HFAP

2019

Partnering for Success:
The 2019 HFAP Quality Review



FROM THE BOARD CHAIR

This year, HFAP's parent company, the Accreditation Association for Hospitals/Health Systems (AAHHS) adopted a new mission:

To become the valued partner for healthcare organizations committed to improving their quality of care, through accreditation standards and education, with a focus on advancing the health and welfare of our customer's communities.

We believe that the ASCs, hospitals, laboratories, and others that choose HFAP are looking for an accreditation experience founded in **shared commitment** to building efficient, effective, people-focused organizations. This shared commitment is visible in the coaching relationship we seek to build with each healthcare organization we accredit. Together, we can improve the quality of care in the communities we serve.

Partnering with HFAP surveyors

While assessing compliance with individual standards, your surveyor/survey team will be simultaneously taking in ancillary information to place the evaluation in context. We are interested in how the elements of each individual organization—departments, teams, functions—fit and work together.

HFAP surveyors are trained to be open to a variety of ways of achieving compliance. Your job is to be an advocate for your organization's approach. The more effectively you can paint that picture for your surveyor/survey team, the more they'll have to offer with regard to meaningful educational support.

Partnering with HFAP staff

Pre- and post-survey and throughout a term of accreditation, HFAP staff members are available to support problem-solving and lend process expertise. We use data—like the findings of this year's **Quality Review**—combined with knowledge gained from daily interaction with our accredited organizations to develop tools and educational programming. We also use this information to enhance our customer service by bringing new solutions like HFAP Compass, our new IT platform, that will launch later this year.

I hope you find value in this publication and in all HFAP tools and resources. We are aiming to create a community of excellence that learns from its members.

Gary Ley
Board Chair, AAHHS

Introduction

Welcome to the 2019 edition of the **HFAP Quality Review**. This document represents an analysis of deficiencies identified on 2018 surveys for HFAP ambulatory surgery center, acute care hospital, critical access hospital, and clinical laboratory accreditation programs.

Using the report

The Deficiency Report that you receive after an onsite survey details areas of specific focus for improving your organization. This **Quality Review** places your organization in context with your peers by evaluating trends from all surveys conducted in 2018. Use it as a guide for self-assessment and to identify areas of secondary focus when the deficiencies differ from citations for your organization.

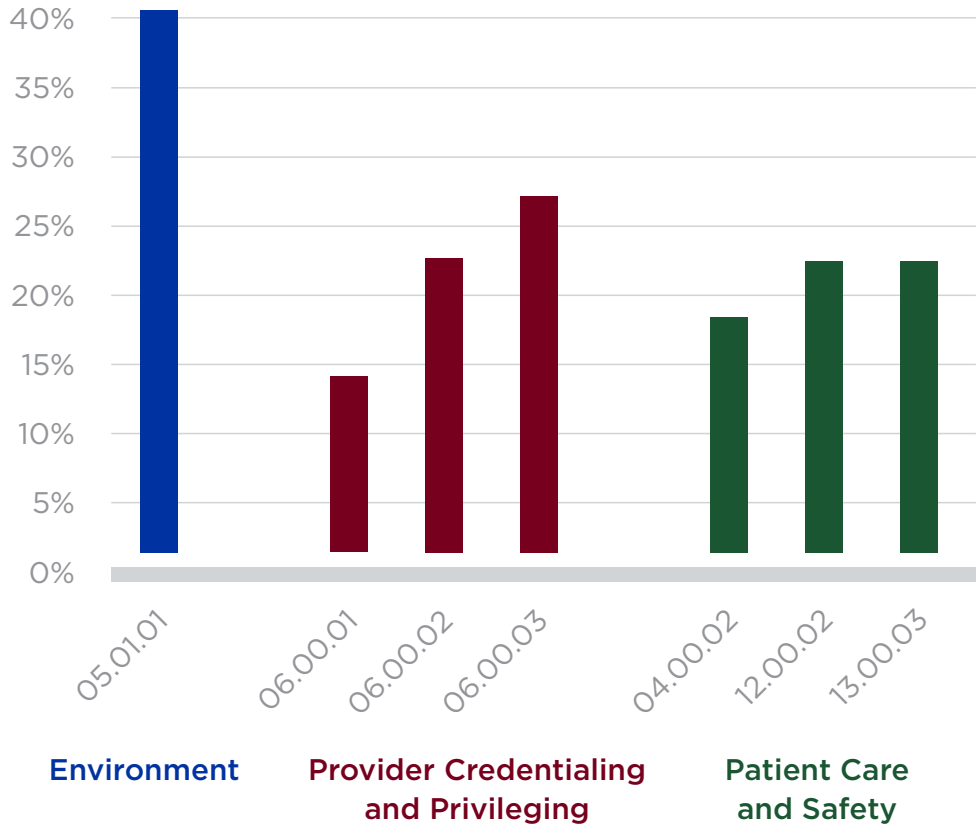
Across HFAP manuals, the standards follow a pattern: policy > implementation > evaluation > reporting. This aligns with several models of performance improvement and underscores our shared objective to bring quality care to the communities we serve. Understanding this pattern can bring contextual meaning to individual standards and show you the big picture of where your organization may have opportunity for improvement. For example, consider:

- how those in your organization know what to do (policy).
- whether those in your organization do what policies say will be done (implementation).
- how effectively you achieve the intended result (evaluation).
- whether and how your organization disseminates these ideas, actions, and results (reporting).

These answers, your accreditation manual, your most recent HFAP Deficiency Report, and this **Quality Review** can be used to reveal whether your deficiencies tend to cluster in one of these categories. If so, you may be able to solve multiple problems more easily by addressing policy, implemenation, evaluation, or reporting organization-wide.

Table of Contents

Ambulatory Surgery Center Deficiencies



For 2018 surveys of ASCs, the most frequently-cited deficiencies fall into three categories: environment, provider credentialing and privileging, and patient care and safety, as illustrated above. The horizontal axis identifies the specific standard using identifiers from *Accreditation Requirements for Ambulatory Surgical Centers*, 2017v2 edition) and the vertical axis shows the frequency with which that standard was cited as a deficiency.

The detailed information that follows includes the 2018 standard identifier indicated above and, where applicable, the new 2019 standard identifier, an overview of the requirement(s), examples of surveyor citations, and tips for compliance.

Environment

CHAPTER	STANDARD
5 Environment	**05.01.01 – Safety from Fire** (manual: 2017 v2 edition, used for surveys prior to April 1, 2019)
14 Life Safety	**14.00.01 – Life Safety Code Compliance** (manual: 2019 edition, used for surveys on or after April 1, 2019)
Overview of the requirement:	This standard requires compliance with the 2012 edition of **NFPA 101 Life Safety Code** via a systematic process for review of relevant systems and environmental conditions. The frequency with which this standard was cited led to the addition of a new chapter In the 2019 edition of *Accreditation Requirements for Ambulatory Surgery Centers*: 14 – Life Safety. Chapter 14 provides a robust overview of the relevant life safety requirements within the resource of the HFAP manual. ASCs are still advised to review NFPA 101, 2012 edition, chapters 20 and 21, for full compliance requirements.
Frequency of citation:	41%
Examples of surveyor citations:	▪ Unprotected penetration in fire-rated walls between the ASC and the adjoining clinic with communications cabling running through. ▪ Ceiling tiles, vents, and escutcheons not seated level with ceiling assembly creating gaps greater than 1/8 inch. ▪ Documentation missing for: – Testing the fire alarm signal transmittal to the responding force. – Inspection/testing of fire-rated door assemblies. – Monthly elevator recall testing. – Weekly generator inspection/load testing. – Fire pump testing. ▪ Fire alarm system device testing records indicate inspection and testing is beyond the 12-month requirement. ▪ Doors in one-hour fire barrier do not latch. ▪ Fire notification system inspection report does not include unique identifiers for each device with a pass/fail result indicated. ▪ Smoke detectors not tested for sensitivity within required two-year cycle.
Tips for compliance:	▪ This standard covers a broad range of systems and conditions in environments that are subject to high-use and constant readiness. The HFAP ASC Life Safety Document Review List (www.hfap.org/resources) is a reference for inspection, testing, and required documentation related to this standard. **Note:** See pages 14–25 for life safety deficiencies in acute care hospital settings.

Provider Credentialing and Privileging

CHAPTER	STANDARD
6 Medical Staff	**06.00.01 – Medical Staff Membership & Clinical Privileges** (manual: 2017 v2 edition, used for surveys prior to April 1, 2019) **06.00.01 – Medical Staff** (manual: 2019 edition, used for surveys on or after April 1, 2019)
Overview of the requirement:	Formal responsibility for the medical staff of the ASC lies with the governing body regardless of the size of the organization. This is a CMS Condition for Coverage (CfC).
Frequency of citation:	14%
Examples of surveyor citations:	▪ Files indicate no credentialing activity since 2014. ▪ Credentialing files include no evidence that privileges have been granted by the governing body. Governing body minutes do not reflect privileging approval. ▪ Privileges granted do not match the scope of services.
Tips for compliance:	▪ Assign one person the oversight of credentialing and privileging activities. ▪ Create a "tickler" file to ensure adequate time for processing reapplications. ▪ Ensure privileges granted are limited to the procedures offered by the ASC. ▪ Ensure the minutes of governing body meetings record the granting of practitioner privileges at time of initial application and reapplication. ▪ Ensure the governing body sends correspondence to each practitioner identifying the privileges granted; a copy is added to the applicant's credential file.

CHAPTER	STANDARD
6 Medical Staff	**06.00.02 – Medical Staff Membership & Clinical Privileges** (manual: 2017 v2 edition, used for surveys prior to April 1, 2019) **06.00.02 – Medical Staff: Granted Privileges** (manual: 2019 edition, used for surveys on or after April 1, 2019)
Overview of the requirement:	Privileges may only be granted to clinicians by the governing body based on medical staff recommendations addressing the competence of the applicant to provide a requested, privileged service.
Frequency of citation:	23%

Comment on deficiencies:	Most citations missed individual, required elements in the privileging process.
Examples of surveyor citations:	▪ Files are missing evidence that privileges were granted for three practitioners. ▪ No evidence of peer review. ▪ No letter of reappointment in file. ▪ Initial application for anesthesia appointment is missing date of completion, is illegible with regard to privileges requested, and includes no performance data. ▪ Files are missing: – Criminal background check. – Peer evaluations. – Current health status.
Tips for compliance:	▪ Develop a medical staff policy listing all requirements for credentialing and privileging. ▪ Develop a checklist to ensure every requirement is met. ▪ Train the minute taker regarding the key privileging decisions to be recorded.

CHAPTER	STANDARD
6 Medical Staff	**06.00.03 – Reappraisals** (manual: 2017 v2 edition, used for surveys prior to April 1, 2019) **06.00.04 – Medical Staff: Reappraisals** (manual: 2019 edition, used for surveys on or after April 1, 2019)
Overview of the requirement:	The scope of services is periodically reviewed and amended. There is a process for reappraising the privileges granted to medical staff; the recommended timeframe is every 24 months.
Frequency of citation:	27%
Comments on deficiencies:	Deficiencies cited on 2018 surveys reflected incomplete documentation and/or failure to complete the process with governing body approval of recommendations.
Examples of surveyor citations:	▪ Missing evidence of privileges granted at time of reappointment. ▪ No peer review documented. ▪ No evidence of governing body approval of reappointment. ▪ No quality data considered in reapplication process.

Tips for compliance:	▪ Be sure applications for initial appointment and reappointment include peer review activities. ▪ Collect quality data for each practitioner to help verify continued competence. Use this information as part of the reappointment process. ▪ With initial applications and reapplications, the governing body must send the practitioner correspondence that: – Identifies the privileges granted. – Lists the effective dates of privileges (start and end). – Is dated and signed by the chair of the governing body. ▪ Retain a copy of the letter in the credential files.

