High Frequency Deficiencies

The 2020 HFAP Quality Review

FROM THE BOARD CHAIR

As I write this message, in the midst of a global pandemic, I've paused to question the value of a retrospective look at deficiencies when so much has changed. The surveys from which this data is drawn took place when emergency management plans were just that — plans — instead of the daily reality that they've become for so many provider organizations.

The AAHHS Board of Directors and the staff that operate HFAP programs are keenly aware that for our customers, the on-site survey is at the center of the accreditation experience. The arrival of a survey team to review your policies, observe how you enact them, assess the safety of your environment, evaluate how effectively your teams work together, and validate the quality of care you deliver to patients, is a heightened experience for an organization and even more so as we navigate the high stakes and high stress brought on by the presence of COVID-19.

We have heard from many of you over the past few months, seeking counsel on federal waivers, on management of PPE, on cross-training staff, on balancing limitations on visitors against contractual expectations for environmental services and systems testing, and more. Despite several months hiatus from onsite survey activity, HFAP has continued to offer support to our accredited (and certified) organizations with resources like this *Quality Review*, with education through HFAP Academy webinars, and with the high level of responsive customer service that you have come to expect.

When we review compliance with HFAP standards, we are really evaluating continuous quality improvement. We know that HFAP customers generally share a mindset that engages with data, compares performance, implements and manages change, and strives to communicate effectively. These are principles that drive active engagement with the accreditation process and bring out its value as a tool especially in a time of challenge and uncertainty.

Ultimately, I've come to believe that it is **because of, not in spite of, the pandemic** that identifying opportunities for improvement is essential and that the annual *HFAP Quality Review* continues to be an important resource for healthcare organizations.

When an airborne virus is present, infection prevention and control standards take on new urgency. When emergency management plans have been activated, it is the best time to assess their effectiveness. When "normal" channels and levels of person-to-person interaction are limited and behavioral health issues heightened, assessing risk becomes essential.

We look forward to seeing your organizations soon. And we salute those of you on the front line of healthcare who have worked tirelessly to support the health of your communities, often at significant personal expense. We are honored to be your accreditor and welcome your feedback on this and other tools we can provide to support your work.

Gary Ley
Board Chair, AAHHS

Introduction

Welcome to the 2020 edition of the **HFAP Quality Review**. This document represents an analysis of deficiencies identified on 2019 surveys for HFAP hospital (acute care and critical access), ambulatory surgery center, and laboratory accreditation programs.

Reading the report

The *HFAP Quality Review* is a resource to help your organization improve.

The Deficiency Report that you receive after an onsite survey details areas that require specific focus and a Plan of Correction. This publication provides a context for your organization's deficiencies by identifying trends across peer institutions using data from all surveys conducted in 2019.

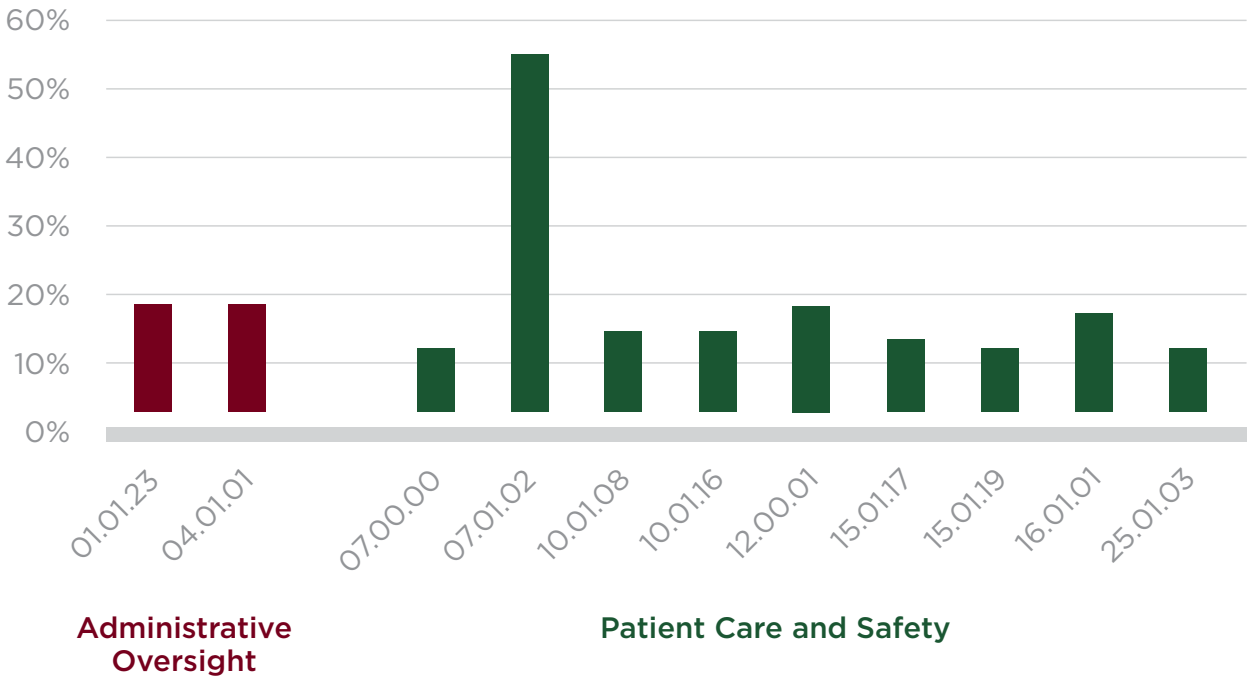
The *Quality Review* identifies the standards that presented the biggest challenges with a succinct overview of their intent. It provides examples of surveyor comments when citing deficiencies, and offers tips for achieving and maintaining compliance. Use it as a guide for self-assessment and to identify areas of secondary focus when the deficiencies differ from citations for your organization.

Where do we go from here?

Just as you can use the data provided in this report for improved compliance within your organization, HFAP uses the data to inform development of educational resources. This year's HFAP Academy Live will be offered virtually on November 4, 5, and 6 to allow for increased access, lower cost, and greater safety for participants. Watch our website for information on the agenda and how to register.

Table of Contents

Acute Care Hospitals Deficiencies Cited in Administrative and Clinical Standards



On 2019 surveys of acute care hospitals (ACH), 39 standards were cited as not compliant for more than 10% of surveys performed — two related to administrative oversight, 17 related to patient care and safety (including 8 emergency management standards detailed as a group on pages 30-37) 20 related to the physical facility (detailed on pages 13-18 and 19-29). The administrative and clinical standards most frequently cited as not compliant are shown above. The horizontal axis identifies the standard by number (as published in *Accreditation Requirements for Acute Care Hospitals,* 2018v2 edition) and the vertical axis shows the frequency with which that standard appeared in an HFAP Deficiency Report.

The two most frequently cited standards in 2019 — 07.01.02 Infection Prevention and 11.00.01 Condition of Participation: Physical Environment — were also the top deficiencies in 2018, but in both cases the frequency of citation was lower. We will continue to emphasize education designed to improve these areas.

Administrative Oversight

CHAPTER	STANDARD
1 Governing Body	**01.01.23 Contractor Quality Monitoring**
Overview of the requirement:	The hospital's governing body holds ultimate responsibility for **all services provided** whether by employees, formal contract, joint venture, informal agreement, shared services, or lease arrangement.
Comment on deficiencies:	Deficiencies identified specific contracts that were neither reviewed by the Quality Committee nor advanced to the governing body for review.
Frequency of citation:	19%
Repeated frequent deficiency? *Previous frequency:*	Yes 50%
Examples of surveyor citations:	▪ The Medical Executive Committee and Board of Trustees reviewed 18 of 22 contracted services that were not reviewed by the Quality Committee. Three contracted services were not reviewed at all. This resulted because the QAPI plan lacked a defined process to evaluate the quality of each contracted service and to advance that evaluation through the Quality Committee to the governing body. ▪ No performance measures were established for governing body review. ▪ In a random sample of nine contracts, the Quality Committee and governing body reviewed descriptions of metrics but no actual data related to performance.
Tips for compliance:	▪ The governing body's responsibility for all services provided by the hospital is seeing renewed focus by CMS. It is important that leadership is not only provided with data, but that they are educated to be able to identify performance problems, review corrective actions, and evaluate the sustainability of these actions. ▪ Within the QAPI plan, define the series of required reviews as ordered steps, for example, department level review, then Quality Committee review, then governing body (Board of Trustees) review.

CHAPTER	STANDARD
4 Human Resources Management	**04.01.01 Staff Training: Identification of Patients at Risk for Harm**
Overview of the requirement:	Staff orientation and annual training address identification of the risk of patient self-harm or harm to others, environmental safety risk factors, and mitigation strategies. Additional training occurs whenever policies and procedures change.

Comment on deficiencies:	This standard was new and effective as of September 20, 2018 and reflected updates to add focus to mitigation of ligature risk in hospital environments. Most deficiencies reflected an overall lack of staff training.
Frequency of citation:	19%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Personnel files indicated that contract employees had not completed training or HR requirements. ▪ There was no evidence of staff training. ▪ A random sample of personnel files revealed ten staff members (including RNs, radiology technicians, physician assistants, and physical therapists) who had not received training per the requirement.
Tips for compliance:	▪ Embed risk assessment and mitigation strategy topics in orientation and annual training for employees, volunteers, contractors, per diem staff, and those providing clinical care under contract. ▪ Appoint personnel, e.g., unit managers, to audit employee files annually for relevant documents such as yearly general and unit-specific competencies.

Patient Care and Safety

CHAPTER	STANDARD
7 Infection Control	**07.00.00 Condition of Participation: Infection Control**
Overview of the requirement:	This is the condition-level requirement for an active, organization-wide program for infection control.
Comment on deficiencies:	As the overall assessment of infection control practice for the organization, this condition is most often cited as a result of aggregate infection control deficiencies identified across units and/or buildings.
Frequency of citation:	12%
Repeated frequent deficiency? *Previous frequency:*	Yes 12%
Examples of surveyor citations:	▪ Infection control issues were observed throughout patient care areas, ORs, and surgical services areas. The cumulative effect of these systematic deficiencies results in this condition-level finding of non-compliance. ▪ OR7: Rust on stools used during surgical procedures. Dialysis unit: Visible dirt ranging from ceiling vents to floors. Labor and Delivery: Expired culture kits, sutures, and food. Kitchen: Dust and grease build-up on vents; dust on fans in produce and milk coolers and on lights and vents in dishwashing area.

Examples of surveyor citations: (continued)	▪ Deficiencies across departments and facility locations include: Baseboard separated from wall in PACU (main site), deep divots in flooring, Infection Prevention Committee meeting minutes lacked evidence that environmental surveillance activity was reviewed, dirty linen carts were overloaded so as to prevent cart flaps from closing, patient supplies were stored in soiled utility room (radiation oncology unit), accumulated dust was visible under clean linen storage.
Tips for compliance:	▪ Focus on individual infection control standards. ▪ Conduct regular infection control surveillance rounds and report findings to the relevant committee. ▪ Promote a culture of cleanliness. For example, if rust is identified during surveillance activities, the item must be removed from service. Rusted surfaces cannot be sanitized.

CHAPTER	STANDARD
7 Infection Control	**07.01.02 Infection Control**
Overview of the requirement:	An individual or individuals are tasked with responsibility for a system of infection prevention and control. **2020 Note:** Substantial revisions to the CMS Condition of Participation to which this standard belongs has resulted in reorganization of the chapter and movement of several Required Elements of this standard into new standards.
Comment on deficiencies:	This was a repeat deficiency from 2018 and although the frequency of citation was lower, it did remain the most frequently-cited deficiency in 2019. Surveyor findings reflect aggregate instances of lack of cleanliness, expired items, and especially, failure to follow policies as written. This is interpreted as a failure of the overall infection prevention and control program.
Frequency of citation:	55%
Repeated frequent deficiency? *Previous frequency:*	Yes 68%
Examples of surveyor citations:	▪ Temperature and humidity checks were reviewed at seven locations. Readings did not meet the facility's approved range for 104 of 147 log entries but no corrective action was documented. ▪ The clean side of sterile processing was under construction. This work was not being completed under the process defined by the infection control permit: – No HEPA filtering in evidence. – Construction space was not maintained in a negative pressure state. – Containment barriers were compromised by staff for ease of circulation. – Construction waste was staged in the corridor.

Examples of surveyor citations: (continued)	▪ The ICU room marked as "soiled utility" included a four-shelf cart with clean respiratory supplies and five respiratory therapy machines. ▪ Inappropriate traffic flow was observed in the sterile and clean supply rooms. ▪ Noted in the emergency department: a crash cart containing expired epinephrine syringes; six boxes of outdated sutures and four outdated insulin syringes in storage; an unlocked drawer with one needle and syringe accessible in room 3.
Tips for compliance:	▪ Train staff to *recognize* and *report* infection control concerns. While this includes cleaning and disinfection (which cannot be effective when delamination, divots, and other surface imperfections are present), it also includes traffic flow (of personnel and materials), and inventory of supplies within manufacturer-defined "use by" date. ▪ Conduct routine infection control surveillance rounds (leadership, infection control personnel, or staff) and document rounding on a tool that can be forwarded to the infection control committee.

CHAPTER	STANDARD
10 Medical Records	**10.01.08 History and Physical Update Requirement**
Overview of the requirement:	Medical records must document an *updated* examination of the patient within 24 hours of admission if an H&P was completed within 30 days of the admission. This update must be in the record prior to any procedure requiring anesthesia services. **2020 Note:** Revisions to this standard allow for an assessment only, immediately prior to a procedure requiring anesthesia services, *when the hospital has a medical staff policy exempting specific outpatient surgical or procedural services* from the comprehensive H&P and H&P update.
Comments on deficiencies:	Deficiencies are based on review of a sample of open and closed medical records and usually identify a percentage without documented updates. Other deficiencies reflect updates performed by providers not privileged for this, or the use of attestation stamps that do not adequately cover the requirement.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Of three open records reviewed, none included the H&P update; 5 closed records reviewed, none included the H&P update. ▪ Based on observation of patient care, no physical exam was completed as part of the pre-surgical update. ▪ A stamp is used to attest to the H&P update but the attestation doesn't reflect required elements of the standard: 1. Review of the original H&P.

Examples of surveyor citations: (continued)	2. Examination of the patient. 3. Change (or lack thereof) in the patient's condition. ▪ The DPM who performed and documented the update was not privileged to complete an H&P.
Tips for compliance:	▪ This is a "just do it" standard that should be a part of any surgical/procedural service. Specify the update as a process step. Consider adding verification to the time-out process. ▪ Ensure that a provider who performs the update is privileged to do so. ▪ Any attestation stamp that is used should reflect the intent of this activity: to compare a recent full H&P to the patient's current condition in order to assess risk of proceeding with anesthesia/surgery.

