- A portable anesthesia carrying case containing succinylcholine, Versed and fentanyl is not secured or placed in a locked anesthesia cabinet.
- Hospital policy “Access to Medication Areas by Non-Professional Personnel” indicates restrictions to nursing and pharmacy staff, but engineering staff have keyed access.
- There is no daily accounting system for what is removed from medication inventory, by whom, for whom.
- An unsecured pediatric resuscitation medication cart was in an unlocked surgical storage room.
- Non-narcotic medications are kept in unlocked bins in medication rooms to which housekeeping has access.

CHAPTER

STANDARD

Infection Control

07.01.02 - Infection Prevention

Overview of the requirement:

The hospital’s infection control officer has a system for identifying, investigating, reporting, and preventing the spread of infections. A successful system is most likely a collaborative endeavor that includes active surveillance of the entire physical facility.

Surveyors will assess compliance by combining document review with visual inspection to determine how effectively infection prevention is addressed.

Trending the citations:

Most citations from 2017 surveys addressed aspects of the facility that indicated a lapse in how a sanitary environment is assessed and maintained. A second area of concern reflected internal policies that were found to be in conflict. Details matter. The range of findings reflects the scope, focused surveillance, and level of collaborative engagement required by the standard.

Examples of surveyor citations:

- Rust was observed (on casters, on shelves, on cabinets).
- Drywall showed water damage, deterioration, visible dirt, penetrations.
- Dust was apparent on high surfaces (cabinet tops, overhead bed lights, TV wall mount arms).
- Patient care supplies are stored under the sink.
- Soiled linens are stored in the surgical handwashing area.
- Cardboard shipping boxes in which materials were received are retained in storage areas.
- One infection control policy allows for home laundered scrubs. Another requires scrub attire to be laundered at the hospital’s contracted and accredited laundry facility.
- Janitor’s closet on Med/Surg Unit did not provide separation between clean supplies destined for patient care rooms and dirty items.
- The clean supply room door auto-closure was not working. The room is accessed by a public hallway.
- The policy on Foley catheter use requires that date of insertion and indication for use be noted. A sticker listing CDC indications for use was present with a physician signature and date range, but no marking of relevant indicators.

CHAPTER

STANDARD

**Medical Records
(Health Information) Services**

10.01.16 – Informed Consent

Overview of the requirement:

All inpatient and outpatient medical records must contain a properly executed consent form for those treatments and procedures that have been specified (by the medical staff, federal, or state law) to require written patient consent. This form includes, at minimum:

1. Name of hospital at which the procedure/treatment will take place.
2. The name of the procedure/treatment.
3. The name of the practitioner performing the procedure or administering treatment.
4. A statement that the anticipated benefits, risks, and alternative therapies were explained.
5. Signature of the patient or his/her representative.
6. Date and time the consent was signed by the patient or his/her representative.
7. Surgeon signature

The hospital must have a policy that describes the informed consent process.

Trending the deficiencies:

Most citations of this standard identify one or more required element that is missing.

While consent forms are used in legal proceedings to protect institutions (the documentation of *consent*), they are, first and foremost, evidence of an interactive process that should emphasize *informed* – an act of intentional affirmation on the part of the patient. To this point, informed consent is included in additional locations in the Conditions of Participation relating to patient rights and surgical services. To achieve the intent of the standard, consents must be written in simple language such that the meaning of the document is repeatable by the patient.