Patient Care and Safety

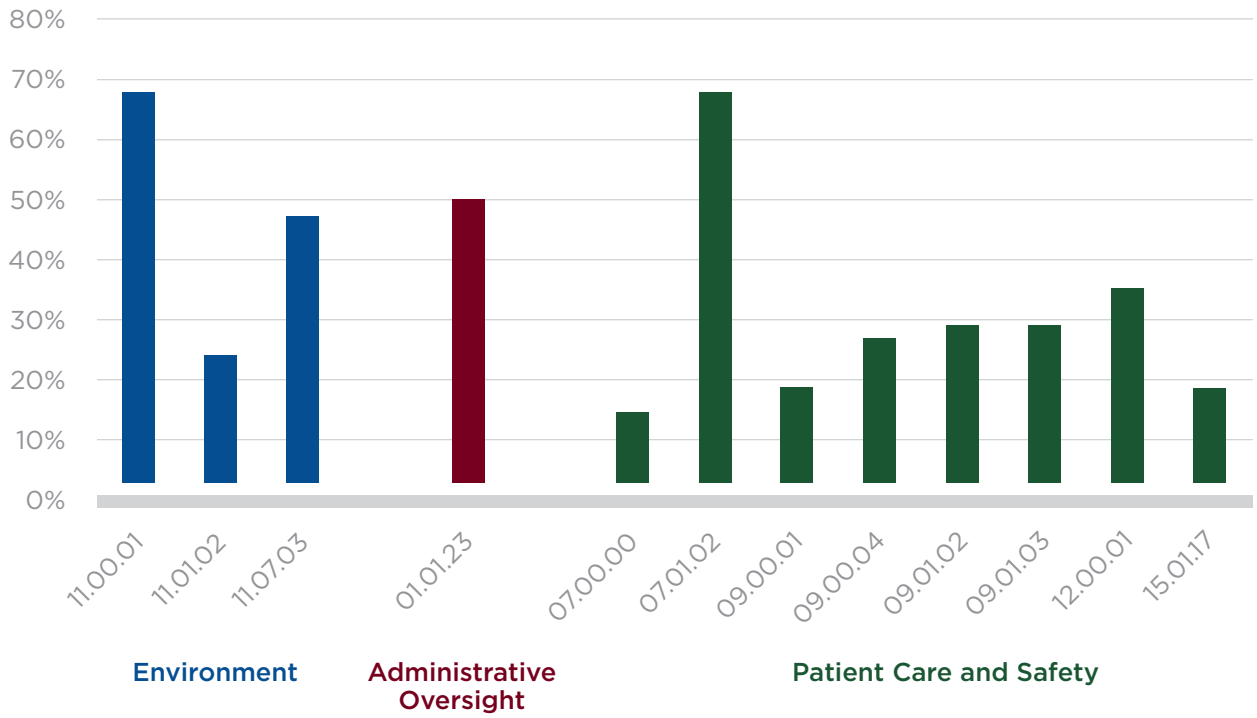
CHAPTER	STANDARD
4 Quality Assessment and Performance Improvement	**04.00.02 – QAPI Program Scope**
Overview of the requirement:	Through the use of quality indicators, the ASC has an on-going program to identify and reduce medical errors with the goal of demonstrable improvement in patient outcomes.
Comments on deficiencies:	The quality program is intended to be broad-based, incorporating all aspects of the ASC's operations.
Frequency of citation:	18%
Examples of surveyor citations:	▪ Contracted services were not integrated in the quality program such as: – Pathology – Pharmacy services – Laboratory services – Anesthesia – Waste management – Linen processing – Biomedical services – General maintenance ▪ Quality program doesn't address infection control, contracted services, anesthesia, surgical processes.
Tips for compliance:	▪ The annual Quality Plan should identify **all** contracted services, the performance indicators to be measured, and frequency for submitting performance/quality reports.

	▪ Prepare a Quality Committee schedule that identifies the reports due each month/quarter. ▪ Record in the Quality Committee meeting minutes the review of quality reports for each service, along with action plans and sufficient detail to track progress over time. ▪ Quality improvement projects should focus on clinical and clinical support areas.
CHAPTER	**STANDARD**
12 Infection Control	**12.00.02 – Sanitary Environment**
Overview of the requirement:	A functional and sanitary environment for surgical services is maintained to avoid sources and transmission of infections and communicable diseases. This extends to all areas of the facility with the expectation that nationally-recognized infection control guidelines are the basis for related policies and procedures.
Comments on deficiencies:	While this is a repeat high-frequency deficiency, the percentage of citations dropped from 75% on 2017 surveys to 23% in 2018. Some of this year's comments related to the lack of consistent cleanliness in all areas in the ASC.
Frequency of citation:	23%
Examples of surveyor citations:	▪ Lack of awareness of manufacturer's instructions for use regarding wet contact time of decontamination product used. ▪ Cleaning supplies in use beyond expiration dates. ▪ Decontamination process initiated before patient left the room. ▪ Sterilization process conducted with closed ratchets. ▪ Container of OPA/28 in use in non-ventilated area without air exchange monitoring. ▪ Cardboard boxes on floor of clean linen room. ▪ Employee food in designated clean area. ▪ Expired food in employee refrigerator. ▪ Dead insects were present on light fixture lenses. ▪ Gas shut off valves had heavy coating of dust. ▪ Visible dust on light fixture in OR. ▪ Rust found on items such as castors, carts, IV poles, door frames, cabinets, instruments. ▪ Divots in walls, chipped paint observed. ▪ Separation of floor seams observed. ▪ Stained or missing ceiling tiles observed.

Tips for compliance:	▪ Develop policies and procedures regarding cleaning, decontamination, and sterilization of surgical instruments based on manufacturer's recommendations and national infection control guidelines. ▪ Provide staff training regarding these policies; evaluate staff to ensure competence. ▪ Conduct regular "environmental surveillance rounds" to ensure the cleanliness of the facility. Include 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.

Acute Care Hospital Deficiencies



On 2018 surveys of acute care hospitals, 45 standards were cited as not compliant for more than 10% of surveys—36 related to the physical facility (including 33 life safety standards), one related to administrative oversight, and eight related to patient care and safety. Excluding the life safety standards,* these are shown with their frequency of citation in the chart above. The horizontal axis identifies the specific standard by number (see *Accreditation Requirements for Acute Care Hospitals*, 2017 edition, for detail) and the vertical axis shows the frequency with which that standard appeared in an HFAP Deficiency Report for an Initial or Reaccreditation Survey.

The most frequently deficient standards were 11.00.01 Physical Environment and 07.01.02 Infection Prevention. Each of these was a cited deficiency at 68% of surveyed acute care hospitals.

**See pages 14–25 for detail on life safety deficiencies.*

Environment

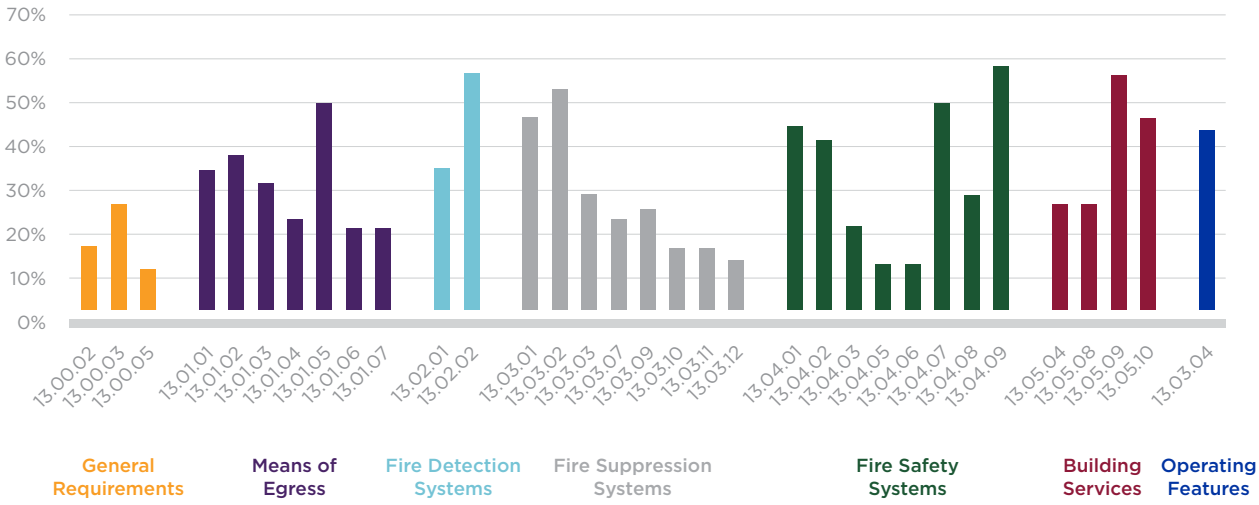
Standard 11.00.01 Physical Environment aligns with a CMS Condition of Participation (CoP) so, for a Medicare Deemed Status Survey, this is a condition-level finding that triggers a second survey event to insure that the Plan of Correction has been fully implemented and the deficiency corrected.

CHAPTER	STANDARD
11 Physical Environment	**11.00.01 – Condition of Participation: Physical Environment**
Overview of the requirement:	The standard language is broad: *the hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment, and for special hospital services appropriate to the needs of the community.* The intent is to tie management of the built environment to patient, staff, and visitor safety.
Comments on deficiencies:	This CoP may be cited based on a single observation, but it is more usually a result of aggregate deficiencies for chapter 11 and chapter 13 Life Safety.
Frequency of citation:	68%
Examples of surveyor citations:	**Note:** These examples reflect findings in chapter 11 only. For relevant, additional citations, see Life Safety Deficiencies, pages 14–25. ▪ The Medical Equipment Management Plan had not been reviewed annually (from 11.00.02). ▪ No documentation that the eyewash station was being tested and inspected (from 11.01.10). ▪ Multiple patient rooms were observed to have the emergency call pull cord wrapped around the handrail (from 11.05.03). ▪ During the building tour, it was observed that the following areas did not have required emergency powered lighting: 1. Generator room. 2. Generator automatic transfer switch room. 3. Surgery rooms (from 11.06.01). ▪ With the ceiling removed in the construction area during construction activity, the ceiling was left open to adjacent patient treatment areas (from 11.07.06).
Tips for compliance:	Develop a robust method for periodic review of physical environment and life safety compliance with strong reporting and follow-up protocols.

CHAPTER	STANDARD
11 Physical Environment	**11.01.02 – Building Safety**
Overview of the requirement:	In addition to maintenance and confirmation of safety for the overall environment, hospitals are expected to proactively review for elements which 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 or geriatric.
Comments on deficiencies:	While some citations relate to temporary hazards that had been overlooked, others reflect a failure to follow established policies or take action to address the findings of risk assessments.
Frequency of citation:	24%
Examples of surveyor citations:	▪ During the building tour, a wall-mounted ladder to the roof was not secure and was available for public access. ▪ During pharmacy documentation review, it was observed that the "Drug Procurement/Inventory Control" policy indicates the refrigerators intended for drug storage will be monitored and data recorded daily through an electronic remote temperature monitoring system. Pharmacy staff interviews indicated email alerts are received when temperatures are outside of range, but staff were not aware of any action required in this situation. No documentation was provided related to a process for mitigating abnormal temperature findings. ▪ Ligature risks were observed in the area designated in the Emergency Department for patients identified as "at-risk" for harm to self or others. The rooms had items including goose-neck faucets, wall-mounted TVs, standard lever door handles, and a magnetic lock assembly with a reinforced hook/metal cover on the swing door.
Tips for compliance:	▪ Read and understand each HFAP standard under 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 used per policy. Facility and clinical staff should be involved in creating and using the same assessment tools.

CHAPTER	STANDARD
11 Physical Environment	**11.07.03 – Ventilation, Light, and Temperature Controls.**
Overview of the requirement:	Hospitals should monitor lighting, temperature, humidity, and air pressure relationships with defined parameters to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort.
Comments on deficiencies:	Overwhelmingly, citations related to incorrect air pressure relationships creating increased risk of spreading infection. This issue contributes significantly to citations progressing to the condition-level.
Frequency of citation:	47%
Examples of surveyor citations:	▪ ORs had negative air pressure relative to adjoining spaces. ▪ The clean supply room has negative air pressure relative to both the corridor and an exterior door missing seals to prevent unfiltered external air from entering the clean supply area. ▪ There is significant dirt and rust on air supply vents and return grilles in the emergency department and the kitchen. ▪ Manufacturers' instructions for use for equipment in the OR is specific to 30% relative humidity. The RH had been reduced to 20% but no documentation of a risk assessment for the reduction was available. ▪ Daily temperature and humidity logs were missing for ORs and sterile supply rooms.
Tips for compliance:	▪ Have a policy and documentation to verify air-pressure relationships and that air changes per hour are checked for critical areas. Test and balance reports (TAB documents) will show this. ▪ Rust cannot be disinfected; be sure that you have a means for verifying maintenance of HVAC air grilles to a cleanable condition and that they are maintained without debris. Remember that high-airflow—especially in ORs—can collect a lot of lint from scrubs and linen. Ever notice that lint build-up is the color of your scrubs?

Acute Care Hospital Deficiencies — Life Safety



Maintaining compliance in the physical environment presents challenges to all organizations based on the number of systems involved and the ongoing change inherent in spaces under continuous use. In 2018, 33 of 62 life safety standards were found to be non-compliant in more than 10% of the hospitals surveyed. In most cases, it was the number of life safety deficiencies that led to a condition-level finding at 11.00.01.

These deficient life safety standards are shown with their frequency of citation above. The horizontal axis identifies the specific standard by number (see *Accreditation Requirements for Acute Care Hospitals*, 2017 edition, for detail) and the vertical axis shows the frequency with which that standard appeared in an HFAP Deficiency Report for an Initial or Reaccreditation Survey.