CHAPTER	STANDARD
10 Medical Records	**10.01.16 Informed Consent**
Overview of the requirement:	This is one of three standards that addresses informed consent. Here, in chapter 10, the requirement is that an informed consent form for procedures and treatments, signed by the patient, is included in all medical records. (The other, related standards are in the Patient Rights chapter at **15.01.11 Participation in decision-making** and the Surgical Services chapter at **30.00.11 Informed Consent**.)
Comments on deficiencies:	Deficiencies most often cited records missing items that are to be included in an informed consent.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Of eleven charts reviewed, one lacked an informed consent; one lacked the complete procedure name; one lacked authentication by the surgeon. ▪ Of eleven charts reviewed, eight included only medical description of the procedure (not at a 4th grade comprehension level) and all of them omitted a description of the anesthesia type. ▪ Endoscopy records lacked informed consents for procedures using conscious or moderate sedation. ▪ The medical record for a patient who underwent emergency surgery lacked next of kin consent, documentation of attempts to reach next of kin, and documentation of emergency rationale in progress notes.
Tips for compliance:	▪ Review the informed consent policy and forms to confirm that all requirements are included and ensure that all staff are appropriately trained on the importance and process for informed consent. ▪ Review the consent as part of the time-out process prior to surgery.

CHAPTER	STANDARD
12 QAPI	**12.00.01 Data Collection and Analysis: Program Scope**
Overview of the requirement:	The intent of the standard is to reflect the ultimate responsibility of the governing body for quality improvement throughout the organization. This is accomplished through a Quality Committee that identifies, tracks, and analyzes quality indicators focused on health outcomes and reduction of medical errors.
Comments on deficiencies:	Most surveyor findings relate to gaps in the scope of data provided to the Quality Committee, indicating that not all services are included in the organization-wide collection of data for analysis.
Frequency of citation:	18%
Repeated frequent deficiency? *Previous frequency:*	Yes 35%
Examples of surveyor citations:	▪ The organization lacks a process for outpatient services and physician offices to submit data to the hospital-wide QAPI program. ▪ Random review revealed that seven services submitted only a narrative description of performance indicators used, and only two of these reflected true quality indicators; the others described operational or vague (not measureable) indicators. ▪ During review of quality data, a gap was noted in Accu-check data. The number of data points varied from 45 to 115 per month but based on patient volume in departments with these devices (med-surg/surgery/emergency), a more likely, accurate number would be approximately 140 per month.
Tips for compliance:	▪ Refer to standard 01.01.23 to cross-reference inclusion of all contracted services in QAPI program. ▪ Include at least two measurable performance metrics approved by the relevant committee and reported to the Quality Committee.

CHAPTER	STANDARD
15 Patient Rights	**15.01.17 Privacy and safety: Safe Setting**
Overview of the requirement:	The intent of this standard is to specify that patients receive care in an environment that protects both physical and emotional health and safety.
Comments on deficiencies:	While this standard is not new, the associated guidance was revised in 2018 to reflect a focus on ligature risk. Most deficiency findings focused on missing environmental safety risk assessments and lack of staff training on how to assess patients for risk of self-harm.
Frequency of citation:	13%
Repeated frequent deficiency? *Previous frequency:*	Yes 13%

Examples of surveyor citations:	▪ A risk assessment tool has been selected but not implemented. No staff or volunteer education had been provided. ▪ Staff training on environmental and psycho-social risk assessment policies was incomplete. For staff oriented to the policy, compliance was 70% in nursing departments; 35% in remaining departments. ▪ A "Suicide Risk Screening, Assessment, and Procedure Policy" was adopted using a risk assessment published in 1988 with no validated identification of risk. The scoring fails to mirror nationally-recognized and validated risk scales. ▪ The "Suicide Risk Assessment Policy" includes no requirement that all patients are to be assessed.
Tips for compliance:	▪ Policies should establish a process to identify patients at risk of harm to self or others throughout the organization, identify environmental safety risks for such patients, strive for a ligature resistant environment, and provide education and training to staff and volunteers. ▪ Conduct a comprehensive risk assessment to identify environmental safety concerns. Develop policies based on nationally-recognized guidelines. ▪ Review security precautions.

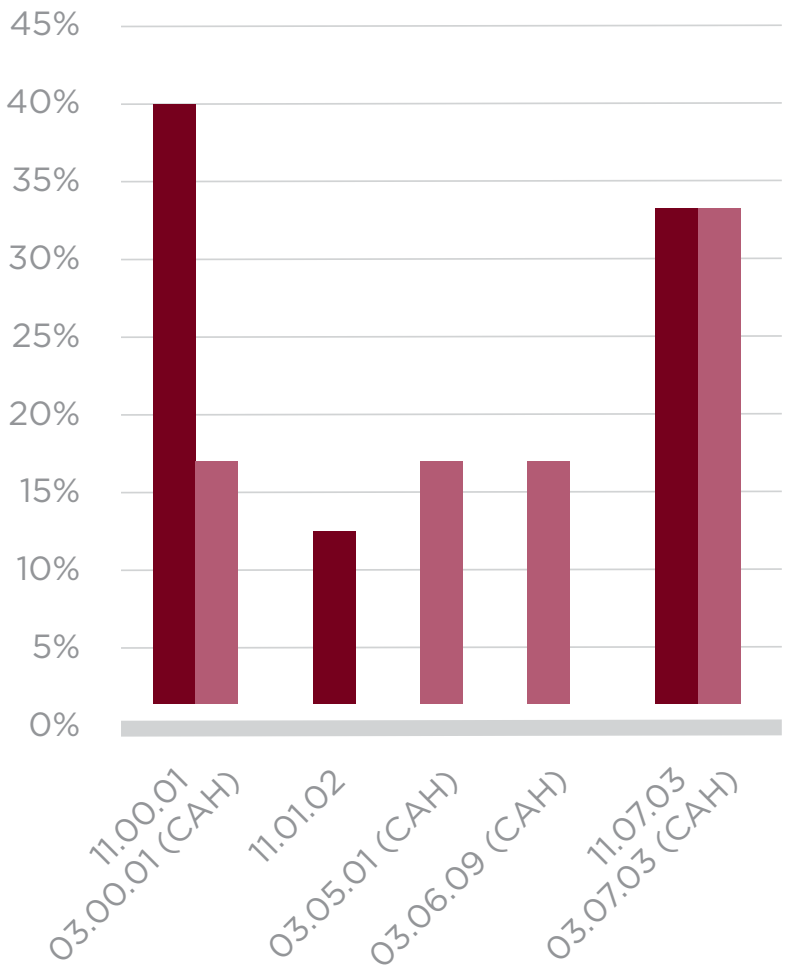
CHAPTER	STANDARD
15 Patient Rights	**15.01.19 Privacy and safety: Identify patients at risk**
Overview of the requirement:	This is an extension of the requirement at 15.01.17 that focuses on the understanding that at-risk patients may present in any area of the hospital. The risk assessment is intended to be organization-wide although the tool or tools selected may vary based on the range of settings that the hospital manages.
Comments on deficiencies:	Deficiencies focus on the failure to implement patient risk assessment across all areas of the hospital and on policies that end with risk assessment rather than defining actions to be taken to ensure safety for those identified as at risk.
Frequency of citation:	12%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ During review of policies and procedures with the CNS, it was identified that the facility has not developed a house-wide policy regarding the identification and care of patients at risk for self-harm. ▪ During medical record review, 5 of 17 records did not contain a psychosocial assessment of risk of harm to self or others.

Examples of surveyor citations: (continued)	▪ The emergency department has adopted the Columbia Suicide Risk Assessment Tool. The hospital has adopted a different assessment tool for the inpatient population, but that tool is not based on nationally-recognized standards and guidelines. ▪ Policy defines the process of patient assessment but fails to define action(s) to be taken based on the risk level identified.
Tips for compliance:	▪ Policy should include evidence-based risk assessment tools appropriate for the patient population and specific care area. The policy should define when the risk assessment is performed, how frequently it is performed, by what healthcare professional roles, and which risk mitigation strategies are to be used based on the finding of the assessment. ▪ Recognize that there may not be a one-size-fits-all assessment tool, but any and all tools used must be evidence-based and part of an organization-wide process to provide a safe environment for all patients.

CHAPTER	STANDARD
16 Nursing Services	**16.01.01 Preparation and administration of drugs**
Overview of the requirement:	Drugs and biologicals are prepared and administered as ordered by relevant practitioners in accordance with federal and state law, and approved medical staff policies.
Comments on deficiencies:	Most deficiencies cited relate to non-compliance with hospital policies — especially those related to pain reassessment and timing of administration.
Frequency of citation:	16%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The hospital's Pain Assessment and Management Policy requires reassessment of patient pain level within one hour of medication administration. In 12 of 14 cases reviewed, reassessment exceeded policy. Documented reassessment ranged from 1½ to 4½ hours. ▪ The Medication Administration Policy identified time-critical medications for which dosing is required with 30 minutes of schedule. Staff does not monitor timeliness of medication administration as it relates to this policy and nurse interviews revealed that they are unaware of the policy and, therefore, not compliant with it.
Tips for compliance:	▪ Add medication policy review to annual staff training. ▪ Include metrics such as time of first dose of antibiotic or reassessment after pain medication administration as quality indicators to report to the QAPI committee. ▪ Pain assessment/reassessment policy must be evidence-based using nationally recognized guidelines with clear processes to reassess pain and physiologic measures within specific timeframes based on the route of medication administration.

CHAPTER	STANDARD
25 Pharmacy Services/ Medication Use	**25.01.03 Security of medications**
Overview of the requirement:	Drugs and biologicals are stored to prevent unmonitored access by unauthorized persons.
Comments on deficiencies:	Deficiencies primarily identify units, medication refrigerators, and medication and crash carts with unsecured drugs.
Frequency of citation:	13%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Replenishing crash carts after use goes from Central Supply for refilling (with the medication trays still in the cart), then to Pharmacy for replacement of the medication trays. Medication trays should be removed by Pharmacy prior to replenishment by Central Supply, then returned to Pharmacy for replacement of medications unless medication trays are separately secured. ▪ Two crash carts in respiratory therapy were located in an area with a push code lock. The code was known by unlicensed staff. ▪ Medication cart keys were located on a nail in the wall in the dermatology clinic. ▪ OR 12 had a 1,000 mg. bottle of propofol, ½ full, unsecured; endoscopy suite Room 2 had a 500 mg., unopened bottle of propofol, two canisters of sevoflurane, and one canister of suprane unsecured in the lower drawer of the anesthesia machine. ▪ The GI sterile supply room had an open drawer with one package of epinephrine, one package of atropine, and one bottle of phenylephrine accessible. ▪ Interview with the chief pharmacist, the director of nursing and the risk manager revealed that ORs are accessible to non-licensed personnel after closure of the unit. The mobile crash cart is not locked in a secure area.
Tips for compliance:	▪ Consider: locking the entire suite when not in use; placing non-mobile carts with drugs and biologicals in a locked room or otherwise secured area. ▪ Verify that policies define who has access to secure medication rooms. ▪ Environmental surveillance could include observation of secured medications and reporting to the Quality Committee.

Acute Care and Critical Access Hospitals — Deficiencies Cited in Physical Environment



Physical environment and life safety standards typically generate the highest number of deficiencies for inpatient settings.

Acute Care Hospital standard 11.00.01 and Critical Access Hospital standard 03.00.01, the CMS Conditions of Participation for Physical Environment are commonly cited as a result of aggregate deficiencies throughout the Physical Environment chapter and in the Life Safety chapter. Life Safety deficiencies are presented beginning on page 19.

Information on the following pages that applies to acute care hospitals will be identifed as “ACH.” Data from critical access hospitals will be indicated with “CAH.”

	STANDARD
	11.00.01/03.00.01 Condition of Participation: Physical Environment (ACH/CAH)
Overview of the requirement:	This is the condition-level requirement for the construction and maintenance of the hospital facilities with regard to their appropriateness and safety for the diagnosis and treatment of patients. The intent is to tie management of the built environment to patient, staff, and visitor safety.
Comments on deficiencies:	This CoP is most often cited as a result of aggregate deficiencies identified across the standards for physical environment and those for Life Safety (chapter 13 for ACH; chapter 14 for CAHs).
Frequency of citation:	40% (ACH); 17% (CAH)
Repeated frequent deficiency? *Previous frequency:*	Yes 68%
Examples of surveyor citations:	**Note:** The examples below reflect findings from the Physical Environment chapters only. See also pages 19-29 for additional, contributing deficiencies. ▪ Observations include lack of eyewash inspections; non-compliant air-pressure relationships and lack of testing evidence for air pressures… ▪ The organization did not have evidence of weekly eyewash station inspections; lacked labels for bio-hazardous exhaust at isolation room exhaust fans; did not carry-out fire drills at the required frequency of one per shift per quarter; lacked annual testing for battery-powered emergency lighting; lacked evidence of potable water testing; had scalding/burning water temperature at the handwashing sink in the kitchen; had non-compliant air pressure relationships to adjoining spaces; lacked a template for pre-construction risk assessments… ▪ The organization was observed to have the following issues: lacked performance improvement goals and objectives for management plans; could not provide Safety Data Sheets within a reasonable time frame; lacked evidence of a state or local fire control authority inspection; had no observable asset tags on the portable air conditioner equipment; positive air pressure relationship at a soiled utility room; portable cooling units used to compensate for inadequate utilities… ▪ Observations include blocked eyewash access and an eyewash requiring two actions to operate; lack of evidence documenting a list of security sensitive areas; lack of documentation that the fire alarm system is activated during fire alarm drills; improper pressure relationships for clean and dirty supply areas; a repurposed operating room housing soiled utility without altered air pressure relationships for compliance with the new use…

Examples of surveyor citations: (continued)	▪ Observations include: a compactor at the exterior of the building allowing unsecured public access; combustible towels left on top of an AHU; non-compliant eyewash stations or lack of access to an eyewash; lack of knowledge by staff regarding access to Safety Data Sheets; lack of consistent refrigerator temperature checks and documentation; patient call system pull-cord length too long; lack of equipment inspection for air-circulating fans; nuclear waste storage and combustibles located in an elevator mechanical room…
Tips for compliance:	▪ Develop a robust, quality-reporting plan for ongoing review of the physical environment with defined goals and benchmarking, results reporting, defined corrective action, and follow-up protocols.