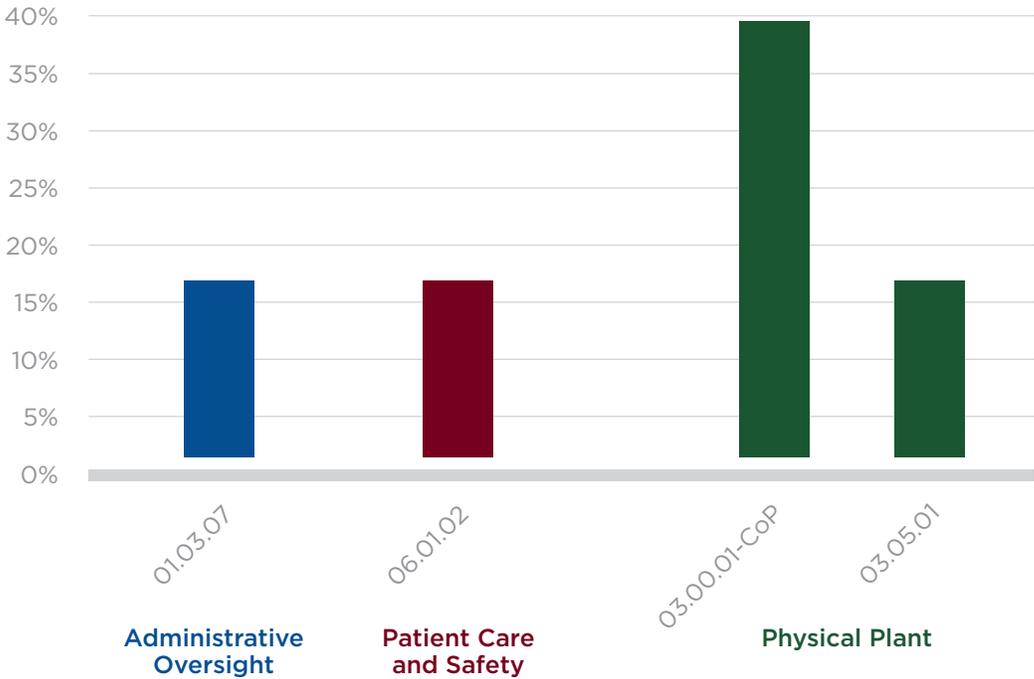
Because of the large percentage of the population with literacy deficits, and the larger percentage with medical literacy challenges, the patient’s primary language and a 4th grade comprehension level have been identified as the goal for a consent document that will be easily understood.

Examples of surveyor citations:

- Missing consent for anesthesia.
- Consent not written in simple sentences/at 4th grade level.
- Consent missing alternative therapies.
- Consent missing anticipated benefits and risks.
- Procedure name abbreviated and not further documented for easy comprehension.
- Date and time missing.

CHAPTER	STANDARD
Surgical Services	30.00.10 - History & Physical
<i>Overview of the requirement:</i>	Prior to a procedure that requires anesthesia, a history and physical examination must be completed. This can take place no earlier than 30 days prior to and no later than 24 hours after admission or registration, except for emergencies. If the H&P was completed prior to admission, an update is required within 24 hours after admission/registration.
<i>Trending the deficiencies:</i>	The standard is very straightforward in its requirements. Citations mostly indicate a failure to perform the required update. A few observations reflect that “updates” were performed without an original, comprehensive H&P to serve as the baseline.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ Missing dated H&P. ▪ Podiatric surgery with no update to H&P. ▪ Orthopedic surgery with no update to H&P. ▪ H&P completed more than 30 days before admission. ▪ Two of six records reviewed had no H&P; four of six had no update prior to anesthesia.
Nursing Department	16.01.01 - Preparation and Administration of Drugs
<i>Overview of the requirement:</i>	Drugs and biologicals must be prepared and administered in accordance with federal and state laws and based on orders of a practitioner responsible for the patient’s care or another practitioner acting within state law, scope of practice, and hospital policy.
<i>Trending the deficiencies:</i>	Most of the deficiencies cited reflect discrepancies between hospital policy and observed practice.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ Hospital policy requires reassessment of the patient one hour post administration of pain medication. Records in the CCU reflect a four hour reassessment; in the ICU, a two hour reassessment; in the Orthopedic unit, no reassessment. ▪ Hospital policy, “Nursing Discretionary Medication,” is not consistent with scope of practice. ▪ Subcutaneous injection observed without preceding hand hygiene. ▪ The use of bar code scanners has resulted in a practice of documenting administration of medications before the actual administration takes place. ▪ The hospital’s policy includes range orders, “as needed,” and “per protocol,” putting nurses beyond scope of practice. ▪ Hospital’s policy on administration of drugs has not been reviewed in four years.

Critical Access Hospital (CAH) Deficiencies



For 2017 surveys of CAHs, the most frequently-cited deficiencies fall into three broad areas: administrative oversight, patient care and safety, and the physical plant, as shown above. The horizontal axis identifies the specific standard by number (see *Accreditation Requirements for Critical Access Hospitals*, 2017 edition) and the vertical axis shows the frequency with which that standard was cited as a deficiency.