SECTION	STANDARD
13 General Requirements	**13.00.02 – Alternative Life Safety Measures – Policy** (citation frequency: 17%) **13.00.03 – Alternative Life Safety Measures – Implementation** (citation frequency: 26%) **13.00.05 – Facility Demographic Report (FDR)** (citation frequency: 12%)
Overview of the requirement:	Life Safety standards under General Requirements address the big picture of life safety compliance through audit documents, timing of inspections and testing, risk assessment triggers, etc. When a life safety deficiency cannot be immediately resolved, as during periods of construction, maintenance, or emergency repair, the hospital must have a policy on implementing compensating measures, commonly called ALSMs.
Comments on deficiencies:	Most deficiencies at 13.00.02 were a result of a policy that was insufficiently comprehensive with regard to life safety features. Because this standard is in tandem with 13.00.03, a missing policy is likely to lead to an additional citation at this standard. **NOTE:** The fire damper citation below is sufficient to trigger a condition-level finding. Deficiencies at 13.00.05 resulted primarily from inaccuracies in the document, e.g. outdated information, features missing from inventory lists, and mistakes in classification.
Examples of surveyor citations:	**13.00.02** ▪ ALSM policy did not identify an actual risk assessment process or template. ▪ Policy scope did not address all life safety deficiencies, whether from construction or maintenance, with compensating measures. **13.00.03** ▪ Hospital policy was not followed for the construction project in progress. Policy requires additional fire drills that have not been performed. ▪ Documentation of fire damper inspections indicated multiple deficiencies, with the majority still unresolved at time of survey. No evidence was present of an ALSM risk assessment.

Examples of surveyor citations:	**13.00.05** ▪ During the building tour, entrance doors to the ICU suite were observed to be access controlled. The doors were not listed on the FDR. ▪ FDR indicated that the facility was protected throughout by an automatic sprinkler system. The north medical office building and basement mechanical room are not sprinklered. ▪ Lines 8, 11, 25 of the FDR identify a contact person who is no longer employed by the hospital as responsible for managing the information.
Tips for compliance:	▪ Align policy with the sections of chapter 13. Include a description of the risk assessment process to be followed and compensatory measures for levels of risk identified. Documentation that reveals deficiencies requires corrective action or an ALSM before the end of day when discovered. ▪ Do not leave any blank lines on the Facility Demographic Report (FDR) and use your Life Safety Plans to record elements that will help you fill out the compliance information. If you do not understand the question, you may not be the best person to complete the document; please consult your architect or qualified life safety code professional for assistance.

SECTION	STANDARD
Means of Egress	**13.01.01 – Doors** (citation frequency: 35%) **13.01.02 – Door Locks** (citation frequency: 38%) **13.01.03 – Corridor Clutter** (citation frequency: 32%) **13.01.04 – Suites** (citation frequency: 24%) **13.01.05 – Signage** (citation frequency: 50%) **13.01.06 – Exit Discharge** (citation frequency: 21%) **13.01.07 – Corridor** (citation frequency: 21%) **13.01.10 – Exit Enclosures** (citation frequency: 30%)
Overview of the requirement:	Means of egress standards address providing a safe and protected means of travel from any point within the building to the exterior during emergency situations, especially fire and smoke incidents. This includes prescriptive requirements for life safety features like: travel distances, fire-rating integrity and the capacity of the means of egress, size limitations of spaces based on fire protection systems, requirements for doors within the egress pathway, and testing or inspection requirements for fire sprinkler and fire alarm system components.
Comments on deficiencies:	Facilities should review NFPA requirements periodically to confirm that ALL components meet the specific code sections that govern them. Maintain accurate life safety drawings that contain compliance evidence. Reliance on inspection reports by other authorities having jurisdiction to confirm compliance with all requirements under the Life Safety Code (NFPA 101, 2012 edition) is not generally adequate to confirm full compliance.

Examples of surveyor citations:

13.01.01

- The doors to ORs were observed to be power-operated sliding doors without positive latching. These doors are serving as corridor doors.
- Three sets of sliding doors in the means of egress were observed to be designed as breakaway. These doors had means of locking from the non-egress side with a deadbolt. The deadbolt function would negate the breakaway ability of the door and thus create non-compliant locked doors in the means of egress.
- Dialysis patient bathrooms will not open to 90 degrees due to items stored in the path of the door swing.

13.01.02

- Access-control locks at multiple locations were not equipped with motion sensors mounted on the egress side to automatically unlock the door when someone approaches.
- The mother-baby unit has two doors to the exit stair that require two actions to egress and locking hardware that is not tied to the fire alarm or fire suppression system. These doors are locked at all times.

13.01.03

- During the building tour, the following areas contained items not in use and stored within the required exit access corridor width:
  - On the third floor, two temporary HVAC units were located within the required egress width.
  - In the back Surgery department corridor, storage carts were stored in the required width of the exit access corridor.
- An exit access corridor on the second floor was observed to be 91 inches wide. The unit was renovated after the adoption of the 2000 edition of NFPA 101 which would require compliance with the new construction code requiring exit access corridors to be 96 inches wide.

13.01.04

- On grade level at the north perimeter of the suite, the end of the corridor exiting the suite was observed to lack either a door or a wall separating the suite and providing a complete suite enclosure.

Examples of surveyor citations:

13.01.05

- Multiple doors lead to a public area in the middle of the facility. In the event of a fire, these doors could be mistaken as an exit due to a view that appears to be the exterior. These doors do not have signage that states NO EXIT.
- During the building tour, the exit sign at the entrance vestibule was not illuminated. During the document review session, the monthly inspection of exit signs was only completed for battery-powered exit signs and not all exit signs.

13.01.06

- During the building tour of the clinic, it was observed that the four exterior exit stairs discharged across an unimproved area and uneven surface (a lawn).
- The exit discharge at the maintenance shops does not have normal and emergency illumination to the public way.

13.01.07

- Throughout the facility, fire extinguisher cabinets were protruding more than four inches into the corridor width.
- The wall mounted TV located in the exit access corridor was projected more than four inches into the corridor.

13.01.10

- Flooring installation equipment was stored in the exit stairwell at the business occupancy.
- Two exit stairs were missing a means for interrupting occupant travel to ensure exiting is at the designated floor level without occupants needing to double-back to find the exit.

Tips for compliance:

- Use facility rounding to manage recurring compliance issues (corridor clutter, door swings and exit stairs being clear, etc.). Do not believe or portray these issues as insignificant; coworkers will believe the same.
- Follow-up and train.
- Be sure that facility staff are well versed in identifying egress compliance issues and understand suite requirements.
- Review Life Safety Plans to confirm they do not show non-compliance.

SECTION	STANDARD
Fire Detection Systems	**13.02.01 – Fire Alarm System – Installation and Maintenance** (citation frequency: 35%) **13.02.02 – Fire Alarm System – Testing** (citation frequency: 56%)
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:	System testing is not compliant far more frequently than system installation and maintenance. A process for review and acceptance of compliance testing documentation is required for every piece of evidence that is used to prove compliance.
Examples of surveyor citations:	**13.02.01** ▪ Smoke detectors were located within 36 inches of supply air grilles at nursing stations and waiting areas. **13.02.02** ▪ The report listed six devices as “other devices” and “dampers” were shown as located at air handling units. The testing report listed devices with a status of “Fail” with a comment of “no activation on alarm.” The hospital was not able to clarify the nature of the failure or whether the issue had been corrected. ▪ The fire alarm testing report did not include testing of the following relay modules: – Magnetic hold-opens. – Magnetic locks. – Kitchen hood suppression. ▪ The test of the low air pressure switches did not provide pass/fails for each device. ▪ The water flow and tamper switches were tested annually instead of semi-annually, as required. ▪ The department’s inventory of devices did not match what was tested. ▪ Heat and duct detectors installed did not match the testing documentation (160 inventory vs. 381 tested).
Tips for compliance:	▪ 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 you performed an activity and the results of that activity. ▪ Follow-through on any deficiencies and provide evidence of correction and retesting to a compliant condition.

SECTION	STANDARD
Fire Suppression Systems	**13.03.01 – Water-Based Fire Protection System: Installation and Maintenance** (citation frequency: 47%) **13.03.02 – Water-Based Fire Protection System: Testing and Inspection** (citation frequency: 53%) **13.03.03 – Water-Based Fire Protection System: Control Valves, Piping and Hangers** (citation frequency: 29%) **13.03.07 – Water-based Standpipes & Hoses: Inspection & Testing** (citation frequency: 24%) **13.03.09 – Portable Fire Extinguishers: Installation, Inspection and Maintenance** (citation frequency: 26%) **13.03.10 – Fire Hose Valves** (citation frequency: 17%) **13.03.11 – Internal Inspection of Piping** (citation frequency: 17%) **13.03.12 – Cooking Hood Firs Suppression** (citation frequency: 14%)
Overview of the requirement:	Fire suppression system standards address water and non-water based fire suppression components with regard to installation, maintenance and testing.
Comments on deficiencies:	Installation deficiencies often related to storage elements placed so as to block the intended functional capacity of sprinkler heads. Most other deficiencies related to system testing not performed at the required frequency.
Examples of surveyor citations:	**13.02.01** ▪ In the corridor outside a patient room, a sprinkler head was observed to be covered in foreign material which appeared to be paint. ▪ Patient rooms were observed to have sprinkler heads located within storage closets that have solid wood shelves within six inches of the sprinkler heads and revent. **13.03.02** ▪ During the document review, the hospital was not able to provide monthly control valve and pressure gauge inspection reports. ▪ During the document review, the organization could not produce documentation for the monthly inspection of fire sprinkler control valves. **13.03.03** ▪ Electrical wiring and data cables were observed to be lying on and supported by sprinkler pipes above the ceiling.

Examples of surveyor citations:	**13.03.07** ▪ During the document review, it was observed that the last five-year standpipe water flow test was conducted outside of the five-year interval required by at least six months. ▪ An exit stairwell fire hose connection on the 2½-inch line had a date on the inspection tag that was greater than the three-year interval required. **13.03.09** ▪ During the building tour, at the second floor, fire extinguishers were observed to be in storage and were not restrained. ▪ At the kitchen, access to a fire extinguisher was blocked by a cart. **13.03.10** ▪ No evidence of the testing of 2½-inch and 1½-inch fire hose valves was presented upon request. **13.03.11** ▪ During the document review session, it was observed that the hospital could not provide documentation for the five-year internal inspection of the fire sprinkler system as described in NFPA 25-2011, section 14.2.1. **13.03.12** ▪ During the document review of the semi-annual kitchen hood tests, an eight-month gap was observed between the reports for the end of 2017 and the beginning of 2018.
Tips for compliance:	▪ Review the testing requirements under NFPA 25, other applicable NFPA standards for the specific system, and HFAP standards to verify that the testing documentation accurately portrays and recreates testing activities. ▪ Follow-through on any deficiencies and provide evidence of correction and retesting to a compliant condition.

SECTION	STANDARD
Fire Safety Systems	**13.04.01 – Fire Rated Barriers** (citation frequency: 44%) **13.04.02 – Smoke Barriers** (citation frequency: 41%) **13.04.03 – Fire and Smoke Dampers** (citation frequency: 21%) **13.04.05 – Construction Type** (citation frequency: 14%) **13.04.06 – Separated Occupancies** (citation frequency: 14%) **13.04.07 – Fire Rated Door Assemblies** (citation frequency: 50%) **13.04.08 – Hazardous Areas** (citation frequency: 29%) **13.04.09 – Ceilings** (citation frequency: 59%)
Overview of the requirement:	Fire safety systems reflect standards for building construction designed to impede the ability of smoke or fire to travel through the structure.

Comments on deficiencies:	Whether a fire safety deficiency is observed as a single example or in multiple locations, each observation will be cited.
Examples of surveyor citations:	**13.04.01** ▪ Unprotected penetrations were observed in rated fire barriers at the following locations: 1. Near the cafeteria entrance, above the ceiling grid, an unsealed conduit penetrating the fire barrier was observed. 2. On the lower level near the cafeteria corridor above the ceiling grid, a red, expanding foam was observed sealing a penetration in the fire barrier. The foam did not appear to be a tested fire-stopping product. ▪ During the building tour of the hospital, in the IT closet, a four inch pipe sleeve in the floor was not sealed to provide fire protection. **13.04.02** ▪ At the smoke barrier wall near the soiled utility room, a four inch by four inch unsealed opening was observed to expose a valve located inside the wall. ▪ Near the smoke doors located by the Environmental Services office, an unprotected penetration was observed where two conduits were installed in the smoke barrier walls. **13.04.03** ▪ A damper was observed to have failed testing due to inaccessibility. This had not been corrected at the time of the survey. ▪ The organization did not present evidence that the fire and smoke dampers throughout the facility had been tested at least once in the past six years. **Note:** This deficiency is, at minimum, a condition-level finding. **13.04.05** ▪ During the building tour, it was observed that the fireproofing material that had been applied to the structural steel was missing in several locations. **13.04.06** ▪ The rated double doors within the two-hour rated fire barrier separating the healthcare occupancy from the business occupancy did not have latching hardware as the bottom rods and floor latch receiver openings were not installed.