STANDARD

11.01.02 Building safety (ACH)

Overview of the requirement:	Hospitals are expected to proactively review for elements that would allow at-risk patients to cause intentional harm to self or others, including ligature risk, unattended hazardous items, windows that can be opened or broken, unprotected lighting fixtures, unsecured objects considered dangerous, or other conditions with the potential to pose a risk. Hospitals are expected to address hazards and risk for specific patient populations, e.g. pediatric, geriatric.
Comments on deficiencies:	Deficiencies cited one or more items that posed a risk to patients. Some of these were a result of decisions made for staff convenience; others required a thorough review of the space from the perspective of risk avoidance.
Frequency of citation:	13%
Repeated frequent deficiency? *Previous frequency:*	Yes 24%
Examples of surveyor citations:	▪ Keys were observed left in the trash compactor controls allowing anyone to use the compactor; this area had no controlled access. ▪ In the Behavioral Health Unit, 3rd floor patient rooms 3101-3111, loose furniture was observed that could be used as a barricade or weapon. In the same patient rooms, bedside units with a drawer and shelf could be a ligature point. ▪ The lighting fixtures attached to ceiling-mounted electrical track in the public corridor near the entrance to Administration were suspended at a height approximately 76″ above the floor. This does not meet the minimum vertical clearance requirement of 80″ as required by the Americans with Disabilities Act.

Examples of surveyor citations: (continued)	▪ During the building tour, the following was observed: – Two large rolls of flooring material were stored in the MRI tech room and impeded direct egress from the room. When staff was questioned about the presence of these items, they stated that the flooring material had been stored in this room for six months. – An electric space heater that was not identified as being safety tested was observed in the Food Service office.
Tips for compliance:	▪ Read and understand each HFAP standard in chapter 11 to be sure you have a process and the documentation required by the standard. ▪ Be sure that patient safety risk assessments are written and followed. Facility and clinical staff should be involved in creating and using the same assessment tools. ▪ Train staff to be aware of the safety risk assessments and involved in identifying risks.

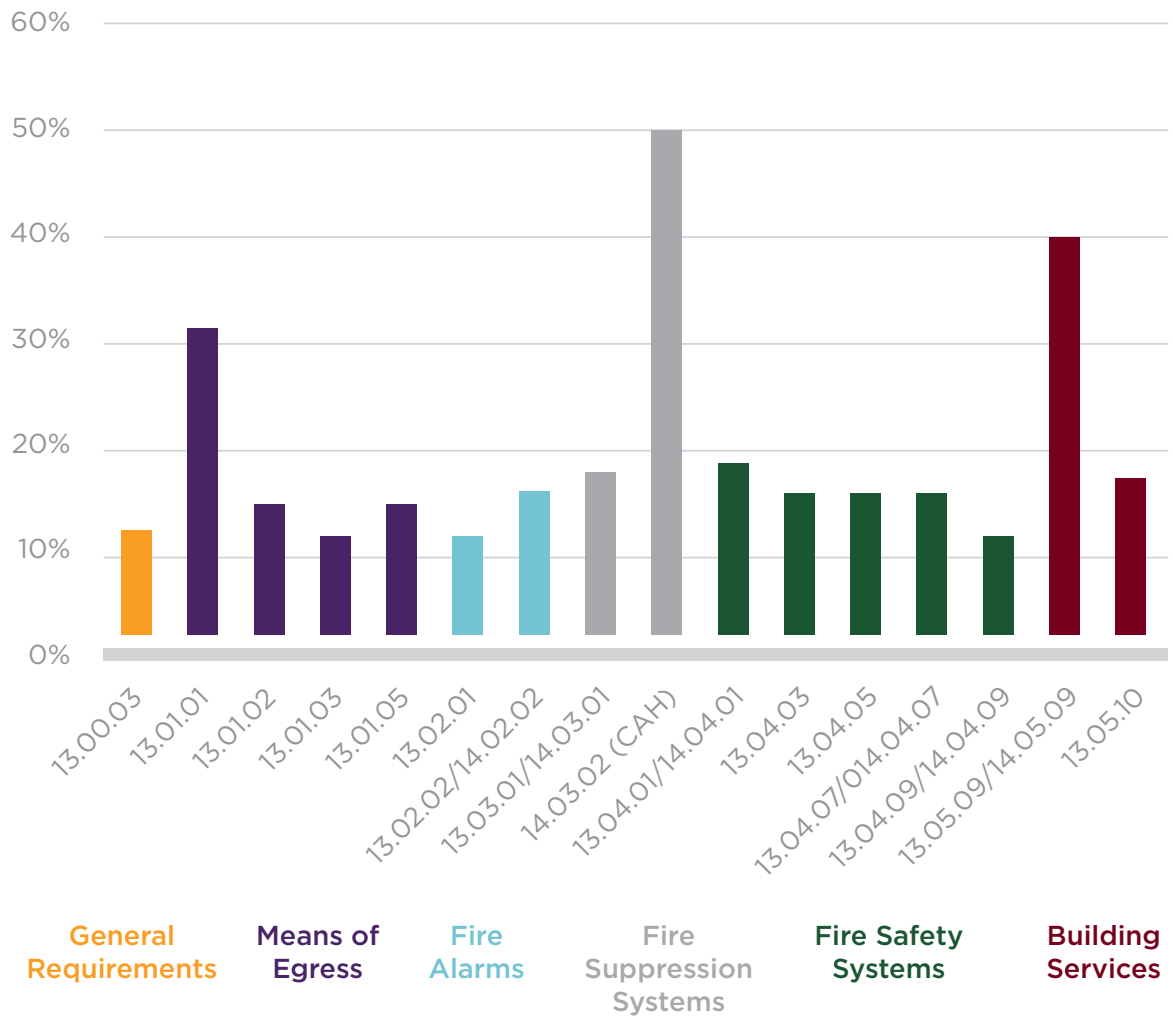
STANDARD	
	03.05.01 Medical Equipment and Systems – Maintenance (CAH)
Overview of the requirement:	Preventive maintenance and testing are performed on all medical equipment per a defined schedule or an Alternative Equipment Management (AEM) program.
Comments on deficiencies:	All medical equipment is subject to this standard. Deficiencies arise when documentation doesn't include a comprehensive list and individual confirmation that testing was performed.
Frequency of citation:	17%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The organization's medical equipment management plan requires the reporting of medical equipment maintenance completion to the Safety Officer. No report of the medical equipment maintenance completion was available for review to demonstrate that 100% of medical equipment maintenance was completed.
Tips for compliance:	▪ Create a comprehensive inventory of relevant equipment and calendar the scheduled maintenance/testing. ▪ Establish an ID for each piece of equipment. ▪ New equipment must be inventoried on the maintenance plan when put into service. **Note:** CMS requires 100% compliance with medical equipment testing and maintenance.

	STANDARD
	03.06.09 Plant Equipment and Systems – Maintenance (CAH)
Overview of the requirement:	Preventive maintenance and testing are performed on all plant (mechanical and electrical) equipment per a defined schedule.
Comments on deficiencies:	All plant and utility equipment is subject to this standard. Deficiencies arise when plant equipment is not included on the inventory and the organization cannot provide confirmation that testing was performed per the inventoried list.
Frequency of citation:	17%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Hot water was not available as follows: patient rooms and administrative back restroom had no hot water.
Tips for compliance:	▪ Create a calendar for equipment testing and respond promptly to failures. ▪ Review utility policies and standards to verify all components are accounted for. ▪ Be sure that all equipment used for heating, cooling, air movement, or water treatment (water heaters, pumps, etc.) are noted on the inventory and maintenance schedule.

	STANDARD
	11.07.03/03.07.03 Ventilation, light and temperature controls (ACH/CAH)
Overview of the requirement:	Hospitals must monitor lighting, temperature, humidity, and air pressure relationships against defined parameters to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort.
Comments on deficiencies:	Citations focused on incorrect air pressure relationships which increase the risk of spreading infection. In several cases, positive pressure ORs had been converted for use without an appropriate change in pressure relationship to adjoining spaces. A second focus of citations was discrepancy between policy for acceptable range of temperature and relative humidity and the log of actual temperature and humidity readings. In these cases, there was no identification of corrective action taken.
Frequency of citation:	33% (ACH, CAH)
Repeated frequent deficiency? *Previous frequency:*	Yes 47%

Examples of surveyor citations:	▪ Temperature and humidity logs maintained in each surgery room were observed to have temperature ranges between 64-68°F while logs indicated that temperature should be maintained between 68-73°F. Actual temperatures for ORs and policy need to be consistent. Relative humidity readings were consistently between 20-25% but the logs indicate that relative humidity should be 30-60%. The organization did not provide a risk assessment indicating equipment and supplies located or used in ORs had been tested to be tolerant of humidity levels below 30%. ▪ During the building tour, the following locations were observed to have non-compliant pressure relationships to adjoining spaces: – ED clean utility room was negative to the suite. – East wing clean utility was negative to the corridor. ▪ During document review, evidence of monthly or weekly logs for checking air pressure relationships of clean and dirty utility rooms was unavailable for review. ▪ The hospital had changed the use of OR 2 to mixed storage (trash bin, soiled linen, records, surgery equipment) and the room was still maintained in positive pressure to the sterile corridor.
Tips for compliance:	▪ Policy and procedures include processes and timelines for verification of conditions. They also should include steps to be taken when conditions fall outside of the defined range. ▪ Verification testing and corrective action need to be documented for proof of process and policy.

Acute Care and Critical Access Hospitals — Deficiencies Cited in Life Safety



The Life Safety standards (chapter 13 for acute care hospitals and chapter 14 for critical access hospitals) are organized by system (means of egress, fire alarms, fire suppression, fire safety, building services, etc.) and maintaining compliance across all systems challenges many organizations. The aggregate number of life safety deficiencies often results in a condition-level finding for physical environment. Standards discussed in this section are identified as acute care hospital requirements (ACH), or as critical access hospital requirements (CAH).

SECTION	STANDARD
General Requirements	**13.00.03 Alternative Life Safety Measures - Implementation (ACH)**
Overview of the requirement:	When an observed life safety deficiency cannot be immediately resolved (as during periods of construction, maintenance, or emergency repair) the hospital must implement its policy for compensating measures (ALSM).
Comments on deficiencies:	Deficiencies at this standard are often paired with the preceding standard: 13.00.02. The first requires a policy on ALSM; 13.00.03 focuses on implementation of the policy. Most deficiencies reflected an observed failure in a system or element thereof, without action taken to mitigate risk.
Frequency of citation:	12%
Repeated frequent deficiency? *Previous frequency:*	Yes 26%
Examples of surveyor citations:	▪ During document review, the annual fire alarm test report dated 4/19/2019 stated that the following devices failed at [offsite location redacted]: 23 smoke detectors, 2 heat detectors, and 15 notification devices. The hospital explained that [the location] is no longer occupied and is expected to be decommissioned. During the days of survey, the fire alarm panel was observed to show two active issues associated with the devices at [the location]. The hospital did not conduct a risk assessment for the failed devices on the test report and explained that this condition had existed for about nine months. The hospital has not completed an ALSM risk assessment for the Life Safety Code deficiencies. ▪ During document review, the organization did not present evidence that ALSM had been implemented when the annual fire pump test performed in January 2019 resulted in a failure to transfer to emergency power and back to normal power under peak load. ▪ During document review, evidence was not provided for an ALSM assessment for repair projects including demolition of the current pain procedure scrub sink and the ED walk-in entrance.
Tips for compliance:	▪ Anytime that a life safety requirement is not in compliance for fire alarm, sprinkler system, building component, or egress element, ALSM must be implemented per the facility ALSM assessment and policy. ▪ An ALSM assessment must also be completed for all construction or modification work, even if the ALSM determination is that no compensating measures are required.

SECTION	STANDARD
13.01 Means of Egress	**13.01.01 Doors** (citation frequency: 31%) (ACH) **13.01.02 Door locks** (citation frequency: 12%) (ACH) **13.01.03 Corridor clutter** (citation frequency: 12%) (ACH) **13.01.05 Signage** (citation frequency: 15%) (ACH)
Overview of the requirement:	Means of egress standards address provision of a safe, protected means of travel from any point in the building to the exterior during emergency situations, especially fire and smoke incidents. The cited standards focus on requirements for doors within the egress pathway, the access provided by the pathway itself, and how egress access is communicated.
Comments on deficiencies:	Deficiencies were cited primarily for non-latching doors that would fail to protect a corridor in case of a smoke or fire incident, egress doors with non-compliant locking systems, moveable items reducing corridor width, and insufficient signage.
Examples of surveyor citations:	**13.01.01** ▪ A door to the upper mechanical room area was observed to be blocked from opening to ninety degrees by the flange of an operable air grille assembly. ▪ Sliding glass patient room doors at exit access corridor walls were incapable of latching at the 7th floor Critical Care Unit and at rooms 3045, 3046, 3047, 3048, 3049, and 3050. Doors within the path of egress in Behavioral Health were observed to not swing in the direction of egress when traveling toward the northwest exit stair. Side-hinged, swinging doors serving surgery room entrances at exit access corridor walls were observed to be incapable of latching. The life safety drawings gave no indication that Surgery is enclosed within a suite of rooms which would allow the doors to remain unlatched. **13.01.02** ▪ According to the Facilities Demographic Report (FDR) and as confirmed during the building tour, the building is not fully fire-sprinklered nor fully smoke detected. – The Emergency Department hallway door in the means of egress is labeled as fifteen-second delayed egress but when tested, it did not release for over thirty seconds. – A magnetic locking system that does not meet the requirements of the Life Safety Code for locking systems located in the means of egress was observed at the double doors near room W211, 2nd floor. These locking systems do not comply with the required provisions under the Life Safety Code, 2012 Edition.

Examples of surveyor citations: (continued)

- The floor level door at stair tower A-1 was observed to be delayed egress and provided with compliant signage. The door had a cylindrical doorknob and did not have a panic bar thus preventing the ability of an occupant to push the door to start delayed egress functionality and release within 15 seconds.
- An access control locking system was observed to be installed on the double doors at the NICU. The access control hardware did not meet the requirements for access control under the Life Safety Code. The motion sensor mounted on the egress side of the doors did not release the doors and the "Push to Exit" button was mounted more than five feet (5′-0″) from the doors on the egress side.