The most frequently identified deficiency (39% of surveys) is a condition-level finding for Physical Environment. (See page 19 for additional detail on this and related deficiencies.) This failure to meet a CMS Condition of Participation will trigger a second survey event to insure that the Plan of Correction submitted by the hospital has been fully implemented and the deficiency corrected.

Specific examples of surveyor findings related to deficiencies in administrative oversight and patient care and safety standards are noted at right.

CHAPTER

STANDARD

Compliance with Regulations

01.03.07 - Distant Site Telemedicine Entity/Non-Hospital Based Agreement

Overview of the requirement:

The CAH governing body is responsible for all services provided by the hospital regardless of whether they are provided directly by hospital employees or indirectly through contractual relationships (including services provided via telemedicine). Services provided must be assessed to ensure that the hospital, as a whole, is in compliance with Conditions of Participation and standards.

The CAH's governing body or responsible individual may choose to rely on the credentialing and privileging decisions made by the governing body of the contracted distant-site telemedicine entity regarding individual physicians or practitioners, provided that those decisions maintain the hospital's compliance with CoP and relevant standards.

The contracted telemedicine entity provides a current list of its privileged physicians and/or practitioners with delineation of privileges.

The individual physicians or practitioners hold a license issued or recognized by the State in which the CAH is located.

The CAH has evidence of an internal review process of the telemedicine physician's or practitioner's performance and participates in this process by providing information including, at a minimum, all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

Trending the deficiencies:

This standard is similar in intent and findings to a frequent deficiency for acute care hospitals: 01.01.22 (see page 11). Maintaining an inventory of all contracts and including governing body review on an annual basis can support compliance with each element of the requirement.

Examples of surveyor citations:

- Tele-radiology contract does not include a list of physicians providing interpretation services.
- Telemedicine agreement has not been reviewed in the past three years.

The Preparation & Administration of Medications

06.01.02 - Medication Administration

Overview of the requirement:

Drugs and biologicals must be prepared and administered in accordance with federal and state laws and based on orders of a practitioner responsible for the patient's care or another practitioner acting within state law, scope of practice, and hospital policy.

Trending the deficiencies:

Most of the deficiencies cited reflect missing policies or discrepancies between hospital policy and observed practice.

CHAPTER

STANDARD

Examples of surveyor citations:

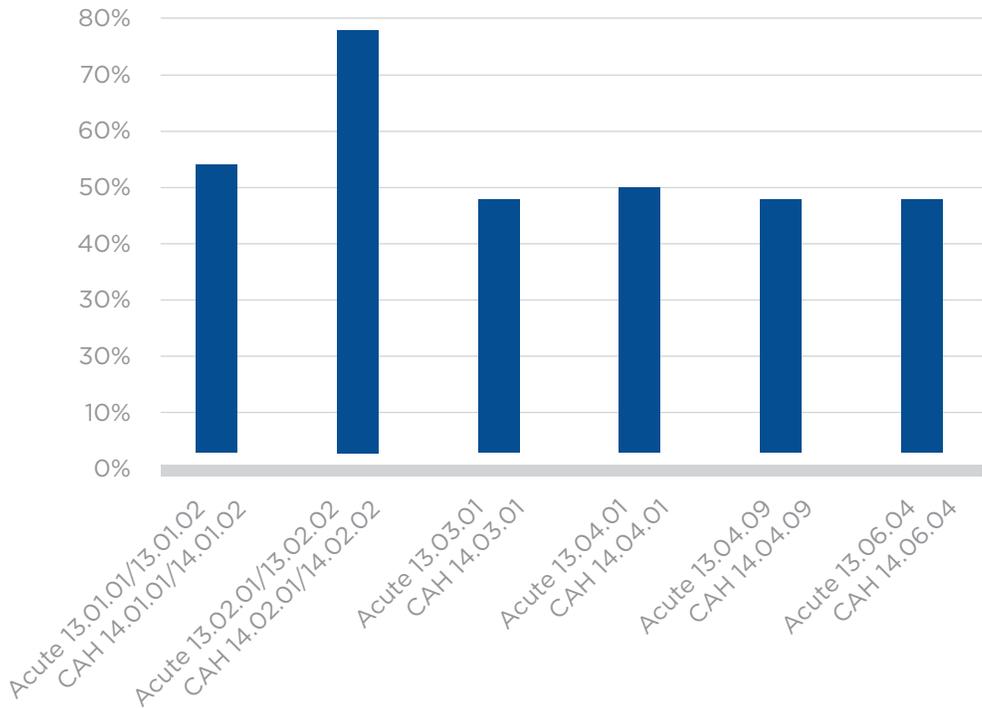
- Pharmacy was missing policies on timing of medications and administration and monitoring of high-alert medications including IV opioids.
- In 5 of 7 records reviewed, PRN pain medications administered did not include a written initial or follow-up patient pain assessment.
- OR: An unlabeled syringe of propofol, ketamine, and fentanyl was in the anesthesia area.
- One patient chart noted a pain score of 9 and a Norco order to be given for moderate pain breakthrough. Hospital policy identifies 4-6 as moderate pain, 7-10 as severe.