Examples of surveyor citations:	**13.04.07** ▪ The fire-rated frame of the double doors on the fourth floor was observed to have holes after the facility removed the magnetic locks from the frame. ▪ In the second floor mechanical room, a hazardous location, the door had no rating label at the required one-hour fire barrier. **13.04.08** ▪ In the mechanical room, there was a large amount of storage of a variety of combustible building materials, doors, equipment, and supplies. This mechanical room is not designated as a hazardous location on the life safety drawings. ▪ The loading dock hazardous area corridor doors are not equipped with required latching hardware. **13.04.09** ▪ During the building tour, gaps at ceiling tiles were observed in the following locations… ▪ In the third floor area formerly used for Central Sterile, there are six pipes penetrating the ceiling with large gaps.
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 annual inspection to the next annual inspection. ▪ Be sure everyone knows to report maintenance issues promptly. ▪ Identify a list of approved fire-stopping materials and wall repair designs and use these consistently throughout the facility.

SECTION	STANDARD
Building Services	**13.05.04 – Generator Inspection** (citation frequency: 26%) **13.05.08 – Medical Gas Shutoff Valves** (citation frequency: 26%) **13.05.09 – Utility Systems** (citation frequency: 56%) **13.05.10 – Medical Gas Systems and Equipment: Maintenance** (citation frequency: 47%)
Overview of the requirement:	This set of standards defines requirements for other systems within the hospital.
Comments on deficiencies:	A process for review and acceptance of compliance testing documentation is required for every piece of evidence that is used to prove compliance. Be sure that rounding processes include review of standards compliance issues that are a result of staff action and attention.

Examples of surveyor citations:	**13.05.04** ▪ The weekly sealed lead-acid battery electrical conductive test had not been documented for the past 12 months for the three emergency generators at the facility and one emergency generator at [second location]. **13.05.08** ▪ During the building tour, the medical gas shutoff valves at the ICU nursing station were observed to be obstructed by a supply dispensing unit. ▪ At the main oxygen storage area located outside the building, no sign was observed to indicate the shut-off valve of the main oxygen tank. **13.05.09** ▪ In the surgery electrical room, the electrical panels had no legend/ circuit labels. ▪ In the mechanical room, an electrical panel was missing the required interior metal panel cover required by the panel listing. **13.05.10** ▪ The medical gas O_2 e-cylinders were not segregated into full and empty cylinder storage and a five-foot clearance from combustibles was not provided in the storage area. ▪ During the document review session, the medical gas systems had not been tested within the past year, which is the frequency established by the organization's medical gas testing policy.
Tips for compliance:	▪ Review the testing requirements under NFPA 99, other applicable NFPA standards for the specific system, and HFAP standards to verify that the composition of the testing 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 you performed an activity and the results of that activity. ▪ Follow-through on any deficiencies and provide evidence of correction and retesting to a compliant condition. Note that compliance issues from Medical Gas testing reports may not be required for existing systems and should be noted as such in the documentation.

SECTION	STANDARD
Operating Features	**13.06.04 – Life Safety Drawings** (citation frequency: 44%)
Overview of the requirement:	The required drawings serve as a reference to life safety features throughout the facility and should indicate fire-rated walls and barriers, exit information, boundaries and areas of suites, hazardous rooms, smoke compartments with area and travel distance to closest door, sprinklered areas (and those without sprinklers).

Comments on deficiencies:	Deficiencies were the result of inconsistency between life safety drawings and actual conditions.
Examples of surveyor citations:	▪ During the building tour, the following was observed as varying from the life safety prints: 1. The areas of the building with fire sprinkler coverage are not identified. 2. The furthest travel distance to the exit is not identified on all the floor plans. ▪ The following areas were labeled as hazardous with a one-hour separation on the life safety drawings. The rooms did not meet the requirements for a one-hour separation, but did meet the requirements for hazardous areas per Chapter 19 and the date of original construction… **Hint:** The rooms were compliant, but the drawings reflected a higher level of compliance than required. You will be surveyed to the greater of what YOU require or what HFAP requires.
Tips for compliance:	▪ With the FDR, life safety drawings should serve as a reference for how your egress and rating arrangement meets specific HFAP and NFPA requirements. It is the key map of how the surveyor will review and determine compliance of your facility. The drawings should be reviewed regularly and updated whenever there is a change in room arrangements or use of space, as well as when non-compliance is discovered and requires correction. ▪ Forward a copy of the HFAP standards for life safety drawings to the entity or staff preparing your drawings; many deficiencies could be avoided by providing all elements noted in the HFAP Standard that do not appear on the drawings.

Administrative Oversight

CHAPTER	STANDARD
1 Governing Body	**01.01.23 – Contractor Quality Monitoring**
Overview of the requirement:	The hospital's governing body is ultimately responsible for all services provided whether by employees, formal contract, joint ventures, informal agreements, shared services, or lease arrangements.
Comments on deficiencies:	Deficiencies identified specific contracts that were not reviewed by the governing body.
Frequency of citation:	50%

Examples of surveyor citations:

- Based on review of the QAPI program, it was noted that five contracted services failed to report data to the QAPI program and therefore did not report data to the Governing Body. These services were:
    1. Laundry
    2. Biohazard waste
    3. Medical director
    4. Confidential shredding service
    5. Dialysis
- Based on review of documents, policies and procedures, and interviews with administrative staff, there are 155 agreements for services for which no documentation exists demonstrating that an evaluation has been completed.
- Document review indicated that the facility has a process for evaluating contracted services, but the mechanism did not include the use of relevant and meaningful indicators to assess the quality of services rendered.
    - The process includes six questions reviewed for each contract, but they were general in nature and did not provide an adequate basis for the Quality Committee to reach a conclusion.
    - Appropriate indicators exist at the departmental level but they were not submitted to, or reviewed by, the Quality Committee. Therefore, the governing body was unable to be assured that contracted services were provided in a safe and effective manner.
    - This omission applied to all 16 of the facility's contracted patient care services. Specific examples include:
        1. blood center
        2. lithotripsy services
        3. dialysis

Tips for compliance:

- Develop a written policy that describes the process for evaluating contracted services.
- Evaluations travel through the quality review process up to the governing body.

Patient Care and Safety

Standard **07.00.00 – Infection Control** and **09.00.00 – Emergency Preparedness** align with CMS Conditions of Participation (CoP) so, for a Medicare deemed status survey, these are condition-level findings that trigger a second survey event to insure that the Plans of Correction have been fully implemented and the deficiencies corrected.

CHAPTER	STANDARD
7 Infection Control	**07.00.00 – Condition of Participation: Infection Control**
Overview of the requirement:	Infection control is proactive, addressing prevention, containment, and investigation in a broad-based program that includes all locations, departments, and services. Beyond maintaining a sanitary environment, the hospital maintains an active surveillance program with appropriate interventions. The infection control program is integrated into the hospital-wide QAPI program.
Comments on deficiencies:	This CoP may be cited based on a single egregious observation, but it is more usually a result of aggregate infection control issues throughout the organization. **Note:** the citation examples were edited and do not include the list of chapter standards found "not compliant."
Frequency of citation:	15%
Examples of surveyor citations:	▪ Based on touring the facility, infection control issues were observed throughout patient care areas, the diet kitchen, operating rooms and surgical service areas. The severity and cumulative effect of these systematic deficiencies results in this Condition of Participation being not-compliant in regard to infection control requirements. The following standards were found not compliant… ▪ Based on building tour, observations, document review, and interviews it was determined that the Condition of Participation for infection control was not met as evidenced by the prevalence of rust throughout the hospital surgical services and off-campus surgical center; lack of an effective process to disinfect metal equipment and environmental surfaces; presence of divots in the operating room floors; presence of floor separations in the operating rooms; presence of stained ceiling tiles; presence of ceiling tiles with gouges; lack of evidence the infection control committee had approved infection control policies and cleaning products inventory; presence of expired blood tubes; presence of shipping cartons in patient care areas; lack of an effective process to monitor refrigerator temperatures; presence of grossly dirty medication carts; a biohazard storage room located in the area of food supplies; observations of a build-up of dust in the air wall grille on the nursing unit; presence of dirty and soiled staff refrigerator and microwave oven; and presence of a dusty environment on the fourth floor nursing unit.

Tips for compliance:	▪ A Condition of Participation may be cited based on a prevalence of infection control concerns throughout a facility. ▪ The hospital should conduct regular infection control surveillance rounds and report findings to the QAPI Committee. ▪ Develop action plans to correct the infection control deficiencies identified through surveillance. ▪ Adopt a culture of cleanliness.

CHAPTER	STANDARD
7 Infection Control	**07.01.02 – Infection Prevention**
Overview of the requirement:	An individual or individuals are tasked with responsibility for the infection prevention and control program which is developed and implemented collaboratively across all departments/services and addresses sanitary environments; staff policies related to immunizations, screening for infection, restrictions on direct patient care, training to prevent HAI; mitigation of risk associated with patient infections; active surveillance; reporting requirements.
Comments on deficiencies:	Citations touch on everything from outdated policies to cleaning methods to storage issues. Most of the various deficiencies cited reflect infection control issues "hiding in plain sight."
Examples of surveyor citations:	▪ A total of 13 metal cabinets had evidence of significant rust on the horizontal top surface. Each cabinet was located next to the bed of patients being held for pre-op and post-op surgical services. Patient supplies (bandages in boxes, tape in boxes, and EKG stickers in boxes) were placed on the rusty top surface of each of the 13 cabinets. ▪ During evaluation of central sterile, it was noted that the policies and procedures for processing instrument trays and the use of biological indicators was last approved in January 2009. ▪ During a tour of the kitchen, there were unlabeled items without a "use by" date; labeled item past their "use by" date; a rodent trap adjacent to a bulk food bin; and four open containers of cleaning solution in food preparation areas. ▪ During the tour of the surgical department, an IV pole with corrosion on the base and wheels was in OR 6. A pediatric bronchoscope was stored uncovered in a foam container in the difficult airway cart with no known date of cleaning noted. Review of scope cleaning policy did not indicate a frequency for cleaning and review of scope cleaning logs indicated that some scopes had not been reprocessed for up to 12 days.

Tips for compliance:	▪ Teach staff to recognize infection control concerns and report to the infection control practitioner. Effective cleaning and disinfection cannot occur where rust, torn furniture, wall and floor divots, and separations in flooring are noted. ▪ Infection control-related policies are to be approved at least every three years by the Infection Control Committee. ▪ Be sure food products are labeled with the "use by" date. ▪ Cardboard boxes cannot be stored in the hospital due to the risk of vermin.

CHAPTER	STANDARD
9 Emergency Management	**09.00.01 – Condition of Participation: Emergency Preparedness**
Overview of the requirement:	The hospital must develop a comprehensive emergency preparedness program focused on capacity and capability for any type of emergency or disaster in compliance with all federal, state, and local requirements.
Comments on deficiencies:	Citations for this condition reflect cumulative deficiencies across the chapter.
Frequency of citation:	18%
Examples of surveyor citations:	▪ The Emergency Preparedness Program had not been integrated into the hospital-wide QAPI plan; some Emergency Operations Plan (EOP) policies did not have an annual review or update; the emergency supply list had not been reviewed and updated on a semi-annual basis; there is no written vendor agreement for replenishment of generator fuel; the EOP staff call-back roster had not been updated semi-annually; the EOP physician and volunteer call-back rooster did not include names and contact information; no off-site outpatient facilitates had participated in EOP exercises within the past calendar year. ▪ The facility did not define the special needs of patients at-risk in the event of an emergency; pharmacy and materials management did not define the supplies needed to meet the needs of patients in an emergency situation; the facility did not have a written plan or agreement for the continuation of sewage and waste disposal; the evacuation plan was not reviewed with the local emergency response agency; no policies or procedures to upload the paper emergency charts to the EMR were provided; no plan to verify each volunteer's identity, license, credentials, certifications, malpractice insurance, and hospital privileges; the names of the local hospitals with which the facility has signed transfer agreements were not identified; no definition of the facility's role in the 1135 waiver process; security policies did not identify how supplemental security personnel may be obtained under the security company contract; the security plan did not define procedures to be implemented in an emergency, including lock down, redirection, crowd control, and media control; the plan failed to identify the location of the staff call-back roster;

Examples of surveyor citations:	the communication plan lacked names and contact information of entities providing services under arrangement, physicians, other hospitals and CAHS, volunteers, federal, state, tribal, regional and local preparedness staff, and other sources of assistance; the emergency communication plan did not address the hospital's plan to share patient information with other healthcare providers and lacks a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance.
Tips for compliance:	▪ Review the HFAP standard and know what part of the EOP relates to proving compliance with that standard. Staff responsible for Emergency Management need to be able to locate the relevant part of the EOP with ease.