13.01.03

- At the hospital at [location redacted], a workstation on wheels was observed to be left unattended and obstructing the minimum 8'-0" width required at the exit access corridor near patient room 436.
- The minimum 8′-0″ required width at the exit access corridor in the physician's sleep area was observed to be obstructed by three baby cribs, two litters, and three mattresses.
- Five workstations on wheels were observed to be left unattended and obstructing the minimum 8′-0″ width required at the exit access corridor at the 2 Main nursing station.

13.01.05

- The facility was observed to use its work order system to document monthly illuminated exit sign inspections, which were noted as 'pass.' The work order did not provide for a unique identifier for each exit sign location to document a pass or fail for each individual device.
- The lower level glass patio door did not have a "NO EXIT" sign. It was not readily apparent that there was not an exit from the patio.
- During document review for the Rehabilitation Center, the hospital could not provide documentation for monthly inspection of the battery-operated Exit signs. During the building tour no exit sign was visible from the north end of the adult rehabilitation gym area.
- The exterior set of glass doors near the Facility Department offices was observed to lead to an outside exit discharge without a sidewalk leading to a public way. As this path appears to be an exit path but was not labeled as an exit, this set of doors is required to be labeled with compliant signage stating "NO EXIT" per NFPA 101, the 2012 edition of the Life Safety Code.

Tips for compliance:	▪ Use facility rounding to manage recurring compliance issues with clutter and blocked door swings. ▪ Review life safety plans to confirm that they do not show non-compliance. ▪ Illuminated exit signs may not be blocked and must be located to label egress correctly. ▪ Doors that may be mistaken for egress doors but are not part of the means of egress must be posted with signage stating "NO EXIT" in compliance with NFPA 101.

SECTION	STANDARD
13.02/14.02 Fire Alarms	**13.02.01 Installation and Maintenance** (citation frequency: 12%) (ACH) **13.02.02/14.02.02 Testing** (citation frequency: 16%) (ACH, CAH)
Overview of the requirement:	Fire alarm systems must be installed and maintained in accordance with NFPA 101 (2012 edition) and NFPA 72 (2010 edition). Basic and secondary components must be tested at specified frequencies.
Comments on deficiencies:	Deficiencies reflect poorly located smoke detectors and missed elements of system testing (or missing documentation thereof).
Examples of surveyor citations:	**13.02.01** ▪ The following areas have smoke detectors within 3′–0″ of return or supply air grilles: 1. Seventh floor housekeeping closet. 2. First floor administration corridor (two detectors). 3. Kitchen bakery area. ▪ Smoke detectors were observed to be mounted more than 12″ from the deck in open ceiling rooms, including: 1. Seventh floor machine room. 2. Third floor electrical room 3201. 3. Second floor electrical rooms 2513, 2107, and 2505. 4. First floor medical vacuum room. In room 1206, smoke detector 1-045 was mounted less than 36″ from a diffuser. ▪ The new cardiovascular physician sleep room did not have a smoke detector installed.

Examples of surveyor citations: (continued)	**13.02.02/14.02.02** ▪ During document review, no documentation after 2017 was available for the fire pump interface relay testing. ▪ The following interface relays and modules were not identified in the test report: 1. Air handler shut down. 2. Kitchen hood suppression system. 3. Elevator recall. 4. Magnetic locks/electric strikes. 5. Fire pump. 6. Smoke dampers. 7. CO_2/clean agent suppression. 8. Sprinkler dry-pipe/pre-action.
Tips for compliance:	▪ The presence of a smoke detector is not always sufficient to ensure compliance. Review locations relative to other features per NFPA requirements. ▪ Review the testing requirements under both NFPA 72 and HFAP standards to verify that the documentation will portray and recreate testing activities. Since these activities cannot be witnessed by surveyors, the testing documentation is legal proof and evidence of how the activity was performed and whether it would pass or fail testing.

SECTION	STANDARD
13.03/14.03 Fire Suppression Systems	**13.03.01/14.03.01 Water-based fire protection: Installation and maintenance** (citation frequency: 18%) (ACH, CAH) **14.03.02 Water-based fire protection: Testing and inspection** (citation frequency: 50%) (CAH)
Overview of the requirement:	Fire suppression systems standards address both water and non-water-based fire suppression components with regard to installation, maintenance and testing.
Comments on deficiencies:	Most deficiencies cited reflect a change in condition post-installation. System components must be maintained to have their intended reach and functioning unimpaired.

Examples of surveyor citations:

13.03.01

- The organization's FDR identified the facility as fully sprinklered. During the building tour, the following observations were made:
    1. The nitrous oxide manifold room was not equipped with automatic fire suppression sprinklers.
    2. Three hazardous materials storage rooms located at the dock area were not equipped with automatic fire suppression sprinklers.
    3. Escutcheon plates were observed to be missing from fire suppression sprinkler heads at the following locations…
- The hospital did not have a document identifying the different types of sprinkler heads in the facility and the required number of spare heads needed. A wrench for sprinkler head removal and replacement in the fire pump room in the basement was not available. Sprinkler heads were observed to be dirty:
    1. In the first floor ED physician room.
    2. In the fourth floor electrical room.
    3. Throughout the lower level.

  The following areas had missing escutcheon plates:
    1. Second floor in the MIPS staff lounge.
    2. Second floor, dialysis room 212.
    3. Lower level, laundry curtain room.

14.03.02

- During document review, the following observations of noncompliance with the NFPA 25 requirements were made relative to the Fire Suppression Systems Test Report:
    1. The monthly pressure gauge inspections were not documented.
    2. The quarterly fire department connections inspection was not documented.
    3. The fire system primary backflow preventer annual testing was not documented.

Tips for compliance:

Maintain an inventory of all equipment components and include inspection on regular rounding of the physical environment, including areas about the ceiling.

CHAPTER	STANDARD
13.04/14.04 Fire Safety Systems	**13.04.01/14.04.01 Fire-rated barriers** (citation frequency: 16%) (ACH, CAH) **13.04.07/14.04.07 Fire-rated door assemblies** (citation frequency: 16%) (ACH, CAH) **13.04.09 /14.04.09 Ceilings** (citation frequency: 12%) (ACH, CAH)
Overview of the requirement:	Fire safety systems reflect standards for building construction and maintenance designed to impede the ability of smoke or fire to travel through the structure.
Comments on deficiencies:	A few deficiencies result from actual construction that is inconsistent with construction type; more often, it is subsequent maintenance (or lack thereof) that results in a deficiency. When a fire safety deficiency is observed, whether a single example or in multiple locations, each observation will be cited.
Examples of surveyor citations:	**13.04.01/14.04.01** ▪ An incomplete one-hour rated drywall assembly was observed at the ground floor corridor, SPD hallway, across from the locker rooms. The assembly was missing drywall above the ceiling, thus impairing the one-hour fire rating of the wall. ▪ The fire barrier in Labor and Delivery between rooms 139 and 137 was not installed per the life safety drawings which called for two-hour construction. It was built as single ⅝″ gypsum board on one side of the wood studs only and contained non-rated, egress double doors. Data cables were observed in an unprotected penetration in a two-hour rated wall assembly above the 90-minute fire doors at patient room 102. A two-inch sleeve and another data cable wire were unprotected penetrations above the 90-minute fire-rated doors at the barrier adjacent to the radiologist office. ▪ Above the ceiling at the entrance to Inpatient Rehab, one 3″ conduit and one ¾″ conduit were observed to be penetrating the rated assembly and were unprotected. On the third floor, at the entrance to the Heart Center, a 10″ duct was observed to go through a two-hour fire rated barrier and did not have a fire damper installed. The wall was noted as a two-hour fire rated barrier per the Life Safety Plans. At the second floor two-hour rated building separation between the Women's Center and the Outpatient Center two unprotected 4′ low voltage conduits were observed to be going through the rated assembly.

Examples of surveyor citations: (continued)

13.04.07/14.04.07

- The fire-rated doors at the one-hour fire rated barrier at the second-floor case management office did not have a legible label and one leaf did not latch upon closure.

  The fire-rated door at the second floor east in a one-hour fire and smoke barrier did not have a fire rating label.

  At the Birth Center, in the one-hour rated fire/smoke barrier at the north corridor, one leaf of the set of fire doors did not latch upon closure.

- At the [location redacted], the 90-minute fire-rated door from the generator room to the electrical switch gear room was observed to be held open by a piece of steel I-beam.

- The door rating label on the door to the south stair in the obstetrics unit was painted over and no longer legible.

13.04.09/14.04.09

- The following instances of gaps greater than ⅛″ at the smoke deck in rooms that had fire sprinkler coverage were observed during the building tour:

  1. On the first floor in the Cath Lab equipment room, there were gaps around 3″ electric conduits and one missing ceiling tile.
  2. At the first floor MRI mechanical room, several gaps were observed around conduits and equipment at the ceiling. In some areas there were no ceiling tiles installed.
  3. At the first floor Lab ceiling, gaps were observed around conduits located at the ceiling throughout the space.
  4. The kitchen pots and pans room has three ceiling gaps around pipes near the hood area.

- Multiple 2′ by 2′ ceiling access panels were observed to be open to the room throughout the 7th floor. All of the rooms were provided with fire sprinklers. A 2′ by 4′ section of ceiling tile was missing in the suspended ceiling in Room 712. This room has fire sprinklers and a smoke detector.

Tips for compliance:

- Review the physical state of rated assemblies and smoke partitions, especially when above ceiling systems are changed or installed. Rated doors are high-use items and their state of compliance may not be consistent from one annual inspection to the next.
- Promote the practice of reporting maintenance issues promptly throughout the organization.
- Identify a list of approved fire-stopping materials and wall repair designs and use these consistently throughout the facility.

CHAPTER	STANDARD
13.05/14.05 Building Services	**13.05.09/14.05.09 Utility systems** (citation frequency: 40%) (ACH, CAH) **13.05.10 Medical gas systems and equipment maintenance** (citation frequency: 18%) (ACH)
Overview of the requirement:	This section defines requirements for systems other than fire suppression within the hospital.
Comments on deficiencies:	When a system deficiency is observed, whether a single example or in multiple locations, each observation will be cited. When aggregated, these deficiencies can rise to the condition level.
Examples of surveyor citations:	**13.05.09/14.05.09** ▪ Access to the emergency generator 480-volt switchboard in the basement of [location redacted] was obstructed by a large pulling rope bundle. The switchboard did not have the required 36″ clearance. Access to the main distribution panel in the mechanical room in the basement was obstructed by conduit bending equipment and the panel did not have the required 36″ clearance. The pull cords for the nurse call system duty stations in the bathrooms of rooms 366, 368, and 372 of the Obstetrics Unit were more than four inches above the floor. The two-hour fire-rated door to the generator room was blocked by a large gang box that belongs to a mechanical contractor. One open electrical junction box with exposed wiring was observed above the ceiling on the fourth floor in the corridor above fire alarm system pull station #6-57. Two open electrical junction boxes with exposed wiring were observed above the ceiling on the third floor Respiratory Therapy corridor. ▪ An electrical junction box in the third floor, east wing electrical closet was missing its cover. ▪ In the Emergency Department, the following issues related to electrical equipment were observed: 1. At the staff office near the main ED waiting area, electrical panels SLP1A and 11-CRLP-1 were not locked. Staff confirmed that the panels were to be locked per the organization's policy. 2. At the exam rooms across from the staff office, access to electrical isolation panels ISO-CRLP1 and ISO-SLP1A was obstructed by an equipment cart (leads attached). 3. At the hand sink station across from Soiled Utility 1522, access to a light switch for the station was obstructed by a floor-standing ice maker.

Examples of surveyor citations: (continued)

- Above ceilings in six locations throughout the facility, electrical wires and Cat 5 cables were observed to be supported by or zip-tied to conduit or fire sprinkler piping.
- An outlet box was observed in OR 3 that had been built in-house and was not a Special Purpose Relocatable Power Taps (SPRPT) listed as UL 1363A or UL 60601-1, as required.
- On the third floor connector electrical room, the panel schedule for electrical panel ELCB4N was not properly labeled. Some of the breakers labeled as spares were in the ON position.
- At the bulk oxygen storage tanks located outside the building, woodchip mulch was spread along the entire length of the bulk oxygen storage system. Per NFPA 99, 2012 edition, no combustible items can be stored within 10′-0″ of bulk oxygen tanks and the emergency fill hook-up, where there was mulch as well.

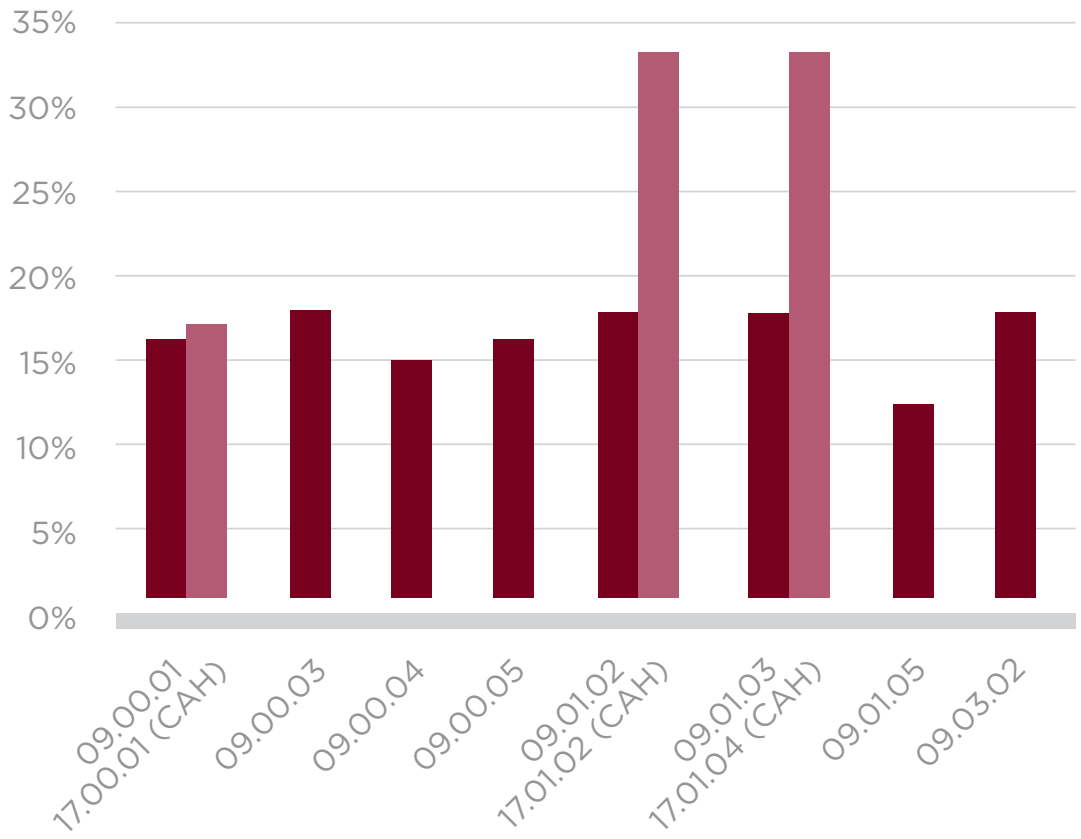
13.05.10

- The organization's medical gas policy did not specify the frequency of testing the medical gas system.
- The Receiving Dock medical gas storage room had only one vent which was 6′ from the top of the ceiling. This room requires either natural ventilation, with one vent located 12″ from the ceiling and another located within 12″ of the floor, or mechanical ventilation designed with venting and makeup air.
- The medical gas outlet test report dated 7/12/2019 documented medical gas outlets in the patient rooms 3, 7 and 14 as "not tested." The organization's medical gas testing policy requires outlet testing to be completed annually.
- The medical gas tank storage area as well as the N_2O medical gas tanks and manifold located outside of the facility were not protected from direct sunlight exposure as required by NFPA 99, 2012 edition, section 11.6.5.4.
- In the Laboratory Department, access to CO_2 cylinders were blocked by boxes.