Physical Environment Deficiencies

CHAPTER	STANDARD
Condition for Coverage Condition of Participation	ASC standard 05.00.01 – Environment Acute Care Hospital standard 11.00.01 – Physical Environment CAH standard 03.00.01 – Physical Environment
<i>Overview of the requirement:</i>	<p>This standard is met by compliance with systems for building safety, building security, hazardous materials and waste, fire safety, medical equipment management, and utility systems management. Issues related to the physical environment, including Life Safety, that rise to the condition level will be cited here. The condition may be cited based on a single observation or on cumulative noncompliance with other standards in this chapter or under Life Safety.</p>
<i>Trending the deficiencies:</i>	<p>This condition ties management of the built environment to patient, staff, and visitor safety. When this CoP is cited, it is usually as a result of cumulative deficiencies in Life Safety and Emergency Management standards.</p>
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ Accumulative effect of system deficiencies including: Interior finishes, Door Locks, exit Discharge, Fire Rated Barriers, Construction Type, and Generator Inspection ▪ No inventory of supplies needed for an emergency event; safety policies had not been reviewed in 36 months; eyewash stations missing where caustic materials are handled; doors with magnetic locks did not comply with Life Safety Code; fire alarm system relays had not been tested in 12 months; no sprinkler control valve exercises in 12 months ▪ Doors are locked in path of egress (out of compliance with LSC); fire alarm batteries had not been tested in 12 months; annual fire pump test did not include a simulated power failure; fire hose valves had not been inspected quarterly in over a year. ▪ Fire alarm and sprinkler systems had not been fully tested; annual backflow preventer test was not completed; 5-year replacement or testing of pressure gauges had not been performed; monthly control valve and pressure gauge inspection was not conducted. The emergency generator was not load tested on a monthly basis.

CHAPTER	STANDARD
Environment	ASC standard 05.00.05 – Health Care Facilities Code
<i>Overview of the requirement:</i>	<p>This standard addresses the 2012 edition of NFPA 99: Health Care Facilities Code that establishes requirements for a range of health care building systems including medical gases, electrical, HVAC, gas equipment, and hyperbaric facilities. The standard also requires a risk assessment of building services, including:</p> <ul style="list-style-type: none"> ▪ Gas & Vacuum Systems ▪ Electrical Systems ▪ HVAC Systems ▪ Electrical Equipment ▪ Gas Equipment
<i>Trending the deficiencies:</i>	<p>Each system listed above must be evaluated for its potential impact should the system fail (risk-assessment). Based on worst-outcome scenarios, the system is categorized in Chapter 4 of NFPA 99-2012 with associated requirements.</p>
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ No risk assessment had been performed for the required systems.
Environment	ASC standard 05.01.01 – Safety from Fire
<i>Overview of the requirement:</i>	<p>This standard addresses compliance with the 2012 edition of NFPA 101: Life Safety Code. Buildings with construction completed, or plans approved after July 5, 2016 must meet the requirements of Chapter 20. Buildings or portions thereof that were approved on or before July 5, 2016, must meet the requirements of Chapter 21.</p>
<i>Trending the deficiencies:</i>	<p>Deficiencies related to human interference with protective barriers, deferred maintenance, and errors in testing frequency for fire safety equipment.</p>
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ A fire rated door was held open with a door stop mounted to the bottom of the door. This was corrected during survey, but a Plan of Correction must be submitted and approved. ▪ Multiple unsealed penetrations were present in fire-rated barriers. ▪ Fire alarm test reports did not indicate testing of: <ul style="list-style-type: none"> - interface relay for elevator recall - smoke detector sensitivity since 2012 (required every five years at minimum) ▪ Sprinkler system test report missing: <ul style="list-style-type: none"> - evidence of annual control valve exercise - evidence of annual backflow preventer test - pressure gauge calibration and replacement every five years (last documented replacement in 2007)