CHAPTER	STANDARD
9 Emergency Management	**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 who would need additional assistance in the event of evacuation.
Comments on deficiencies:	Deficiency citations uniformly found that at-risk patient populations were not specifically identified in the EOP.
Frequency of citation:	26%
Examples of surveyor citations:	▪ Based on review of documents, the Emergency Operations Plan (EOP) did not identify at-risk patient populations who have special needs during an emergency.
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.

CHAPTER	STANDARD
9 Emergency Management	**09.01.02 – Nutritional Services**
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:	Citations resulted from either lack of policy or required elements missing from an existing policy.
Frequency of citation:	29%
Examples of surveyor citations:	▪ There was no policy and procedure addressing methods to ensure the nutritional needs of patients, staff and visitors are met during emergencies including major facility disruptions. ▪ The plan did not address: loss of water, electricity, gas equipment; disruption of deliveries; required agreements with other providers for priority deliveries; or three day calculated volumes of items required by this standard.

Tips for compliance:	Provide a detailed and quantitative outline of menus, supplies, required inventory, and preparation required under emergency circumstances.

CHAPTER	STANDARD
9 Emergency Management	**09.01.03 – Supplies**
Overview of the requirement:	The standard addresses the need for an inventory of medical and pharmaceutical supplies and equipment, documented and reviewed semi-annually, to meet subsistence needs of staff and patients who may be sheltered in place during an emergency.
Comments on deficiencies:	Citations resulted from either lack of policy or failure to conduct and document semi-annual inventory review.
Frequency of citation:	29%
Examples of surveyor citations:	▪ Neither the pharmacy nor materials management has defined the medical and pharmaceutical supplies the facility must maintain to meet the potential needs of patients in an emergency situation. ▪ During document review, the hospital was not able to provide documentation or identify that there were sufficient additional medical supplies and medical gas onsite to service patients and staff for 96 hours. There was nothing prepared to clarify that what was on hand was adequate. ▪ During the EOP review session, it was observed that the emergency supply list had not been reviewed semi-annually. There was no evidence that a supply list review had taken place in the past twelve months of the Safety Committee minutes.
Tips for compliance:	Provide a detailed and quantitative outline of the required inventory and required maintenance activities.

CHAPTER	STANDARD
12 Quality Assessment & Performance Improvement (QAPI)	**12.00.01 – Data Collection and Analysis: Program Scope**
Overview of the requirement:	The standard requires that the hospital define and measure quality indicators organization-wide, collect these data, and use them to demonstrate improvement in outcomes.
Comments on deficiencies:	Deficiency citations related to the scope of data collection with some departments or contracted patient care services failing to report on quality indicators.
Frequency of citation:	35%

Examples of surveyor citations:	▪ During document review with the Director of Quality it was noted that quality metrics were not received and reviewed from all contracted services. Examples of these omissions included: 1. Telemetry (for two locations). 2. Endoscopy (for two locations). 3. Nutritional Services (one location). 4. Radiology (two locations). 5. Laboratory (two locations). ▪ During document review, the facility lacked evidence that the following services submit quality data to the QAPI Program: 1. Department of Rehabilitation Services. 2. Contracted Services: No data could be produced for the following contracted services: – Linen Services – Laser Services – Organ Procurement
Tips for compliance:	▪ The organization is at risk of a Condition of Participation if a department is not integrated with the hospital QAPI program. ▪ Ensure the Director of Quality is knowledgeable of the requirements for evaluating contracted services, consistent with standard 01.01.23 (see page 25). ▪ Be sure the annual Quality Plan incorporates every department, service, and contracted service, as well as the performance indicators and frequency for reporting to the Quality Committee.

CHAPTER	STANDARD
15 Patient Rights & Discharge Planning	**15.01.17 – Privacy & Safety: Safe Setting**
Overview of the requirement:	Hospitals comply with this standard by demonstrating a safe environment for vulnerable patients including newborns and children. The organization must identify patients at risk for intentional harm to self or others, identify and mitigate environmental safety risks for such patients, and provide education and training for staff and volunteers.
Frequency of citation:	18%
Examples of surveyor citations:	▪ Based on review of open patient medical records, five of five patients did not have a risk assessment completed to determine if they were at risk to themselves or others at the time of admission or during their hospitalization.

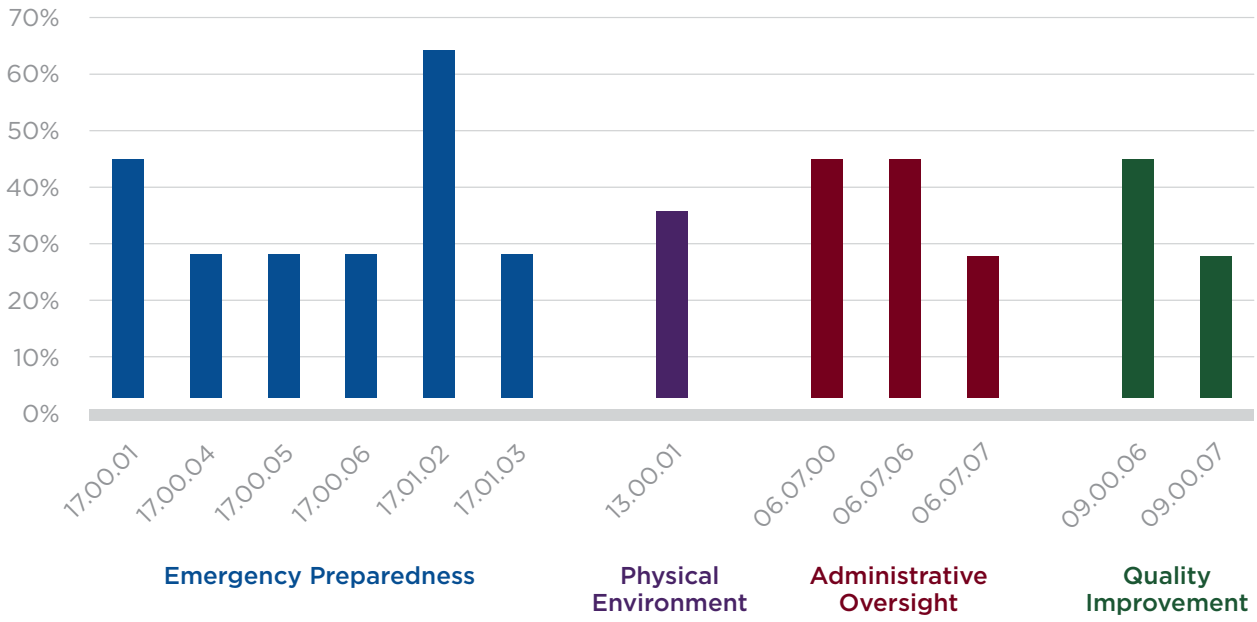
Examples of surveyor citations:

- During the facility tour on the geriatric behavioral health unit with the Chief Nursing Officer and Director of Nursing, the following patient safety risks were observed:
  - Shower valve that presents a looping and hanging potential for patient self-harm was observed in one of one community bathrooms on the unit.
  - Ten of ten electric beds in patient bedrooms on the unit have approximately three foot long electrical cords attached. These cords are kept shortened with a cable tie; however, if a patient opened this tie, the cords present a looping and hanging potential for patient self-harm.
  - One of ten beds has a fall prevention bed alarm with an approximately three foot cord attached.
  - Five of five patient bedrooms have privacy curtains with hooks attached to the ceiling that present a looping and hanging potential for patient self-harm.

Tips for compliance:

- Hospitals must demonstrate they have processes to identify patients at risk for harm to self or others, and have identified environmental safety risks for such patients.
- Hospitals are expected to implement a patient risk assessment tool; there are numerous tools available and no one size fits all.

Critical Access Hospital (CAH) Deficiencies



On 2018 surveys of critical access hospitals, 12 standards were cited as "not compliant" for more than 10% of surveys including two condition level standards. Six related to emergency management (including the relevant Medicare Condition of Participation); one related to physical environment (also at the condition level); three related to administrative oversight of contracted services; and two related to evaluation and performance improvement. Each of these is shown with its frequency of citation in the graph above. The horizontal axis identifies the specific standard by number (see *Accreditation Requirements for Critical Access Hospitals*, 2018 edition, for detail) and the vertical axis shows the frequency with which that standard appeared in an HFAP Deficiency Report for an Initial or Reaccreditation Survey.

Emergency Management

CHAPTER	STANDARD
17 Emergency Management	**17.00.01 – Condition of Participation: Emergency Preparedness**
Overview of the requirement:	The CAH must develop a comprehensive emergency preparedness program focused on capacity and capability for any type of emergency or disaster in compliance with all federal, state, and local requirements.
Comments on deficiencies:	Citations for this condition reflect cumulative deficiencies across chapter 17.
Frequency of citation:	45%
Examples of surveyor citations:	▪ Based on observations, documentation review, and interviews with hospital staff, the hospital failed to develop and maintain a comprehensive emergency preparedness program that meets the requirements of this chapter and the health, safety, and security needs of the staff, patient population, and community during an emergency situation. ▪ The Emergency Operations Plan (EOP) did not describe the type of services the hospital will provide under EOP activation. The EOP did not adequately describe provision for the loss of emergency gas, fuel and electric, provision for equipment failure, or provision for the potential disruption of grocery and food preparation items. The emergency supply list had not been reviewed and approved semiannually and had not been reviewed by the quality and safety committee. The EOP failed to address security of supplies from misappropriation and how supplemental security is addressed in an emergency event. Contact information for entities listed is not included. The communication plan does not describe how to provide information about the CAH's occupancy, needs, and its ability to provide assistance to the authorities having jurisdiction and the incident command center. No outpatient sites had participated in an emergency exercise in the past year. ▪ The Emergency Operations Plan (EOP) lacks full details for the strategies and activities designed to reduce the risk associated with emergency events. There is no provision in the EOP to address: the needs of various patient populations; delegation of authority and staff assigned roles in another's absence; communication with the authorities; policies and procedures required to flesh-out the EOP; or disaster dietary services (calculations for a 3-day supply of food and related products), THe EOP is missing: policy/procedure on supplies, pharmaceuticals and equipment; policy/procedure regarding alternate sources of energy and usage; policy/procedures for tracking on-duty staff and sheltered patients; policy/procedures for safe evacuation; policy/procedures for sheltering in place; policy/procedures regarding preservation of medical documentation including patient

Examples of surveyor citations:	information, security of information, availability of records, and record information sharing; policy/procedures for continuity of services; policy/procedures addressing security of patients, walk-in patients, staff, or visitors; policy/procedures for chemical, biological and radioactive decontamination; policy/procedures for the incident command center; an emergency communication plan with required contact information elements; policy/procedures regarding a primary and alternate means of communicating with staff, federal, state, tribal, regional, and local emergency management agencies; policy/procedures regarding release of information in the event of an evacuation; policy/procedures for providing information including occupancy, needs, and the ability to provide assistance; policy/procedures for training and testing new and existing staff, contractors, volunteers and physicians regarding their expected roles in emergencies.
Tips for compliance:	Establish a set of scenarios and, using the EOP, attempt to walk through the process of set up for an incident command center and all of the services that would need to be provided. Note where the EOP fails to define who (recipients and providers of services), what, when, or where. Then use this critique to create/augment/revise policies and procedures until you achieve confirmation that the EOP can be successfully implemented based on the provisions of the plan.

CHAPTER	STANDARD
17 Emergency Management	**17.00.04 – Patient Population**
Overview of the requirement:	The Emergency Operations Plan (EOP) must address 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 defined in the EOP.
Frequency of citation:	27%
Example of surveyor citations:	▪ Based on review of documents, the EOP did not identify at-risk patient populations within the CAH.
Tips for compliance:	This is a "who" issue within emergency management. Cross reference the EOP against each hospital department to ensure that the range of "at-risk" patients is addressed in the plan. This includes disabled, elderly, pediatric, and anyone with a reduced capacity to care for themselves. Within the EOP, include descriptions of how the identified patient populations will be accommodated.