Tips for compliance:

- Conduct regular facility rounding to verify compliance and follow through immediately to correct deficiencies.
- Verify that medical gas testing documentation will portray and recreate activities. Since this testing cannot be witnessed by surveyors, the documentation is legal proof and evidence of how you performed an activity and the result of that activity.

Acute Care Hospitals and Critical Access Hospitals — Deficiencies Cited in Emergency Management



In 2019, eight acute care hospital standards from chapter 9 and three CAH standards from chapter 17 were cited on more than 10% of all surveys. The graph above identifies standards by number (as published in *Accreditation Requirements for Acute Care Hospitals*, 2018v2 edition and *Accreditation Requirements for Critical Access Hospitals*, 2018 edition) on the horizontal axis and by frequency on the vertical axis.

	STANDARD
	09.00.01 Condition of Participation: Emergency preparedness (ACH) **17.00.01 Condition of Participation: Emergency Preparedness** (CAH)
Overview of the requirement:	The condition-level requirement is for a comprehensive program that meets the health, safety, and security needs of staff, patients, and the community in an emergency.
Comments on deficiencies:	This condition is cited as a result of aggregate deficiencies identified across the standards within this chapter. Depending on the severity of individual citations, more than four or five standards out of compliance may result in the Condition of Participation being cited.
Frequency of citation:	16% (ACH); 17% (CAH)
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Medical supplies, pharmaceutical supplies, and general equipment designated for emergency response are not inventoried, documented, or reviewed and updated semi-annually; written agreements with vendors, suppliers, or other vendors intended to provide utilities during an emergency event were missing or outdated; a written policy addressing a system to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency was not available; a written policy addressing the means to shelter in place for patients, staff, and volunteers who remain in the facility during an emergency event was not available; emergency management policies and procedures do not address a comprehensive process to provide for the security of the patients, staff and visitors during an emergency event; and there was no evidence of annual training for Medical Staff regarding Emergency Management. ▪ The organization was lacking documentation that the Hazard Vulnerability Analysis (HVA) and the Emergency Operations Plan (EOP) had been shared with community partners; the EOP did not identify the services the hospital has the ability to provide during an emergency event; the EOP did not address a system to track on-duty staff and sheltered patients during an emergency; and the EOP failed to specify the locations to which patients would be evacuated. ▪ The Emergency Operations Plan (EOP) function is not integrated into the QAPI program; multiple policies identified as part of the EOP were not referenced in the EOP base plan within the written text or by electronic link; potential Nutrition department equipment failure and dishwasher failure had not been addressed in the EOP; the EOP did not contain a written section or referenced policy that clearly distinguished the verification requirements between clinical and non-clinical volunteers; the EOP did not contain a section in the base plan that describes decontamination protocols or references the hospital's existing decontamination policies; the EOP communication plan did not contain contact information for hospital volunteers; evidence of emergency exercises had not been provided for off-site locations.

Tips for compliance:	▪ Read the standards to determine specific HFAP requirements to be delineated within your policies and procedures. ▪ Use the 2020 public health emergency as a chance to review lessons learned. ▪ Promote a culture of inclusiveness and communication between the Emergency Preparedness Officer/designated EM staff leader and other departments that play a role under Emergency Operations through frequent committee meetings and drill evaluation.

	STANDARD
	09.00.03 Emergency Operations Plan (ACH)
Overview of the requirement:	The emergency operations plan (EOP) is intended to provide an organization-wide framework to manage the range of foreseeable risks that the hospital and/or the community at large could face.
Comments on deficiencies:	Deficiencies cited one or more individual elements missing from the EOP or a failure to share the plan with other emergency response agencies beyond the hospital walls.
Frequency of citation:	18%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The organization was not able to provide documentation to confirm the hospital had shared or attempted to share their EOP with local authorities and reviewed it with the community emergency preparedness and response stakeholders. ▪ The frequency of plan updates could not be determined due to a lack of evidence for past revision dates for the plan. ▪ Documentation was not provided to show that the EOP had been approved by the Safety Committee within the past 12 months. ▪ Based on review of the EOP and the Quality Committee meeting minutes, was no evidence that emergency management is integrated into the facility-wide QAPI plan.
Tips for compliance:	▪ Define and schedule the process of update and review of the EOP beginning with the annual Hazard Vulnerability Analysis, continuing through every department (including the QAPI function) and closing with communication to local authority within the community to ensure continuity of services and collaboration in the event of an emergency. ▪ Use lessons learned from the 2020 public health emergency to strengthen the current EOP. ▪ Under current HFAP standards, the accredited organization will only have to show that they notified other emergency response agencies about their EOP.

	STANDARD
	09.00.04 Patient population
Overview of the requirement:	The Emergency Operations Plan (EOP) considers and addresses the range of individuals who may be considered "at-risk" in the event of an emergency, including those with limited mobility needs who would need additional assistance in the event of evacuation.
Comments on deficiencies:	Deficiency citations uniformly identified that at-risk patient populations were not identified in the EOP.
Frequency of citation:	15%
Repeated frequent deficiency? *Previous frequency:*	Yes 26%
Examples of surveyor citations:	▪ The EOP did not contain information regarding at-risk patient populations within the hospital; these include individuals with disabilities, with limited English proficiency or who are non-English speaking, with chronic medical disorders, or pharmacological dependency. The EOP did not include a plan for an influx or surge of patients. ▪ The EOP did not include definitions of at-risk populations of patients and visitors who may require attention during a surge event or those at-risk in the event of an evacuation. ▪ During review and discussion of the EOP, it was noted that prison inmates are transported to the hospital for medical care. The inmates' special population requirements are not included in the EOP.
Tips for compliance:	▪ Cross reference the EOP against each hospital department to ensure that the range of "at-risk" patients is addressed in the plan.

	STANDARD
	09.00.05 Services
Overview of the requirement:	The Emergency Operations Plan (EOP) must include identification of the services that the hospital will continue to furnish under activation of the plan including an identification of staff roles and a plan for implementation of these services in an emergency.
Comments on deficiencies:	Non-compliance was frequently linked with other standards in this chapter, resulting in a finding of deficiency at the condition level (see 09.00.01).
Frequency of citation:	15%
Repeated frequent deficiency?	No

Examples of surveyor citations:	▪ The EOP did not identify the types of services that the hospital has the ability to provide under activation of the EOP. ▪ The EOP did not address the assumption of specific roles through succession planning and delegation of authority in the absence of the individual legally responsible for operations of the facility. ▪ The EOP did not include identification of services that can function in an emergency because they are organized to not be affected by staff shortages or utility failure.
Tips for compliance:	▪ Verify with each department in the organization what can be provided during an emergency. Example: Radiology may not be available if the hospital is running on emergency power or a mobile PET scan will be unavailable. Example: If dialysis will not be provided during an EM event, patients may need to be transferred. ▪ All services need to be evaluated and those that can be provided shall be listed in the EOP.

STANDARD	
	09.01.02/17.01.02 Nutritional Services (ACH/CAH)
Overview of the requirement:	The hospital emergency plan must address strategies for meeting nutritional needs in the event that services or utilities are interrupted. The plan includes calculating and inventorying the volume of food, drinking water, and supplies needed to sustain patients, staff, and visitors who may be sheltered in place for up to three days.
Comments on deficiencies:	Most deficiencies resulted from missed required elements of the EOP or lack of knowledge within the nutrition department with regard to emergency equipment.
Frequency of citation:	18% (ACH), 33% (CAH)
Repeated frequent deficiency? *Previous frequency:*	Yes (ACH only) 18%
Examples of surveyor citations:	▪ The EOP lacked a defined and stored three-day inventory of: – Fresh and frozen foods – Dairy products – Drinking water – Paper products – Special dietary requirements, e.g. diabetic, Kosher, vegetarian. ▪ During department review, the dietary department head indicated that there was no calculation of the volume of food, drinking water, paper products, and utensils needed to feed patients, staff, and visitors for at least three days.

Examples of surveyor citations: (continued)	▪ The Nutrition Department EOP lacked a description of how the department would respond to: 1. Fuel loss and generator failure. 2. Equipment failure (dishwashing, refrigeration, pumps, cooking appliances). Nutrition department staff did not know which equipment is powered by the emergency generator.
Tips for compliance:	▪ Provide a detailed and quantitative outline of menus, supplies, required inventory, and means of preparation under emergency circumstances. Show the assumptions for occupancy and the math used to determine quantities required.

STANDARD

09.01.03 Supplies (ACH)

Overview of the requirement:	The standard requires an inventory of medical and pharmaceutical supplies and equipment, documented and reviewed semi-annually, to meet the basic needs of patients and staff who may be sheltered in place during an emergency.
Comments on deficiencies:	Citations often indicated partial compliance with a or lack of semi-annual review of inventoried emergency supplies.
Frequency of citation:	18%
Repeated frequent deficiency? *Previous frequency:*	Yes 18%
Examples of surveyor citations:	▪ Semi-annual review of the emergency supply list and inventory had not been documented. ▪ The facility lacked an inventory of emergency medical supplies, pharmaceutical supplies, and equipment. ▪ The EOP did not address a means of emergency supply replenishment. ▪ No policies and procedures for emergency pharmaceutical supplies, medical supplies, or general equipment was available for review. ▪ While the hospital maintains medical supplies, pharmaceutical supplies, and equipment stored for immediate use in an emergency, there is no evidence that an inventory is performed, reviewed, and documented semi-annually.
Tips for compliance:	▪ Provide a detailed and quantitative inventory of supplies. ▪ Schedule and document the semi-annual review per the inventory list; evaluate individual levels of items on the inventory against the calculated quantities required.

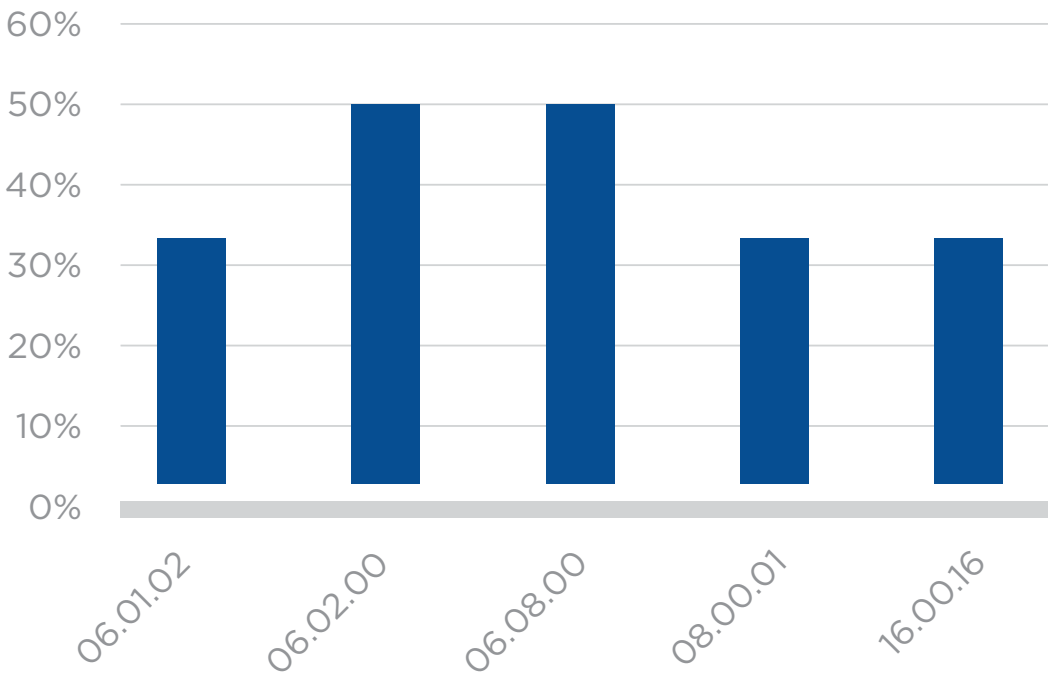
	STANDARD
	17.01.04 Utilities (CAH)
Overview of the requirement:	The Critical Access Hospital must ensure the operation of strategic utilities in the event of an emergency.
Comments on deficiencies:	Citations identified missing policies for multiple utilities.
Frequency of citation:	33%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ There was no policy available for review related to alternate sources of energy. There were no written agreements presented from vendors, suppliers or others to provide the following utilities: a. Service and repair for generators. b. Replenishment of fuel for generators and boilers. c. Portable cylinders of medical air and gases. d. Portable vacuum. e. Non-potable water.
Tips for compliance:	▪ Inventory all critical utilities with alternate operational solutions. Review and confirm annually.

	STANDARD
	09.01.05 Patient and Staff Tracking (ACH)
Overview of the requirement:	The intent of the standard is to reflect the responsibility of the hospital for those within its care during an emergency. The ability to locate individuals is essential to meeting this responsibility.
Comments on deficiencies:	While citations were consistent and directly stated that the requirements of the standard were missed, non-compliance was frequently linked with other standards in this chapter, resulting in a finding of deficiency at the condition level (see 09.00.01).
Frequency of citation:	12%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ A written policy to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency was not available for review. ▪ The policy did not address patient and staff transfers to other facilities.
Tips for compliance:	▪ The facility must outline what system or paper-chain is used to track on-duty staff and sheltered patients so their whereabouts are known for in-house communication or other issues.