Life Safety Code deficiencies in Acute Care Hospitals and CAHs



Note: Life Safety Code deficiencies for ASCs are included in the Physical Environment section, page 19.

CHAPTER	STANDARD
Means of Egress	Acute Care Hospital standards 13.01.01/13.01.02 - Doors and Door Locks CAH standards 14.01.01/14.01.02 - Doors and Door Locks
<i>Overview of the requirement:</i>	Corridor doors resist the passage of smoke. Corridor doors and doors to hazardous rooms have positive latching hardware. Doors in the path of egress may have locks where patient needs dictate special protective measures for security. Locks may only be provided under the requirements of NFP 101, sections 18/19.2.2.2.5.
<i>Trending the deficiencies:</i>	These standards for doors and locks are often cited together and range from simple-to-correct issue with doors being held open intentionally with a wedge, or inadvertently made less accessible by being blocked with clutter or equipment.

CHAPTER	STANDARD
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	<p>More complex issues relate to either a lack of positive latching on doors, or the inappropriate use of specific types of locks. Life safety compliance overrides security. For example, do not install delayed egress locks in buildings that are not fully protected with smoke detection or compliant fire sprinklers.</p>
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| <p><i>Examples of surveyor citations:</i></p> | <ul style="list-style-type: none"> ▪ Push buttons to control magnetized access control locks are more than 5' from the door. ▪ Delayed egress locks used where there is no smoke detection or fire sprinkler system. ▪ Egress door operated by key only and not all staff carry keys. ▪ Doors are prevented from opening 90 degrees by wall-mounted or stored equipment. |
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Fire Alarm Systems	<p>Acute Care Hospital standards 13.02.01/13.02.02 - Installation and Testing</p> <p>CAH standards 14.02.01/14.02.02 - Installation and Testing</p>
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<p><i>Overview of the requirement:</i></p>	<p>A fire alarm system must be installed where required by section 18/19.3.4 of NFPA 101 (2012 edition). NFPA 72 (2010 edition) defines the installation, testing and documentation requirements.</p>
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<p><i>Trending the deficiencies:</i></p>	<p>This is another pair of standards that are frequently found “not compliant” in tandem. With regard to installation, citations focused on smoke detectors missing or being installed outside prescribed parameters for distance from other system elements.</p> <p>With regard to testing requirements, deficiencies often point to the lack of a complete inventory of relevant devices with testing frequency noted for each.</p>
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| <p><i>Examples of surveyor citations:</i></p> | <ul style="list-style-type: none"> ▪ Fire alarm pull blocked by a rolling file cabinet. ▪ Fire alarm visual notification device blocked by shelving. ▪ Smoke detector too far from the deck. ▪ Interface testing for functionality not documented for magnetic hold-opens, air handler shut-down, smoke dampers, fire pump, kitchen hood suppression system, waterflow switches, etc. ▪ Manufacturer’s expiration date for system batteries noted as occurring before testing, but the testing log indicates all batteries passed. Other documentation indicated that the expiring batteries had been replaced a year earlier, but the expiration dates were not updated in the inventory list. |
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CHAPTER

STANDARD

Fire Suppression Systems

Acute Care Hospital standard 13.03.01 – Water-based fire protection system: Installation and Maintenance

CAH standard 14.03.01 – Water-based fire protection system: Installation and Maintenance

Overview of the requirement:

Just as requirements for the installation and maintenance of fire alarm system are specific, so too are the requirements for fire suppression. The expectation is that an NFPA 13 water-based fire protection system is installed and maintained in accordance with section 18.3.5 of NFPA 101 (2012 edition) for new construction and in accordance with section 19.3.5 in existing construction or renovated areas.