CHAPTER	STANDARD
17 Emergency Management	**17.00.05 – Services**
Overview of the requirement:	To facilitate coordination of services, the hospital must identify the type(s) of services it can expect to provide in an emergency.
Comments on deficiencies:	Deficiencies indicate that the EOP is not sufficiently comprehensive.
Frequency of citation:	27%
Example of surveyor citations:	▪ The EOP did not address the types of services that the CAH has the ability to provide during an emergency or a plan for continuing those services during an emergency.
Tips for compliance:	This is a "what and where" issue within emergency management. Some services that are normally provided by the hospital may not be available during an emergency, such as a mobile MRI or services that are not available when the facility only has emergency power. Cross reference the EOP against each hospital department to address what will be provided and where it will occur.

CHAPTER	STANDARD
17 Emergency Management	**17.00.06 – Continuity of Operations**
Overview of the requirement:	Compliance with this standard includes identifying how authority/ responsibility will be delegated under an emergency management structure.
Comments on deficiencies:	Deficiencies indicate that the EOP is not sufficiently comprehensive regarding authority delegation and assigned responsibilities.
Frequency of citation:	27%
Examples of surveyor citations:	In reviewing the EOP, the following was observed: 1. There was no provision for delegation of authority. 2. There was no plan for which staff would assume specific roles in another's absence.
Tips for compliance:	This is a "what and who" issue within emergency management. The EOP must specifically delineate the leadership structure during an emergency, including who is in charge of critical operations and who manages of processes enacted under the plan.

CHAPTER	STANDARD
17 Emergency Management	**17.01.02 – Nutritional Services**
Overview of the requirement:	The CAH 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:	Citations resulted from inadequately defined procedures or failure to integrate dietary services with emergency management.
Frequency of citation:	64%
Examples of surveyor citations:	▪ The nutritional services emergency preparedness plan consisted of a series of fragmented individual policies and did not adequately describe the following responsibilities of the department: 1. Provision for the loss of emergency gas, fuel and electric. 2. Provision for equipment failure that includes dishwashing machines, pumps, refrigeration and cooking appliances. 3. Provision for the potential disruption of the delivery of grocery and food preparation items. ▪ In reviewing departmental emergency management procedures, there was no documentation regarding the provisions for disaster dietary services, including dealing with utility loss, equipment failure, and disruptions of food supplies. There was no evidence of calculations for a three-day supply of food and food service related products. ▪ No evidence was presented confirming that the nutritional services department coordinated emergency services planning with emergency management.
Tips for compliance:	Review the EOP to confirm that nutritional requirements are included or referenced. For food and water supply, include sample menus and a way to quantify supplies; show how many people you anticipate needing services and what food you need based on that number and the sample menus. Be sure that the menus coordinate with the cooking methods you have stated will be available when the EOP is active.

CHAPTER	STANDARD
17 Emergency Management	**17.01.03 – Supplies**
Overview of the requirement:	The standard addresses an inventory of medical and pharmaceutical supplies and equipment, documented and reviewed semi-annually, to meet subsistence needs of staff and patients who may be sheltered in place during an emergency.

Comments on deficiencies:	Citations resulted from failure to conduct or document an emergency supply inventory.
Frequency of citation:	27%
Examples of surveyor citations:	▪ Safety Committee minutes did not indicate that the emergency supply list had been reviewed semi-annually. ▪ Review of the EOP produced no policy/procedure for emergency supplies, pharmaceuticals, or equipment.
Tips for compliance:	Inventory supplies and update the inventory twice a year. This is important to manage supply expiration and maintain security of access to the supplies.

Physical Environment

CHAPTER	STANDARD
3 Physical Environment	**03.00.01 – Condition of Participation: Physical Environment**
Overview of the requirement:	The standard language makes broad reference to access, safety, and adequacy of space for services provided. Surveyors will look for compliance with standards throughout this chapter and chapter 14 – Life Safety when assessing compliance.
Comments on deficiencies:	This CoP may be cited based on a single observation, but it is more usually a result of aggregate deficiencies for chapter 3 and chapter 14 Life Safety. Review pages 14–25 for life safety deficiency descriptions for acute care hospitals. The two facility types had significant overlap in this area of non-compliance as the requirements for life safety systems testing and maintenance are the same if the CAH has the required system.
Frequency of citation:	36%
Examples of surveyor citations:	▪ Based on observations, documentation review, and interviews with hospital staff, the hospital failed to ensure that the physical environment was constructed, arranged, and maintained to ensure the safety of the patients (standard level deficiencies detailed). ▪ The facility did not provide evidence of: six required management plans under 03.00.02 and the responsible individual for each; Safety Committee Chairperson appointed by the Chief Executive Officer; thirty-six month review for safety policies; annual emergency eyewash and shower inspections; annual review for security sensitive areas; designation in writing for an individual to coordinate hazardous materials handling; update for paper Safety Data Sheet (SDS) references; fire drill critique review by the Safety Committee; 100% requirement for maintenance in medical equipment policy; evidence that operators and maintenance staff for equipment participate in new equipment acquisition;

Examples of surveyor citations:	emergency lighting inside the generator enclosure; review of water testing reports by the Safety Committee; 100% requirement for maintenance in plant equipment policy; operating room environment monitoring; policy statement for contacting the insurance company regarding fire alarm and fire sprinkler outages. A wrong lock-type was identified on the Facility Demographic Report (FDR); delayed egress doors were not labeled. Chairs and blood-pressure equipment stands were stored in the exit access corridor required width; required illuminated exit signs were missing; fire alarm circuit identification was missing; fire alarm pull station was blocked. Multiple components of the fire alarm not tested or pass/fail not noted; pressure gauge inspection and some valve exercise or inspections missed; wire supported by sprinkler piping; K-type fire extinguisher placard missing; no monthly kitchen hood inspection; multiple unsealed penetrations in fire-rated barriers; issues with fire and smoke damper testing; lack of annual fire-rated door assembly inspections; lack of generator remote shut-off switch; electrical panel access blocked; lack of policy to identify medical gas system testing interval; lack of resolution to OR #3 medical gas issue; building systems risk assessment not reviewed by the Safety Committee; the life safety drawings did not contain all required elements under the HFAP standard.
Tips for compliance:	Develop a robust method for periodic review of physical environment and life safety compliance with strong reporting and follow-up protocols.

Administrative Oversight

CHAPTER CHAPTER	STANDARD
6 Provision of Services, Section 7: Contracted Services	**06.07.00 – Contracted Services**
Overview of the requirement:	Agreements to provide healthcare services to patients must be with a Medicare-certified provider or supplier except in the case of telemedicine services. The CAH's governing body is responsible for these services and they are integrated into the CAH's quality program just as services provided directly.
Comments on deficiencies:	Deficiencies identified specific contracts that were not reviewed by the governing body.
Frequency of citation:	45%
Examples of surveyor citations:	▪ During document review there was no evidence in the board minutes for the previous twelve month period of a verbal or written report assessing the clinical services furnished directly or indirectly to patients provided under contract. ▪ The facility lacked evidence of written evaluations for approximately 30 medical related contractors.

	▪ Laundry services are provided through a contract. There was no evidence that the Quality Committee had evaluated the services.
Tips for compliance:	Using the list required by 06.07.06, the organization must funnel review of contracted services to the governing body through the QAPI program/committee.

CHAPTER	STANDARD
6 Provision of Services, Section 7: Contracted Services	**06.07.06 – List of Contracted Services**
Overview of the requirement:	The CAH maintains a list of services furnished under arrangement and describes the nature and scope of each.
Comments on deficiencies:	Most deficiencies identified missing elements or missing contracts, an indication that the list is not updated with sufficient regularity.
Frequency of citation:	45%
Examples of surveyor citations:	▪ Based on document review, the list of contracted services does not describe the nature and scope of the services provided. The following elements were missing: 1. Whether the services are offered on-or off-site. 2. Whether there is any limit on the volume or frequency of the services provided. 3. When the service is provided. ▪ The current list of contracted services identifies the name of the contracted provider but no description of the service(s) being provided. ▪ The contract list is missing the new dialysis service provider.
Tips for compliance:	▪ Review the list on an identified schedule and as services are added, changed, or removed. ▪ Conduct a gap analysis to ensure each contracted service is listed and includes: – A description of the services offered (nature and scope). – Whether the services are offered on-site of off-site. – Whether there is a limit on the volume of services. – When these services are available.

CHAPTER	STANDARD
6 Provision of Services, Section 7: Contracted Services	**06.07.07 – Responsibility for Contract Services**
Overview of the requirement:	The CEO or other individual responsible for operation of the CAH is also responsible for services furnished by contract.
Comments on deficiencies:	Deficiencies identified specific contracts that were not reviewed by the governing body.

Frequency of citation:	27%
Examples of surveyor citations:	▪ The hospital lacked a mechanism to ensure all contracted service providers meet all the Conditions of Participation. ▪ Based on document review, staff interview and review of board minutes from January 2016 to the present, there was a lack of oversight by the board and CEO of contracts for services provided directly to patients and services related to patient care, such as environmental cleaning, laundry, etc. This was evidenced by the non-compliance for: – Standard 06.07.00 – Standard 06.07.06 – Standard 09.00.06
Tips for compliance:	1. Be sure the Quality Director is knowledgeable of standard 06.07.06 in order to incorporate contracted services into the Quality Plan. 2. The CAH should have a process through which all quality reports are forwarded to the Governing Body for review. These reviews are memorialized in meeting minutes along with the respective action plans that enable the CAH to comply with all applicable conditions of participation for that service.

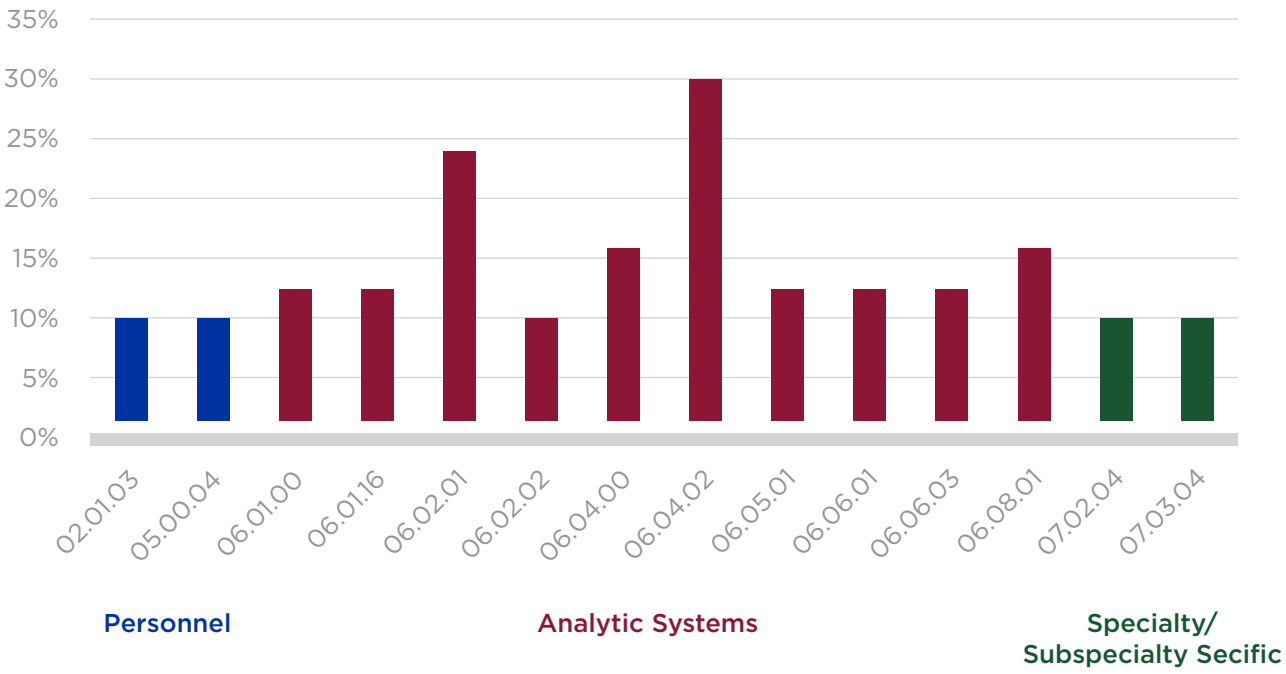
Quality Improvement

CHAPTER CHAPTER	STANDARD
9 Periodic Evaluation and Performance Improvement	**09.00.06 – Quality Assurance**
Overview of the requirement:	The CAH has a quality program that is organization-wide.
Comments on deficiencies:	Deficiencies represent errors in addressing quality “organization wide.”
Frequency of citation:	45%
Examples of surveyor citations:	▪ Data from the following processes are collected but not submitted to the quality program: 1. medication management. 2. discharge planning. 3. blood use. 4. complaints. 5. restraints. 6. mortality review.