	STANDARD
	09.03.02 Emergency Exercises (ACH)
Overview of the requirement:	Emergency exercises are the basis of a testing program for the Emergency Operations Plan. The goal of this standard is to analyze the hospital's response to drills — across all locations — in order to evaluate and revise the EOP as needed.
Comments on deficiencies:	All but one citation of deficiency was due to the failure to conduct emergency exercises at all off-site locations delivering patient care. **2020 Note:** Under current HFAP Standards, the annual exercises may alternate between a community-based or facility-based exercise and, a functional exercise, a drill, or two tabletop exercises.
Frequency of citation:	18%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The hospital could not demonstrate that a minimum of one annual emergency drill was carried out for 6 of 7 off-site locations (Business Occupancies) in which patient care is provided. ▪ Off-site locations have not had an emergency preparedness drill within the prior year. ▪ After-action reports for emergency exercises had not been shared with any committee having oversight of the emergency management program.
Tips for compliance:	▪ Emergency exercises must include the participation of all locations and all staff. ▪ Be sure all provider-based care sites and business occupancies housing an organization's staff participate in required annual emergency exercises; if services are billed under the organizations' CCN, it must participate.

Notes

CAH Clinical Standards



On 2019 surveys of critical access hospitals (CAH), 5 clinical/administrative standards, 11 related to the physical facility (including 7 life safety standards detailed on pages 19-29), and 3 related to emergency management (pages 30-37) exceeded the threshold of 10% to be categorized as "frequent deficiencies." The clinical/administrative standards are listed in the graph above. The horizontal axis identifies the standard by number (as published in *Accreditation Requirements for Critical Access Hospitals*, 2018 edition) and the vertical axis shows the frequency with which that standard appeared in an HFAP Deficiency Report.

CHAPTER	STANDARD
06.01 Provision of Services: The Preparation and Administration of Medications	**06.01.02 Medication administration**
Overview of the requirement:	Drugs and biologicals are prepared and administered as ordered by relevant practitioners in accordance with federal and state law, and approved medical staff policies.
Comments on deficiencies:	Deficiencies cited incomplete orders and non-compliance with hospital policy regarding pain reassessment after medication administration.
Frequency of citation:	33%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Medical record review identified an order written as "20mEq IVPB now." The medication administration record indicated a nurse administered 20mEq of potassium in 50 ml of normal saline to a patient. This IV medication was administered despite an order with: – No medication listed. – No identification of IVPB solution. – No amount of IVPB to be administered. ▪ Two of seven charts reviewed lacked documentation of a pain reassessment within one hour of pain medication administration, per hospital policy.
Tips for compliance:	▪ Include documentation of pain reassessment as a quality indicator to report to the QAPI committee. ▪ Pain assessment/reassessment policy must be evidence-based using nationally recognized guidelines with clear processes to reassess pain and physiologic measures within specific timeframes based on the route of medication administration.

CHAPTER	STANDARD
06.02 Provision of Services: Infection Control	**06.02.00 Infection control**
Overview of the requirement:	The standard is broad and encompasses controlling the spread of infection across all locations. Infection control is assessed through observation of sanitary environments and infection control practices, management of communicable disease outbreaks, documentation of staff training, surveillance, and corrective actions.
Comments on deficiencies:	Citations document a range of issues from environmental conditions to observed breaches in practice.

Frequency of citation:	50%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Doors with exposed raw wood, which cannot be appropriately cleaned, were observed in the following areas: 1. OR Suite 5: The interior surface of the door leading into the suite has a 6 inch-area of exposed raw wood. 2. OR Suite 3: The interior surface and edge of the door leading into the suite has an area that measures 12 inches that is partially taped with exposed raw wood. In Obstetrics, doors with exposed raw wood were observed: 1. In the dirty utility room. 2. Inside the intensive care nursery door. ▪ Corrugated cardboard shipping boxes were not broken down in a separate room or storage area; instead, the boxes with their contents were transported to their site of usage, including: 1. The storage room for dry goods (food products). 2. The storage room for clean patient supplies. ▪ Multiple divots were observed in the flooring of OR #3 and OR #4; these divots measured ¼–⅜ inch in length and up to ⅛ inch depth. ▪ Masks, goggles/face shields or hand sanitizer were not present on the contact isolation cart being used for a patient on contact isolation. ▪ The facility's back up isolation cart located on the med-surg unit in the supply room had not been stocked. ▪ On the medical-surgical unit, the door of a patient room on contact isolation remained open to the corridor and was never closed.
Tips for compliance:	▪ Develop a written plan for infection control that defines how it is applied by each department/unit. ▪ Provide education to staff on entering maintenance work orders to address infection control issues when found, e.g. chipped paint, damaged door jambs with exposed wood, stained ceiling tiles, bugs in light fixtures, etc. ▪ Conduct infection control rounding and submit surveillance reports to relevant committees. Celebrate observations that lead to improvement in practice or conditions.

CHAPTER	STANDARD
06.08 Provision of Services: Nursing Services	**06.08.00 Nursing Services**
Overview of the requirement:	An RN must provide or assign qualified, competent nursing care for each patient to meet the patient's needs.
Comments on deficiencies:	Most deficiencies related to staffing level; either practice did not align with hospital policy or staffing patterns indicated insufficient nursing care to meet the needs of patients.
Frequency of citation:	50%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The policy "Assignment of Care – Patient Acuity" failed to address the number of staff required for the acuity of the unit and minimum staffing levels. The processes defined do not match the current process: – Acuity totals are to be documented on the nursing assignment sheet. No acuity levels were located on the assignment sheets reviewed (May 1 – July 31, 2019). ▪ The facility was unable to demonstrate it had sufficient staff to provide the services essential to ensure patient care. The facility has asked or required nursing staff to come in early or stay late on: – Day shift: 21 of 93 days – Night shift: 8 of 93 days ▪ The facility scheduled nursing staff to work stretches of 12 to 16 hours each for four to seven consecutive days for four of the twelve weeks reviewed. ▪ Based on review of the nursing schedule, on June 26th, the facility used a certified aide in place of an RN. ▪ Agency personnel did not receive orientation for skills or tasks to be performed. The facility was unable to provide evidence of any orientation checklists. ▪ The facility did not have an RN assigned during the intra-operative phase of care for surgical procedures or endoscopies. ▪ Although surgical procedures and endoscopic procedures are performed at this facility, there is not a trained operating room nurse on staff.

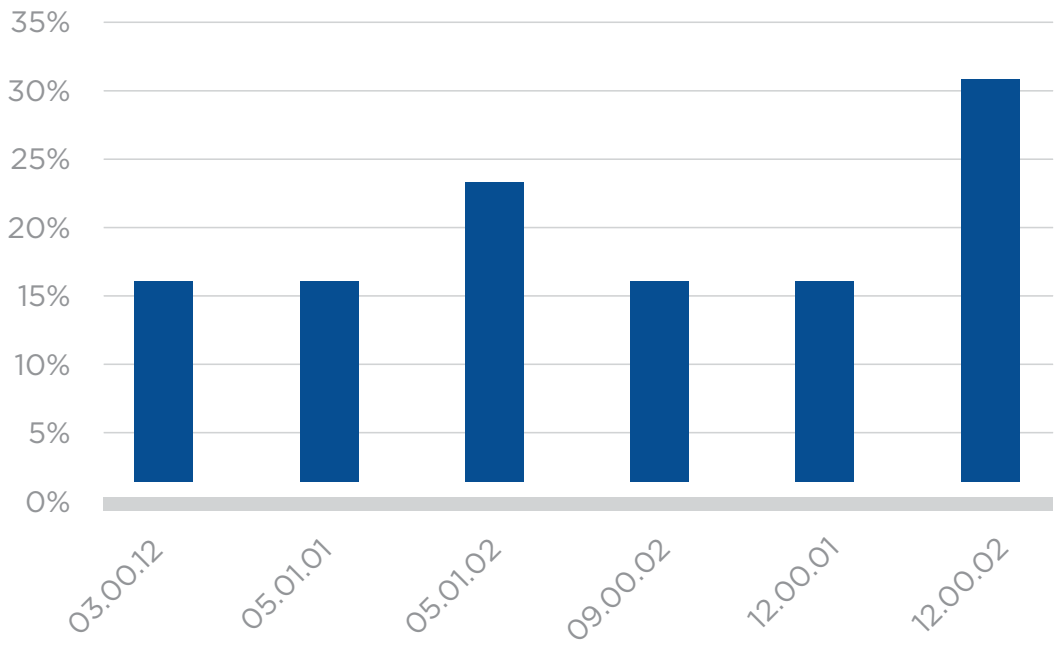
Tips for compliance:	▪ Conduct annual review of policies and provide education to ensure awareness of these requirements. ▪ Develop a monitoring process to ensure orientation is completed. ▪ Audit acuity grid for completion and to identify trends in staffing. ▪ Create a procedure for assigning and coordinating staffing that adjusts for nursing staff absenteeism. Review and revise regularly for process improvement. ▪ Ensure ongoing training and supervision of staff within assigned roles and responsibilities including resource and agency staff, if applicable.

CHAPTER	STANDARD
8 Surgical Services	**08.00.01 Condition of Participation: Surgical Services**
Overview of the requirement:	This COP covers the requirements for a CAH offering any type of surgical services. Policies and procedures must be written and implemented consistently so as to provide safe care for patients.
Comments on deficiencies:	Deficiencies were cited for infection control issues, policy breaches, and staffing concerns.
Frequency of citation:	33%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The floors in OR #1 and OR #2 had seams that were separated, which prevents effective cleaning and is therefore an infection control concern. ▪ It is hospital policy to affix two patient identifiers on medical records. The defined procedure is to print labels with the identifiers and affix them to the pages of paper medical records. With diagnostic photographs, the hospital's procedure is for staff to type the patient identification information into the photographic equipment. It is then imprinted onto each photograph. During tour of the main operating room, five open charts from patients that had endoscopic procedures earlier on the day of survey were reviewed. The practice of affixing patient identification on every patient record was inconsistent with hospital policy, as follows: 1. One of five charts was missing patient identification; this chart contained no identifiers — there was no patient name, date of birth, medical record number. 2. One of five patient photographs taken during a colonoscopy lacked all patient identification; there was no patient name, date of birth, medical record number, date of procedure, or physician name affixed to the image.

Examples of surveyor citations: (continued)	▪ During discussion with the director of nursing it was confirmed that surgical and endoscopy procedures were performed the presence of an intra-op RN, and the facility did not have a trained OR nurse on staff.
Tips for compliance:	▪ On surveillance rounds by personnel responsible for infection control, facilities maintenance, and unit managers, include observation of floor seams in ORs. Splits and divots require immediate repair/replacement. ▪ Assign a qualified RN to perform OR circulation duties. HR files must reflect training in OR duties. ▪ Conduct regular chart audits to ensure that all required elements (e.g., patient identifiers) are included.

CHAPTER	STANDARD
16 Restraints	**16.00.16 Monitoring of the Patient**
Overview of the requirement:	Hospital policies must define appropriate intervals for assessment and monitoring by trained staff of a patient for whom restraint or seclusion is used.
Comments on deficiencies:	Deficiencies reflect a gap between policy and practice.
Frequency of citation:	33%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Based on review of restraint patient records, two of three charts failed to document the monitoring of patient safety every 2 hours for patients in restraint or seclusion. ▪ Practice was inconsistent with policy. One of two charts was missing documentation of the "restraint initiation assessment," as required per hospital policy.
Tips for compliance:	▪ Make policy review part of annual staff training. ▪ Conduct chart audits for compliance with required documentation of restraint use.

Ambulatory Surgery Centers Deficiencies Cited in Administrative, Clinical, and Physical Environment Standards



On surveys performed in 2019 for ambulatory surgery centers (ASC), 12 standards were cited as not compliant for more than 10% of organizations. The deficiencies were evenly divided between administrative/clinical standards and emergency management standards. Administrative and clinical standards are shown above. The horizontal axis identifies the standard by number as published in *Accreditation Requirements for Ambulatory Surgery Centers*, 2017v2 edition (in use until April 2019) and 2019 editions. The vertical axis shows the frequency with which that standard appeared in an HFAP Deficiency Report for an Initial or Reaccreditation Survey.

Emergency management standards are addressed beginning on page 51.

CHAPTER	STANDARD
3 Surgical Services	**03.00.05 Administration of Anesthesia** (2017v2 edition) **03.00.12 Administration of Anesthesia** (2019 edition)
Overview of the requirement:	Privileges for administration of anesthesia must be formally granted by the governing body and in accordance with applicable state law.
Comment on deficiencies:	Citations resulted when credentialing records failed to reflect appropriate privileging.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The ASC has three licensed physicians granted privileges by the board of trustees to perform procedures requiring conscious sedation; these include two anesthesiologists and one neurologist. Based on document review, it was identified that the neurologist has not been granted the privilege to perform conscious sedation. ▪ The state is not an opt-out state for supervision of CRNAs. However, during review of the credential files of seven gastroenterologists, four of the seven physicians had crossed out the privilege of oversight for the provision of anesthesia.
Tips for compliance:	▪ Assign one person oversight of credentialing and privileging activities. ▪ Ensure privileges granted align with services offered by the ASC and that all services are included.

CHAPTER	STANDARD
5 Physical Environment **14 Life Safety**	**05.01.01 Safety from Fire** (2017v2 edition) **14.00.01 Life Safety Code Compliance** (2019 edition)
Overview of the requirement:	**Note:** Prior to the effective date of the 2019 edition of *Accreditation Requirements for Ambulatory Surgery Centers*, compliance with the NFPA Life Safety Code was addressed in a single standard (05.01.01 Safety from Fire). With the release of the 2019 manual, chapter 14 Life Safety Code was introduced to detail critical requirements of the code. The standard requires compliance with the 2012 edition of NFPA 101 The Life Safety Code and specific Tentative Interim Amendments (TIA).
Comment on deficiencies:	Deficiencies reflected missed testing of fire suppression system elements and issues with fire-rated doors.
Frequency of citation:	15%
Repeated frequent deficiency?	No

Examples of surveyor citations:	▪ The fire suppression system maintenance lacks documentation for current testing or inspection of: 1. Monthly fire pump churn test. 2. Monthly control valve inspection. 3. Monthly pressure gauge inspections. The facility provided evidence for inspections listed on a quarterly basis only, with the last inspection being done 12/21/2018. ▪ A set of 20-minute rated fire doors lead into the pre-op area and PACU area. The doors did not latch; the push-to-exit hardware (panic bars) installed on the doors did not work correctly.
Tips for compliance:	▪ ASCs often rely on vendors/contractors to perform required life safety testing or inspection. These vendors may not be familiar with HFAP standards and may not automatically perform required testing per the applicable code referenced in HFAP standards. Be sure that the vendor(s) have copies of all applicable standards. ▪ Review documentation provided by your testing and inspection vendors to verify that requirements are met.