Trending the deficiencies:

Deficiencies in meeting this standard often result from failing to coordinate different aspects of facilities management. Sprinkler heads are installed and later, signage and/or furnishings are added that compromise the ability of the sprinklers to function as intended.

Examples of surveyor citations:

- Rolling medical records storage is less than 18 inches from sprinkler heads in the medical records room.
- Exit sign is installed too close to sprinkler heads.
- Annual inspection report indicates that 44 sprinkler heads were corroded and required replacement. At the time of survey, this work had not been performed.

Life Safety Drawings

Acute Care Hospital standard 13.06.04 – Life Safety Drawings

CAH standard 14.06.04 – Life Safety Drawings

Overview of the requirement:

Clear and accurate drawings of the facility are critical to support maintenance and identification of required life safety provisions of the building. Drawings should include elements defined by the standard and facility representatives must be able to interpret all aspects.

Trending the deficiencies:

Citations tend to occur either because not every element of the standard is addressed on the drawings, or because the use of spaces in practice varies from the indication on the drawing.

Examples of surveyor citations:

- Drawings did not include required elements.
- Soiled utility room was not noted as a hazardous area.
- Drawings did not indicate the farthest distance to the closest smoke compartment or exit.
- No indication of suite boundaries.
- Large space adjacent to the fitness center is being used for storage of patient files; no indication that this is a hazardous area.

CHAPTER	STANDARD
Fire Safety Systems	Fire Rated Barriers (Acute care Hospitals standard 13.04.01; CAH standard
<i>Overview of the requirement:</i>	Fire rated barriers must be properly rated, free of unsealed penetrations and with appropriately fire-rated opening protectives.
<i>Trending the deficiencies:</i>	Most deficiencies relate to unsealed penetrations in fire-rated wall assemblies.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ Above the cross-corridor fire doors, penetrations were not properly fire-stopped. Drywall repairs must be stud to stud. ▪ Pipes from the Chiller Room into the Receiving room were unprotected at wall. ▪ Multiple shafts were constructed of less than one-hour rated fire barrier assemblies. ▪ A two-hour rated fire barrier at building separation had unsealed penetrations with greenfield conduit passing through.
Fire Safety Systems	Acute Care Hospital standard 13.04.09 - Ceilings CAH standard 14.04.09 - Ceilings
<i>Overview of the requirement:</i>	Ceilings are expected to resist the passage of smoke where there is a fire suppression system present and therefore cannot have any missing tiles, cracks or holes exceeding 1/8 inch.
<i>Trending the deficiencies:</i>	Missing or damaged ceiling tiles are the most frequent citations. Often these occur in areas less likely to be noticed without rigorous inspection of all areas.
<i>Examples of surveyor citations:</i>	<ul style="list-style-type: none"> ▪ IT closet is missing ceiling tiles. ▪ Janitor's closet is missing ceiling tiles. ▪ Compressor room is missing ceiling tiles. ▪ Surgical Sterile Processing Room is missing ceiling tiles. ▪ Waiting room light fixture has gap of more than 1/8 inch. ▪ Sprinkler head escutcheons missing. ▪ Piping escutcheons had fallen leaving gaps of greater than 1/8 inch.

Emergency Management

New CMS regulations for Emergency Management went into effect November 15, 2017. While there were few findings with regard to these standards, the overall topic is important so we are offering a few tips based on the relatively few deficiencies identified.

CHAPTER

STANDARD

Patient & Staff Tracking

ASC standard 15.01.02
Acute Care Hospital standard 09.01.05
CAH standard 17.01.05

The organization must have a way to track the staff and patients in the organization's care during an emergency. This includes documenting of the name and location of a receiving facility or other location to which patients and/or staff have moved.

Shelter in Place

ASC standard 15.01.04
Acute Care Hospital standard 09.01.07
CAH standard 17.01.07

For patients, staff, and volunteers who remain in the facility during an emergency event, the organization must have a plan that includes criteria and a plan for ensuring the safety of individuals who shelter in place.