Examples of surveyor citations:	▪ The January 2018 report included acceptance of "most" contract reports for Q4 of 2017. However, there was no evidence of a report for laundry services with that meeting. There were no other laundry contract service reports for 2018. ▪ Review of Quality Committee meeting minutes and interview with the Quality Director revealed that contracted services were not collecting, analyzing and identifying actions that may be needed for improvement, as required. ▪ Examples of missing contracted services include: 1. dialysis. 2. rural health network. 3. telehealth.
Tips for compliance:	▪ Ensure the annual Quality Plan identifies monitoring for each required item listed in standard 09.01.04. Include the performance indicators and frequency for submitting quality reports for each. ▪ Document review of each service, strategies for improving patient care, progress achieved, and record sufficient detail to track the progress over time within the minutes of the Quality Committee.

CHAPTER	STANDARD
9 Periodic Evaluation and Performance Improvement	**09.00.07 – Evaluation of Patient Care and Related Services**
Overview of the requirement:	The quality program evaluates all direct and indirect patient care services.
Comments on deficiencies:	Citations identified specific areas related to patient care that were not reviewed by the quality committee or its equivalent.
Frequency of citation:	27%
Examples of surveyor citations:	▪ Based on interview, the facility maintains 43 contracts for services directly or indirectly related to patient care. The Quality Manager indicated that none of these services are reporting quality indicators to the Quality Committee and are not reviewed by the Governing Body. ▪ Based on document review, the facility lacked evidence it had evaluated the quality of the following services: 1. Nutrition services 2. Contracted services
Tips for compliance:	▪ Develop a schedule for each service to submit quality reports. ▪ Be sure all quality reports are submitted to the governing body for review. Meeting minutes reflect review and development/ discussion of strategies to improve patient care.

Laboratory Deficiencies



Laboratory services are addressed on all acute care, critical access, and ASC surveys as applicable to the services provided by those organizations, but clinical laboratories undergo unique, **biennial** surveys to maintain accreditation and CLIA certification. On average, HFAP-accredited labs were cited for 7.6 non-compliant standards.

The chart above shows frequent deficiencies for facilities that participate in the **HFAP Clinical Laboratory Accreditation program**. The horizontal axis identifies the specific standard by number (*Accreditation Requirements for Clinical Laboratories*, 2014 edition) and the vertical axis shows the frequency with which that standard appeared in an HFAP Deficiency Report for an Initial or Reaccreditation Survey. On 2018 surveys of clinical laboratories, 21 standards were cited as "not compliant" on at least 10% of surveys. Two related to personnel requirements; ten related to analytic systems; two related to specialty/subspecialty standards and seven to proficiency testing. The PT standards are identified separately in the graph on page 55.

The detail below includes the standard cited, the new 2019 standard identifier (where applicable), an overview of the requirement(s), trends in deficiencies, examples of surveyor citations, and tips for compliance.

CHAPTER	STANDARD
Laboratory Personnel	**02.01.03 – Delegation of Responsibilities**
Overview of the requirement:	The laboratory director is responsible for all the duties performed within the clinical laboratory. The laboratory director may delegate some of these duties to qualified individual(s). This delegation must be in writing.
Comments on deficiencies:	This standard is most often cited as a result of not having the delegation of responsibilities in writing or not specifying to whom the responsibilities are delegated.
Frequency of citation:	10%
Examples of surveyor citations:	▪ The medical director had not issued an assignment of duties to the laboratory personnel or the responsibility to sign attestation statements for proficiency testing. The medical director did not issue restrictions to laboratory administration from signing the blood bank attestation statement, which can only be signed by a physician. ▪ A clear delegation of responsibility was not present. There were two documents that contradicted each other.
Tips for compliance:	▪ Develop a written document that delegates appropriate responsibilities to qualified individuals. ▪ Assure that the written document is approved by the current laboratory director.

CHAPTER	STANDARD
General Systems	**05.00.04 – Personnel Competency Assessment Policies**
Overview of the requirement:	The laboratory must have a policy regarding employee and consultant competency assessment.
Comments on deficiencies:	This standard is non-compliant when a policy is missing or when the laboratory has developed but does not follow personnel competency policies and procedures.
Frequency of citation:	10%
Examples of surveyor citations:	▪ The laboratory does not do consistency studies for personnel competency for the gram stain, the differential in hematology, or for urine sediment. ▪ Review of documents and interview with the laboratory manager revealed that the procedure in place for competency assessment was from 2006 and was not consistent with the current required competency assessment standards. The procedure does not include competency assessment at six months and does not include the running of an unknown, or using a PT specimen, for each test system on an annual basis.

Tips for compliance:	▪ Establish a policy that defines how each of the six required elements for competency evaluation are to be met. ▪ The policy should include the frequency of competency evaluations and who will perform these evaluations.

CHAPTER	STANDARD
Analytic Systems	**06.01.00 – Procedure Manual** (manual: 2014 edition, used for surveys prior to July 1, 2019) **06.00.01 – Procedure manual** (manual: 2019 edition, used for surveys taking place on or after July 1, 2019)
Overview of the requirement:	The laboratory has a manual detailing the procedure for each test, assay, and examination it performs that is available to, and consulted by, all relevant personnel.
Comments on deficiencies:	Deficiencies noted the use of dual systems (print manuals plus electronic documents) that resulted in inconsistency when only one format was updated. In some cases, actual practice has changed, but the policy/procedure description lagged behind.
Frequency of citation:	12%
Examples of surveyor citations:	▪ The blood bank manual revealed that polices in binders were not the most recent version. Edits were made by writing on the prior version without indication that these edits were approved by the medical director. Interview with the director of performance improvement revealed that staff is told to use the online version. Several edits in printed manuals did not appear in online versions. Examples include: Type and Screen Policy and Immediate Spin Crossmatch Policy. ▪ When staff was asked to find a procedure, many did not know how to use the electronic system or where to find a printed version of the document. Paper copies were not the same version as those in [electronic system name] and there was no documentation that any of the policies were being reviewed by the staff. ▪ Review of records and interview with staff indicated that there was no written policy for testing CSF and using blood warmers. ▪ During review of the procedure manual it was noted that the manual needed to be revised so that it reflects specific procedures that this laboratory uses. Some examples of these were: 1. The procedure for inking the margins of Mohs specimen. 2. The procedure describing the technique to be used for relaxing the specimen before cutting onto a slide within the cryostat. 3. The procedure for the staining and cover-slipping the slide.
Tips for compliance:	▪ Procedures may be organized in a paper-based, electronic, or web-based format. Regardless of the format, procedures must be available in the work area.

Tips for compliance:	▪ If the laboratory uses electronic manuals, staff must be trained on how to access them. In the event of power failure, or network or LIS downtime, staff must have access to procedures. This may be via paper copies or electronic copies on CD or other digital media. Regardless of the back-up system used, the laboratory must ensure that the back-up procedures match those procedures routinely used by staff.

CHAPTER	STANDARD
Analytic Systems	**06.01.16 – Procedure Approval** (manual: 2014 edition, used for surveys prior to July 1, 2019) **06.01.04 – Procedure Approval** (manual: 2019 edition, used for surveys on or after July 1, 2019)
Overview of the requirement:	The intent of this standard is to ensure reliable oversight by the current laboratory director of ALL procedures performed. When there is a change to a previously approved procedure (manual, MIU, package insert, etc.), it must be reviewed and re-approved by the current laboratory director, as evidenced by a signature and date.
Comments on deficiencies:	Deficiencies indicate either that some procedures and test kits were in use without the explicit review and approval of the director, or that procedures in use when a new laboratory director is appointed continued in use without initial review.
Frequency of citation:	12%
Examples of surveyor citations:	▪ Review of the procedure manuals showed that the following procedures in the "Kit Manual" were not signed and dated by the current laboratory director: Hemoccult, Mono Test, strep screen, Amnisure, Fetal Fibronectin, HIV 1/2 Combo Screen, Simplex Flu A/B & RSV, gram stain, and blood culture. ▪ During review of the procedure manual it was noted that the blood bank and microbiology manuals were approved by the previous laboratory director from two years ago. However, the current laboratory director has not approved, signed, and dated the procedures. ▪ Review of documentation and interview with the laboratory manager revealed that the Hematology Operator Guide that staff was using for the CBC procedure had not been signed by the current laboratory director.
Tips for compliance:	▪ Prior to being put into use, the laboratory director reviews and approves all procedures. This review and approval cannot be delegated. ▪ If there is a change in leadership, all procedures must be reviewed and approved by the new director. ▪ Annual review by the director is not required, however, best practice would include a periodic review of all laboratory procedures.

Tips for compliance:	▪ Whenever there is a change to a procedure, the change must be reviewed and approved by the director.

CHAPTER	STANDARD
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 proper storage of reagents and specimens.
Comments on deficiencies:	While in some cases areas were not being monitored, most deficiency citations resulted from expired certification of the instruments used for measurement.
Frequency of citation:	24%
Examples of surveyor citations:	▪ Temperature and humidity logs were missing documentation for the blood bank on weekends in June, July, and October. These were dates no testing was performed, however temperature/ humidity still need to be monitored and documented. ▪ Certification for the humidistat and the thermometer in the laboratory expired in 2014. In the room that had the two Ventana IHC strainers, there was no thermometer or humidistat. ▪ Discussion with the immunohematology manager revealed that they were not measuring humidity in the immunohematology department.
Tips for compliance:	▪ Use certified thermometers and humidistats for monitoring in all locations where the temperature and humidity are essential conditions for accurate test results. ▪ Create a tickler file of certification end dates for thermometers and humidistats and address replacement prior to expiration.

CHAPTER	STANDARD
Analytic Systems	**06.02.02 – Labeling of Reagents, etc.** (title change in 2019 edition of the HFAP manual: **06.02.02 – Reagent labeling and storage**)
Overview of the requirement:	Supplies must be labeled with required elements.
Comments on deficiencies:	This standard is cited when secondary containers are not appropriately labeled or when expiration dates are missing on open reagents.
Frequency of citation:	10%
Examples of surveyor citations:	▪ Observation of the open, refrigerated, quality control materials currently in use in chemistry revealed no written expiration date. ▪ In two locations there was no indication as to the open date on the glucose reagents. ▪ Three containers of liquid on a workbench in the main laboratory had no label or an illegible label.

Tips for compliance:	▪ When opening a container changes the expiration date, storage requirement, etc., then the opened date must be noted along with the new expiration date. ▪ When reagents are transferred into secondary containers, the secondary container must be appropriately labeled.

CHAPTER	STANDARD
Analytic Systems	**06.04.00 – Maintenance Checks** **06.04.02 – Modified System Maintenance Checks**
Overview of the requirement:	The laboratory must comply with the manufacturer's maintenance recommendations for each piece of equipment and instrument it uses, including those that are peripherally involved in patient testing (e.g., incubators, centrifuges, safety cabinets, autoclaves, and microscopes). In the absence of manufacturer's instructions, the lab must develop its own policy and procedures.
Comments on deficiencies:	Deficiencies cited some missed maintenance checks for specific pieces of equipment. Microscopes were the most likely to be missing documentation of maintenance.
Frequency of citation:	16% for 06.04.00; 64% for 06.04.02
Examples of surveyor citations:	▪ Review of records and interview with staff revealed that there was no procedure for the maintenance of the microscopes according to manufacturer's instructions or documentation that maintenance was being performed. ▪ Review of the maintenance records for the STA Compact Instrument showed no monthly maintenance performed 7 out of the 12 months for 2017 and 8 out of the 12 months for 2016. Weekly maintenance was not performed 6 times in 2017 and 9 times in 2016. ▪ Review of documents revealed that multiple maintenance checks on the Ortho Vision were missed. Daily probe decontamination was missed on: 5/21/17, 11/29/17, 11/30/17, 12/22/17, 12/27/17, 12/28/17. Weekly decontamination and pump test documentation was missing from March of 2017 and January 2018. ▪ Interview with the laboratory manager revealed that the laboratory was not documenting the required daily maintenance for the microscopes being used. This included the microscopes in the areas of hematology and microbiology. ▪ Review of maintenance records revealed missing documentation of: 1. Monthly maintenance on the ACL Elite in coagulation in January and February 2018. 2. Weekly maintenance on the ACL Elite in coagulation for March and August 2017 and November 2016. 3. Weekly maintenance on ESR AutoPlus in hematology for February, June, July, November and December 2017, January 2018. 4. All maintenance records on the Architect in chemistry for 2016 and for 6 months of 2017.

Tips for compliance:	▪ Assure that daily, weekly, and monthly maintenance is completed and documented for all test systems in place. ▪ Assure that annual preventative maintenance is completed and documented for all test systems and equipment. ▪ The laboratory should have a process for monthly review of the maintenance logs. If issues are identified such as lapses in completion, during the monthly reviews, the laboratory should document appropriate corrective actions.