CHAPTER	STANDARD
5 Physical Environment	**05.00.03 OR Design** (2017v2 edition) **05.01.02 Temperature, Airflow and Humidity Requirements** (2019 edition)
Overview of the requirement:	ASCs must verify that appropriate temperature, humidity and air flow are maintained in operating rooms.
Comment on deficiencies:	Citations indicate that organizations may be measuring temperature, humidity and airflow, but have no defined process for action if the data falls outside policy range.
Frequency of citation:	23%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Temperature and humidity logs were available and complete; however, no records of air flow measurements specific to OR or sterile processing rooms were available for review. ▪ The temperature and humidity documentation form indicates an acceptable range of 30–70% humidity which is inconsistent with operating standards under ASHRAE 170. ▪ During the two days surgery has been performed since the facility opened, temperature was below requirements both days. A temperature of 68-75°F is required. The following temperatures were recorded:

Examples of surveyor citations: (continued)	1. On date 5/29, a temperature of 64.6°F 2. On date 7/8, a temperature of 67.8°F There was no documentation of adjustment of the temperature and a recheck prior to patient procedures being done.
Tips for compliance:	▪ A policy regarding testing and maintenance for temperature, humidity, air exchanges, and pressure relationships needs to include the process for notification and action when a required air environment parameter is not compliant. The policy should outline: – how to document non-compliance. – required staff communication/committee reporting. – action to be taken by assigned staff. – what is required to document the means of correction. – what further testing frequency or evaluation is required, especially if it is a recurring problem.

CHAPTER	STANDARD
9 Pharmaceutical Services	**09.00.02 Administration of Drugs**
Overview of the requirement:	Drug administration within the ASC must conform to formal policies that reflect accepted standards of practice.
Comment on deficiencies:	Citations focused on security of drugs and safe injection practices.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ During a tour of the medication administration area, it was identified that: 1. Propofol was secured in a single lock drawer. 2. A perpetual inventory was not maintained to monitor and control drug use. Because this is a frequently abused drug, security and oversight of use need to be increased. ▪ Patient bay #1 was prepared to receive a patient for removal of an access catheter. A prefilled syringe was on the preparation table. The RN who prepared the equipment and syringe stated that the syringe contained 10 cc of 1% lidocaine to be used by the physician prior to removing the catheter. There was no label on the syringe. Based on document review, the facility lacked evidence of a policy requiring medications in pre-filled syringes to be labeled with the initials of the person who drew up the medication, the date and time the medication was drawn up, and the name and expiration date of the medication.
Tips for compliance:	▪ Add medication policy review to annual staff training.

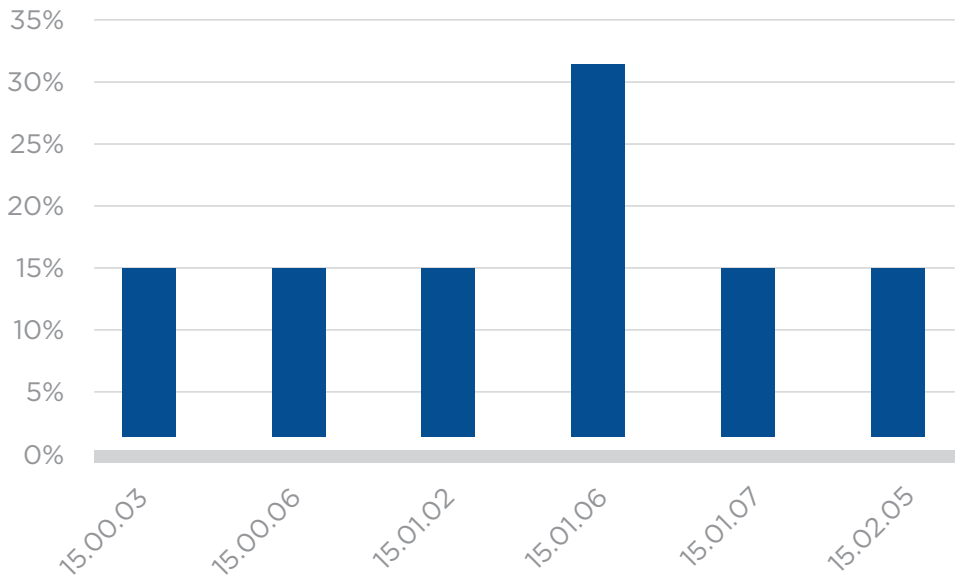
CHAPTER	STANDARD
12 Infection Control	**12.00.01 Condition for Coverage: Infection Control**
Overview of the requirement:	This is condition-level requirement for an active program for organization-wide infection control.
Comments on deficiencies:	As the condition-level assessment of infection control practice for the organization, this standard is most often cited as a result of aggregate infection control deficiencies identified.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Based on observation, document review, and interview, the following requirements were not met: 12.00.02 Sanitary Environment 12.01.02 Decontamination and Cleaning of Surgical Instruments 12.01.05 IUSS 12.01.06 Preparing, Assembling, Wrapping, and Distribution of Sterile Equipment and Supplies ▪ Based on observations and interviews with staff, it is determined that the organization failed to maintain an environment in accordance with acceptable standards of practice in infection control. 1. Seven stained ceiling tiles were observed • One above room 12 • Four tiles in the corridor between recovery room and pre-op • Two tiles were observed at the East patient exit. 2. In decontamination areas the following were observed: • According to AAMI guidelines ST-79 three sinks are standard in decontamination and are for soak, wash, and rinse. Observed that the decontamination area only has two sinks. • AAMI guidelines for ST-91 (Scope processing) indicate that the scope cleaning area should have at least two sinks for washing and rinsing or three sinks for soak, wash and rinse. Observed that the scope cleaning area has one sink.
Tips for compliance:	▪ Focus on individual infection control standards. ▪ Conduct regular infection control surveillance rounds and report findings to the relevant committee. ▪ Promote a culture of cleanliness.

CHAPTER	STANDARD
12 Infection Control	**12.00.02 Sanitary Environment**
Overview of the requirement:	The intent of the standard is to focus the organization on the full range of sanitation events that could contribute to infection control issues.
Comments on deficiencies:	Storage issues, dust build-up on surfaces, airflow and faults in floor, wall, and ceiling surfaces contributed to citations.
Frequency of citation:	31%
Repeated frequent deficiency? *Previous frequency:*	Yes 23%
Examples of surveyor citations:	▪ During testing results of the sterile processing air flows, it was observed that the soiled room was listed as "positive" air flow; when required to be negative and the clean room results were unable to be read. No recording was noted from the outside vendor. ▪ Cardboard boxes were observed on the floor in storage areas where laser procedures are performed. Decontamination room — cleaning agents are stored under the sink in a cardboard box. General supplies were stored under the sink in the laser room. Storeroom, located off the sterile corridor and connected by a door to the sterile supply room, had multiple cardboard shipping boxes in use. Current area flow did not allow for flow from one storage area to another without potential for contamination of clean supplies. The sterile storage areas did not have liners on the bottom of all carts to protect from splashing. ▪ Dust build-up was observed in the following areas: 1. Exhaust vent in OR rooms 1, 2, & 3 2. Wall mounted gas shutoff valves: • outside of OR rooms 1, 2, & 3 • pre-operative area • main shutoff valve in PACU area ▪ In the orthopedic OR #1, multiple divots (ten or more) were found in the floor surface, some measuring up to 2 cm in length and .3 cm in depth. In OR #2, there was seam separation in the floor that was approximately 10 cm in length, and it had been filled with white caulking material. In the central sterile area, separation of the floor seams was also noted in three places, and these had also been filled with caulking material.

Tips for compliance:	▪ Develop policies and procedures regarding cleaning. ▪ Train staff on these policies. ▪ Conduct regular environmental surveillance rounds. Include the facilities manager and the infection control officer.

CHAPTER	STANDARD
13 Patient Admission, Assessment, and Discharge	**13.00.03 – Admitting History & Physical Update** (manual: 2017 v2 edition, used for surveys prior to April 1, 2019) **13.00.04 – History & Physical Update: Pre-surgical Assessment** (manual: 2019 edition, used for surveys on or after April 1, 2019)
Overview of the requirement:	The patient's medical record must include documentation that a pre-surgical assessment of the risk of anesthesia and the procedure was completed by a physician. This assessment should consider any changes in the most recent H&P and address allergies or reactions to drugs or biologicals.
Comments on deficiencies:	Deficiencies reflected missing documentation or a missing element within the documentation.
Frequency of citation:	23%
Examples of surveyor citations:	▪ H&P was not dated so it was not possible to validate that an update occurred on the day of surgery. ▪ 20 of 21 records lacked an update to the H&P on day of surgery. ▪ Anesthesia assessment was present but no H&P in 2 of 15 records.
Tips for compliance:	▪ An H&P must be in the medical record prior to surgery. ▪ If the H&P was completed within the 30 days preceding surgery, it must be reviewed and updated by a physician prior to surgery to ensure there are no changes in the patient's condition. ▪ If the H&P is performed on the day of surgery, it must be performed by a physician and include an assessment of the patient's risk for the procedure and anesthesia.

Ambulatory Surgery Centers — Deficiencies Cited in Emergency Management Standards



CHAPTER	STANDARD
15 Emergency Management	**15.00.03 Emergency Operations Plan**
Overview of the requirement:	Based on its Hazard Vulnerability Assessment (HVA), the ASC must evaluate services that it could continue to provide in an emergency and communicate its capabilities to the community's emergency response agencies.
Comment on deficiencies:	Deficiencies arose when the Emergency Operations Plan (EOP) was not developed in concert with the HVA, or when it was not shared with emergency response agencies.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The EOP reviewed was observed to address internal and external disaster scenarios, but was not based on a Hazard Vulnerability Analysis (HVA). ▪ Review of the EOP identified that the plan does not address assessment of the community's ability to meet the needs of the ASC during an emergency.

Tips for compliance:	▪ Establish scenarios and, using the EOP, walk through the process of providing services that will be maintained. Note where the EOP fails to define who, what, when, or where. Use this critique to augment/revise policies and procedures until you have an EOP that can be successfully implemented. ▪ Be sure the components required by the standard are delineated in the EOP or EOP-referenced policies.

CHAPTER	STANDARD
15 Emergency Management	**15.00.06 Continuity of Operations**
Overview of the requirement:	The Emergency Operations Plan (EOP) includes identification of how authority/responsibility will be delegated in an emergency.
Comment on deficiencies:	Deficiencies resulted from missing elements in the EOP essential to continuity of operations.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The EOP did not reflect continuity of operations. Issues such as essential personnel and functions, alternate facility identification and location, and financial resources were not addressed. ▪ The succession of authority was not addressed in the EOP. ▪ During document review, it was observed that the EOP failed to address the continuity of operations except for the delegation of authority during the emergency.
Tips for compliance:	▪ Continuity of operations planning should include essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources, as applicable. ▪ Be sure the components required by the standards are delineated in the EOP or EOP-referenced polilcies.

CHAPTER	STANDARD
15 Emergency Management	**15.01.02 Patient and Staff Tracking**
Overview of the requirement:	Emergency management policies and procedures must include a means of tracking the location of on-duty staff and sheltered patients in the care of the ASC during the emergency.
Comment on deficiencies:	All citations indicated that the Emergency Operations Plan (EOP) was missing a statement regarding how staff and patient location would be identified in the event of an emergency.
Frequency of citation:	15%
Repeated frequent deficiency?	No

Examples of surveyor citations:	▪ Neither the EOP nor written policies were observed to address the tracking of on-duty staff and sheltered patients during an emergency.
Tips for compliance:	▪ Focus on each element required for a complete EOP. Be sure that components required by the standards are delineated in the EOP or EOP-referenced polcieis. ▪ The policy must outline the system or means to be used to accomplish patient and staff tracking. include any referenced forms or communication chain required to accomplish tracking.

CHAPTER	STANDARD
15 Emergency Management	**15.01.06 Volunteers**
Overview of the requirement:	The Emergency Operations Plan (EOP) must address whether and how volunteers will be used in an emergency.
Comment on deficiencies:	All citations indicated that the EOP was missing a statement regarding the use (or not) of volunteers.
Frequency of citation:	31%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The EOP fails to address the use of volunteers in an emergency.
Tips for compliance:	▪ Even if volunteers will *not* be used in an emergency, the EOP must state this explicitly. ▪ Be sure that components required by the standards are delineated in the EOP or EOP-referenced policies.

CHAPTER	STANDARD
15 Emergency Management	**15.01.07 Invoking the 1135 Waiver**
Overview of the requirement:	ASCs must acknowledge when and how any 1135 waivers will be used and that all stipulations associated with a waiver are, or will be, met.
Comment on deficiencies:	Citations indicated that reference to the organization's actions in response to an emergency declaration were missing from the EOP.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ The plan fails to address or outline the means of invoking of the 1135 waiver.

Tips for compliance:	▪ When a blanket waiver is used by CMS or an organization needs to request a CMS waiver during a current emergency (local or otherwise) a policy is needed that outlines the procedures for this so that it can be accomplished expeditiously. ▪ Some CMS waivers have requirements that have to be met to take advantage of the waiver. Compliance with these conditions must be documented. Focus on each element required for a complete EOP. ▪ Be sure that components required by the standards are delineated in the EOP or EOP-referenced policies.