CHAPTER	STANDARD
Analytic Systems	**06.05.01 – Performance and Documentation of Calibration Verification Procedure** (title change in 2019 edition of the HFAP manual: **06.05.01 – Performance of calibration verification procedures**)
Overview of the requirement:	For those procedures that use fewer than three levels of calibration material, the laboratory must perform calibration verification to establish the continued accuracy of the test system throughout the laboratory's reportable range. This calibration verification is required at least every six months.
Comments on deficiencies:	Deficiencies resulted from failure to consistently perform calibration verification.
Frequency of citation:	27%
Examples of surveyor citations:	▪ Review of documents and interview with the staff revealed that the laboratory was not performing calibration verification for the analytes of CEA and T3Uptake (Thyroid Hormone Uptake) on the Vitro Chemistry analyzers. The laboratory staff stated and documentation supported the practice of running the two calibrators as "patients" as the calibration verification. ▪ Review of documents revealed that calibration verifications for the IStat analyzers are completed only once in 2017 on 11/5/2017. Calibration verification is required every six months. In addition, the laboratory did not have defined criteria for the evaluation of data range.
Tips for compliance:	▪ Identify test methods that have fewer than three calibrators. ▪ Develop a system to assure that, at least every six months, the calibration verification is performed. ▪ Data obtained from the calibration verifications must be reviewed and evaluated to determine that the laboratory's reportable range is appropriate.

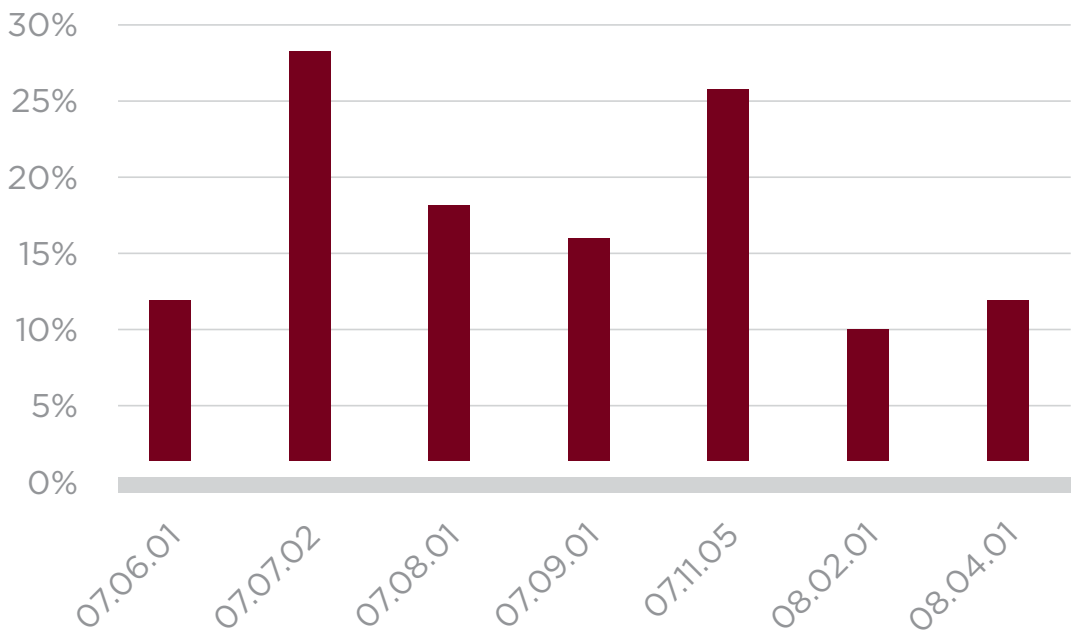
CHAPTER	STANDARD
Analytic Systems	**06.06.01 – Quality Control Procedures** (title change in 2019 edition of the HFAP manual: **06.06.01 – Control procedures/IQCP**)
Overview of the requirement:	The laboratory must perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory to meet the regulatory standards. This may include the development of an IQCP.
Comments on deficiencies:	The most common issues were related to lack of appropriately executed Individual Quality Control Plans (IQCP).
Frequency of citation:	12%
Examples of surveyor citations:	▪ The following IQCP's have not been approved by the present laboratory director and QC was not being performed according to manufacturer/CMS guidelines. These tests include: Procalcitonin, Disk Diffusion, E-Test, Microscan ID/AST, Exempt media, Alere Giardia/Crypto, EHEC, Grp B Strep, BioMerieux API, ACT, Leuko EZ Vue, Campy, Fetal Fibronectin, HIV1/2 AB/AB combo, H. pylori, Amnisure, Mono, Chlamydia/GC, and Trichmonas. ▪ The laboratory was performing control procedures on a new instrument, using the previous IQCP, which was not reflective of the updated quality control practice of the new instrument. ▪ The laboratory has approved IQCPs in place for the Alere HIV Combo test and the Alere Bianax Now Legionella kit. The IQCPs indicated that quality control testing will be done with each new lot, shipment, and monthly. The laboratory was not following the IQCP and testing the quality control monthly. Alere HIV Combo testing was completed 6/8/18, 7/27/18 and 9/10/18. Alere Bianax Now Legionella testing was completed 2/12/18, 4/1/18, 4/7/18, 5/15/18, 6/14/18, 7/31/18, and 9/12/18. ▪ Review of records and interview with the laboratory manager revealed that control procedures were less stringent than the CLIA regulatory requirements for control procedures which include two levels each day of patient testing. The tests where this was observed include C. diff., GBS, GAS, MedTox, and D-Dimer. Partial and incomplete IQCPs were written.
Tips for compliance:	▪ If using IQCP to meet the quality control requirements: – Assure that all IQCPs are approved by the current laboratory director. – Assure that the written IQCP is for the method in use. – Assure that quality control is being performed at the frequency defined in the IQCP.

CHAPTER	STANDARD
Analytic Systems	**06.06.03 – Qualitative Procedure Controls** (manual: 2014 edition, used for surveys prior to July 1, 2019) **06.06.06 – Qualitative Procedure Controls** (manual: 2019 edition, used for surveys on or after July 1, 2019)
Overview of the requirement:	The laboratory must select relevant, meaningful controls for use whenever patient samples are tested.
Comments on deficiencies:	Specific tests are missed for QC whenever patient samples are tested.
Frequency of citation:	12%
Examples of surveyor citations:	▪ Review of the records and interview with the staff revealed that external quality controls were not being tested on the Quidel QuickVue serum pregnancy test. Patient results were being reported, and IQCP had been developed. ▪ Review of documentation indicated that external QC is required for the Monotest each day of use when serum or plasma is being tested (routine is whole blood). However, serum PT survey samples IM-01 thru IM-05 were performed on 4/11/18 with no external QC documented. ▪ Review of the documentation and interview with the staff revealed that the staff was not performing quality control for the post-vasectomy procedure. ▪ Review of records and discussion with the laboratory manager revealed that there was no QC being performed each day of testing for the KOH.
Tips for compliance:	▪ Know the complexity of each test kit or test system used within your laboratory. Some kits are waived on urine or whole blood but moderately complex for serum or plasma. ▪ Assure that for all **waived test** systems, external quality control is performed at the frequency defined by the manufacturer as written in the package insert. ▪ For all **moderately complex tests**, assure that at least two levels of quality control are run each day of patient testing. For qualitative tests, this would include a positive and negative control. For quantitative tests, this would include at least two different levels of quality control material. Control frequency can be reduced if an IQCP is in place.

CHAPTER	STANDARD
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:	Citations indicated failure to perform required comparison studies at least twice per year.
Frequency of citation:	16%
Examples of surveyor citations:	▪ The laboratory had no process in place to compare the results obtained from the automated hematology instruments and manual differentials. ▪ There was no comparison of test results on the ABL 90 blood gas analyzers. ▪ The laboratory did not define the relationship between the different urinalysis methodologies. ▪ The laboratory did not define the relationship between the different DAT methodologies. ▪ The laboratory did not define the relationship between the two I stat analyzers being used for blood gas testing. There was no data as the correlation studies had not been performed. ▪ The laboratory did not have a document which defined the method and criteria used to evaluate and accept or reject the evaluation data.
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.

CHAPTER	STANDARD
Specialty/Subspecialty Specific	**07.02.04 – Documentation of Control Procedures (Mycology)** **07.03.04 – Documentation of Control Procedures (Parasitology)**
Overview of the requirement:	This standard was most often cited due to laboratories not implementing a system to meet the requirement that a positive and negative control be "tested" each day of patient testing.
Comments on deficiencies:	In the case of mycology and parasitology procedures where there is no commercially available control material, the "testing" of controls may accomplished by reviewing pictures of both positive and negative results and documenting the review.
Frequency of citation:	10%
Examples of surveyor citations:	For the subspecialty of mycology/parasitology, during direct observation, review of the manuals, and interview with the technician, it was noted that the laboratory was not performing positive or negative control procedures, for example using a pictograph, when examining the slide as an internal control.
Tips for compliance:	▪ For those tests where there is no commercially available quality control material such as a wet prep, pictures of positive and negative results should be reviewed by the technologist each day of patient testing. ▪ Document review of the pictures.

Proficiency Testing Deficiencies



Note: In the 2019 edition of *Accreditation Requirements for Clinical Laboratories*, all PT performance standards have been moved to chapter 4 **Proficiency Testing**. Previously, PT testing for each individual specialty/subspecialty was a separately scored standard.

CHAPTER	STANDARD
Specialty/ Subspecialty Specific	**07.06.01 – General Immunology Proficiency Testing** **07.07.02 – Routine Chemistry Proficiency Testing** **07.08.01 – Endocrinology Proficiency Testing** **07.09.01 – Toxicology Proficiency Testing** **07.11.05 – Hematology Proficiency Testing**
Proficiency Testing (2019 manual)	**04.02.03 – Specialty/Subspecialty PT Performance by Analyte** (manual: 2019 edition, used for surveys taking place on or after July 1, 2019)

Overview of the requirement:	Each analyte in each testing event must score at least 80% to demonstrate satisfactory performance.
Comments on deficiencies:	Laboratories are required to participate in a CMS-approved PT program and must authorize the PT provider to send results to HFAP. An unsatisfactory result for a single test event is noted as a deficiency and investigation and remedial action is required. Unsatisfactory results on two consecutive or two of three testing events is identified as unsuccessful participation for that specialty or subspecialty. **Unsuccessful participation** in PT will result in the laboratory's CLIA certificate being limited to exclude that analyte, specialty or sub-specialty and patient testing of that analyte must be suspended until reinstatement. HFAP reports unsuccessful participation to CMS.
Frequency of citation:	12%–28%
Examples of surveyor citations:	**07.06.01** ▪ For testing event 2016-3, the laboratory scored 0% for ASO, Mono, and Rheumatoid Factor analytes. For testing event 2017-2, the laboratory scored 60% for Rheumatoid Factor. In all instances, the laboratory documented investigation and remedial action. **07.07.02** ▪ For testing event 2016-1 the laboratory scored 0% for Carboxyhemoglobin and Methemoglobin. The laboratory documented investigation and remedial action. **07.08.01** ▪ Review of documents revealed that for testing event 2016-1 PSA the laboratory scored 0%. **07.09.01** ▪ For testing event 2016-3, the laboratory scored 40% for Phenobarbital. For testing event 2016-3, the laboratory scored 60% for Carbamazepine. The laboratory documented investigation and remedial action. **07.11.05** ▪ For testing event 2017-B, the laboratory scored 67% for Urine Bilirubin and Urine Ketone testing. The laboratory documented appropriate investigation and remedial action. No further response is necessary.

Note: In the 2019 edition of *Accreditation Requirements for Clinical Laboratories*, all PT performance standards have been moved to chapter **4 Proficiency Testing**. Immunohematology PT remains a distinct standard because the threshold for acceptable participation is 100%.

CHAPTER	STANDARD
Immunohematology Compatibility Testing	**08.04.01 – Overall Testing Event**
Proficiency Testing	**04.02.02 – PT Performance by Testing Event or Analyte – immunohematology** (manual: 2019 edition, used for surveys taking place on or after July 1, 2019)
Overview of the requirement:	The overall testing score must be 100%.
Comments on deficiencies:	Laboratories are required to participate in a CMS-approved PT program and must authorize the PT provider to send results to HFAP. An unsatisfactory result for a single test event is noted as a deficiency and investigation and remedial action is required. Unsatisfactory results on two consecutive or two of three testing events is identified as unsuccessful participation for that specialty or subspecialty. **Unsuccessful participation** in PT will result in the laboratory's CLIA certificate being limited to exclude that analyte, specialty or subspecialty and patient testing of that analyte must be suspended until reinstatement. HFAP reports unsuccessful participation to CMS.
Frequency of citation:	12%
Examples of surveyor citations:	▪ For testing event 2016-1, the laboratory scored an overall 80% for compatibility testing. ▪ For testing event 2017-3, the laboratory scored 80% for Compatibility Testing.

Notes

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