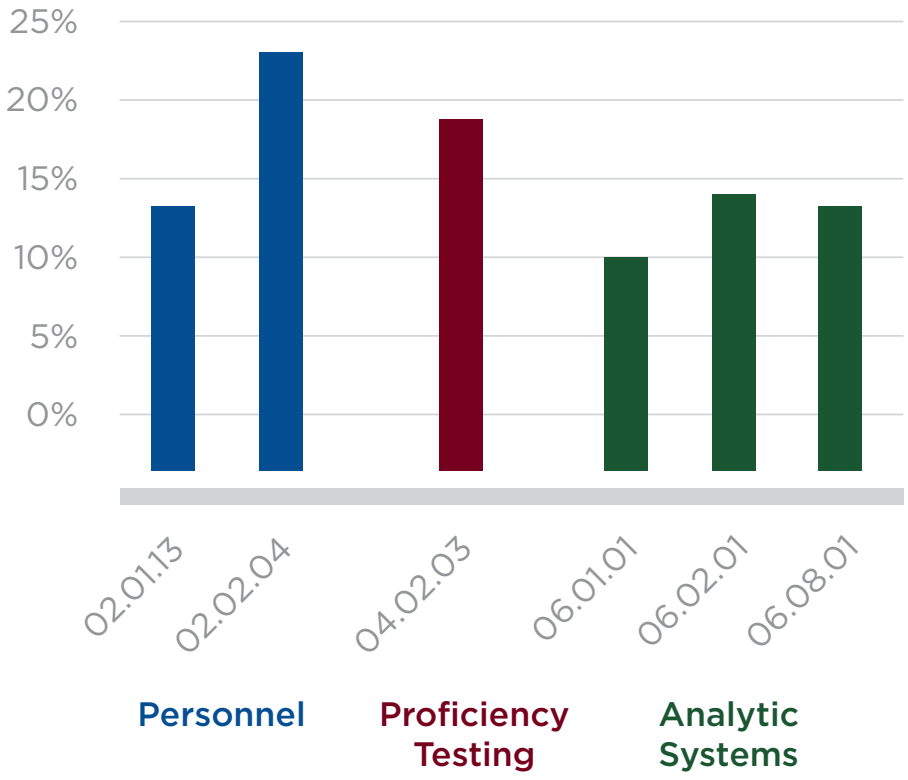
CHAPTER	STANDARD
15 Emergency Management	**15.02.05 Release of Information**
Overview of the requirement:	An ASC may use or disclose protected health information (PHI) to notify or assist in locating a family member, a personal representative, or another person responsible for the care of the individua and may disclose protected health information to a public or private entity authorized by law or charter to assist in disaster relief.
Comment on deficiencies:	Communications plans must include the means for determining what and how information about the general condition and location of patients under the ASC's care is disseminated.
Frequency of citation:	15%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ A communications plan addressing the permitted release of patient information during an emergency was not available for review.
Tips for compliance:	▪ Write a policy for when and how patient information can be released to family, other healthcare entities, and when transferred. Consider that the standard means of communication may not be available. ▪ Focus on each element required for a complete EOP. Be sure that components required by the standards are delineated in the EOP or EOP-referenced policies. ▪ HIPAA requirements are not suspended during a national or public health emergency. However, the HIPAA Privacy Rule specifically permits certain emergency uses and disclosures of PHI.

Notes

Laboratory Deficiencies

Clinical laboratories, whether a department of a hospital or ASC, or an independent entity, undergo biennial surveys to maintain accreditation and CLIA certification. These laboratory surveys are **in addition to** the review of laboratory services that takes place in acute care hospitals, critical access hospitals, and ASC settings during a triennial accreditation cycle.

In 2019, 94 HFAP-accredited labs were surveyed with an average of 3.85 citations made. This is an improvement over the average number of 7.6 non-compliant standards reflected in findings from 2018 surveys. Also improved is the overall number of standards cited as "not compliant" on at least 10% of surveys. Last year, 21 individual standards were cited on at least 10% of surveys. This year, only six standards met that threshold. Of the six, three were repeated from 2018 but in each case, the frequency of citation declined.



The chart above identifies the standards most frequently cited as not compliant with the frequency of citation. The standard identifier comes from the 2019 edition of *Accreditation Requirements for Clinical Laboratories*. This publication became effective for surveys taking place on or after July 1, 2019. In the detailed information below, the prior standard ID is also provided when there was a change for the new edition.

The tables that follow include an overview of the requirement(s), a comment on trends in the deficiency, examples of surveyor citations, and tips for achieving and maintaining compliance.

CHAPTER	STANDARD
2 Laboratory Personnel	**02.01.13 Personnel** Combining prior standards: 02.01.20 Personnel 02.01.22 Personnel Competency 02.08.18 Personnel Competency (Labs Performing Moderate Complexity Testing)
Overview of the requirement:	The laboratory director is responsible for employing personnel in sufficient numbers and with appropriate competency to process specimens, perform test procedures, and report results relevant to the level of testing complexity offered by the laboratory.
Comments on deficiencies:	This standard was cited either because a lab had no program for competency evaluation, or for failing to meet its own procedures for competency evaluation.
Frequency of citation:	13%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Review of the procedure manual and personnel interviews revealed that the laboratory has no comprehensive competency program in place. ▪ For the primary testing staff, the initial competency assessment did not include the mode of assessment. Assessment at one year was signed but did not describe what was assessed. ▪ Competency for grossing tissues, including inking of the margins and relaxing the tissue before sectioning had not been established for the Mohs technician per lab procedure for competency evaluation.
Tips for compliance:	▪ Assure that there are policies and procedures in place that address who will assess competency, what will be assessed, how it will be assessed and how often competency will be assessed. ▪ Annually review practice to ensure that it matches the policies and procedures in place.

CHAPTER	STANDARD
2 Laboratory Personnel	**02.02.04 Testing personnel competency and evaluation** Combining prior standards: 02.02.11 Testing Personnel Competency 02.02.12 Competency Evaluation 02.02.13 Frequency of Competency Evaluation 02.09.12 Competency Evaluation
Overview of the requirement:	The laboratory technical supervisor/consultant is responsible for evaluating and documenting competency of staff to perform test procedures and report results. The standard identifies required elements and intervals for competency evaluations.

Comments on deficiencies:	This standard is cited when one or more of the six elements of evaluation is/are missing, when documentation is incomplete, or when evaluations are not performed in timeframes required by the standard.
Frequency of citation:	23%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Review of documents and interview with the staff revealed that the laboratory was performing competency assessments as required: initially upon hire, at six months and annually thereafter. However, not all six elements were present for each employee at each assessment. The most common elements missing included assessment of problem-solving skills and the testing of an unknown specimen. ▪ The direct observation checklist sheets were signed by the testing personnel but were not signed or dated by the Technical Consultant or the Laboratory Director. ▪ Testing personnel records (5 of 11 reviewed) had no documentation of unknown testing for any of the tests or test systems evaluated. ▪ Review of documents and interview with the staff revealed that the laboratory was not performing competency assessments of testing personnel at initial, six months, and annually. In addition, not all six elements for competency assessment were being completed and documented.
Tips for compliance:	▪ Create a spreadsheet for all testing personnel and list each test or test system for which they are approved. Assure that for each of these test or test systems, all six required elements are documented twice in the first year and annually thereafter.

CHAPTER	STANDARD
4 Proficiency Testing	**04.02.03 Proficiency Testing**
Overview of the requirement:	Laboratories are required to participate in a CMS CLIA-approved PT program and must authorize the PT provider to send results to HFAP. The laboratory must score at least 80% accuracy for each analyte in each testing event to demonstrate satisfactory performance. **Note:** Revisions to the 2019 standards (effective July 1, 2019) combined the requirement for 80% minimum accuracy into a single standard. Surveys conducted under the previous manual scored this requirement at each specialty/subspecialty.
Comments on deficiencies:	Most citations note the score, identify the analyte, confirm an investigation and appropriate corrective action.
Frequency of citation:	19%
Repeated frequent deficiency? *Previous frequency:*	Yes 20% (aggregate across specialties/subspecialties)

Examples of surveyor citations:	▪ The laboratory scored 75% for the analyte Antigen Identification. The corrective action documentation provided by the laboratory was very brief. The comment present indicated that repeat testing resulted correctly, however there was no indication as to why the incorrect result was obtained with the initial testing. In addition, the only corrective action noted was a statement that "Technologist will be careful and interpret the antigen typing results correctly."
Tips for compliance:	▪ Ensure that corrective actions are appropriate to the root cause of the PT failure and that they are sustainable. ▪ Review HFAP Academy webinars (www.hfap.org) for additional coverage of this topic.

CHAPTER	STANDARD
6 Analytic Systems	**06.01.01 Procedure manual elements** Combining prior standards: 06.01.01 Procedure Manual Elements 06.01.03 Procedural Steps 06.01.04 Preparation of Testing Materials 06.01.05 Calibration Procedures 06.01.07 Control Procedures
Overview of the requirement:	The standard identifies 12 elements of testing that must be included described in the procedure manual.
Comments on deficiencies:	Most deficiencies are the result of missing procedures for specific testing equipment or a misalignment between written procedures and laboratory practice.
Frequency of citation:	10%
Repeated frequent deficiency?	No
Examples of surveyor citations:	▪ Review of the microbiology procedures and interview with staff revealed that quality control for the Novobiocin procedure did not match actual practice. The procedure stated QC is performed once per week or with each new lot of Novobiocin discs. Review of QC records showed that Novobiocin is performed infrequently with QC each day of use or each new lot. ▪ Review of procedures revealed that the procedure for Mohs frozen sections CP-L2017A did not include a legend for the doctor's color inking preferences for Mohs surgeons at this site. ▪ Review of records revealed that there were no procedures in place that define preparation of controls used for testing for the Beckman DHX 600, the Beckman AU 480, and Beckman Access 2. ▪ Review of documents revealed that the procedure for performing calibration verification lacked indentification of: a. What material is used. b. What tests require calibration verification.

Examples of surveyor citations: (continued)

c. How results are evaluated (what is considered acceptable or unacceptable).

d. What actions, if any, will be taken as a result a result of findings.

e. Corrective action to be taken if results are unacceptable.

- Review of documents revealed that the quality control policies in place for chemistry testing done on the Beckman AU480 and Beckman Access 2 did not define the type of control to be used; identity of the control material to be used; and number and frequency of testing controls.
- Testing procedure for the Beckman DXH 600 QM 100 stated that 2 levels of control are run each 8 hours of patient testing. However, in practice, the laboratory was testing three levels of control, plus the latron control, once per 8 hours of patient testing.
- Review of documents revealed that the procedure manual for the Stago Compact Analyzer used for coagulation testing did not contain step by step instructions for the performance of PT, PTT, Fibrinogen and D-Dimer testing.
- Review of records revealed that there were microbiology procedures that had an IQCP written but had not been updated to include a reference to the frequency of external quality controls.
- Review of the procedures revealed that the Acid Fast (Kinyoun) Stain procedure did not include quality control testing each day of use as required by the regulations.
- Review of manuals and interview with staff revealed no Laboratory Director approved procedure that detailed the calibration and calibration verification procedures used for the Vitros 350 and the Sysmex XP-300.
- Review of documents and interview with staff revealed that there was no detailed procedure defining control material to be run or timing. The procedure in place only indicated that two levels of quality control would be run each day. Observed data revealed that there was variability in the level of controls run each day as well as the time of day they were run.
- Record review and staff interview indicated that the microbiology procedure manual was missing culture-specific procedures for urine, sputum, CSF, body fluid, wound, blood, and routine bacterial cultures. This included the step-by-step process for reading plates, interpreting results, performing preliminary identification or organisms, and reporting results (e.g., normal flora in sputums, urine colony counts).

Tips for compliance:	▪ For each test performed by the laboratory, the procedure manual must address all 12 elements. Create a template form to prompt inclusion of each element when new tests/new equipment are introduced to the laboratory. ▪ When annual staff competency testing is performed, use the opportunity to audit actual process to ensure that the policies are accurately and fully implemented in practice. ▪ Ensure that the Laboratory Director has signed each procedure initially and with any subsequent revisions.

CHAPTER	STANDARD
6 Analytic Systems	**06.02.01 Essential Conditions**
Overview of the requirement:	The laboratory monitors water quality, temperature, humidity, and fluctuations in electrical current to maintain consistency with MIU and documents corrective actions when the criteria for storage of reagents and specimens are not met.
Comments on deficiencies:	In some cases, areas were not being monitored or no corrective action was taken when readings were out of acceptable range. Other deficiency citations resulted from expired certification of the instruments used for measurement.
Frequency of citation:	14%
Repeated frequent deficiency? *Previous frequency:*	Yes 24%
Examples of surveyor citations:	▪ The temperature in Respiratory Therapy, where the ePOCs are stored, was not recorded for March 11, 2019. ▪ An examination of the humidistat and thermometer revealed that the certification had expired in 2017. ▪ There was no evidence of review of temperatures for the first six months of 2018. The range on the log sheet listed 36°F–45°F as the acceptable temperature range. All the refrigerator temperature logs reviewed showed the documented temperatures were consistently between 30°F–34°F. ▪ The cryostat temperature logs showed no temperatures recorded for the following dates in 2017: November 15, 18–22, 25–29. There was no notation of any testing performed or that the office was closed on those dates. ▪ In July 2018, the cryostat temp was recorded on the 21st, but all other log sheets showed Mohs surgery was performed on the 19th. In August 2018, the cryostat temp was recorded on the 31st, but all other logs indicated that the actual date used was the 30th. ▪ Review of records showed that the temperature of refrigerator #2, which is used for storing hematology reagents, specimens and quality control materials, exceeded acceptable storage temperatures of 2–8°C on a number of days in various months of 2017, 2018, 2019 and no remedial action was documented. Examples of dates…

Examples of surveyor citations: (continued)	▪ Review of documents revealed that the temperatures were not recorded on weekends and holidays when the laboratory was not open. The laboratory had no system in place to assure that essential conditions for the storage of reagents used in patient testing, were maintained at appropriate temperatures during the days that the laboratory was closed. This included room temperature, refrigerator and freezer storage.
Tips for compliance:	▪ Use certified thermometers and humidistats for monitoring in all locations throughout the organization where the temperature and humidity are essential conditions for accurate test results. ▪ Develop a system to review logs on a monthly basis to verify: – Temperatures are recoded. – Out of range temperatures are documented and corrective action is taken.

CHAPTER	STANDARD
6 Analytic Systems	**06.08.01 Comparison of test results**
Overview of the requirement:	If the same test is performed using different methods, different instruments, and/or at multiple locations, the lab compares results at least twice annually and has written criteria for acceptable variation in test values.
Comments on deficiencies:	Deficiencies were cited for failure to perform required comparison studies.
Frequency of citation:	13%
Repeated frequent deficiency? *Previous frequency:*	Yes 16%
Examples of surveyor citations:	▪ Review of documentation and interview with staff revealed that comparisons were not being performed between automated and manual differentials, automated and manual body fluids, cross-matches in tube, automation, and gel. Records revealed that comparisons were being performed between the two hematology analyzers for WBC, HGB and PLT but not the other analytes. ▪ The laboratory did not have written policies to evaluate the test values obtained from comparisons in the hematology, blood bank and coagulation departments.
Tips for compliance:	▪ The laboratory should have a written procedure for performing comparison studies. ▪ Develop a list of test methods that are performed on multiple instruments and/or locations which require comparison studies. ▪ Develop a calendar to assure appropriate comparison studies are performed twice per year.

Notes

Chicago, IL | www.hfap.org