CORNER VIEW

In the fall of 2020, ACHC merged with the parent company of the first U.S. healthcare accreditation program, HFAP. The merger added CMS-deemed accreditation for facility-based care including acute care hospitals, ambulatory surgery centers, clinical laboratories, critical access hospitals; non-deemed accreditation for office-based surgery; and certification for stroke care, wound care, joint replacement, and lithotripsy to ACHC’s existing portfolio of community-based accreditation and education programs.

Part of the assimilation process has been to audit our distinct resources in order to bring the very best from each separate entity to our new, unified company. You are reading one result of that exercise. The Surveyor is an ACHC legacy publication, but the Fall/Winter edition now parallels what was previously HFAP’s annual Quality Review. That publication examined the most frequently cited deficiencies for each accreditation program to give organizations a tool for benchmarking and improving their performance.

In years past, ACHC identified frequent deficiencies by program and made them available annually as a “top ten” list. Now, using The Surveyor to share the data gives us a vehicle to add value by deepening the analysis. This is presented in separate editions for closely affiliated programs. You can access any of them on our website (achc.org) under Resources and Education/Publications.

As you review the edition or editions most relevant to your setting, you will read examples of actual survey findings. These serve to clarify the specific aspects of the standard that were found to be non-compliant. Following the sample citations, you’ll find tips for compliance.

While healthcare is constantly evolving, we are currently emerging from a time of unusually rapid change. Some of the deficiencies cited in the following pages can be traced directly to the impact of COVID-19. Many organizations made significant adjustments to continue to meet the needs of their patient/client populations: adopting new technology for remote visits and patient monitoring; sourcing against PPE shortages; reassigning staff to manage furloughs and quarantines. These are all examples of unanticipated change that required quick action that may have shifted focus away from some areas of required compliance.

Organizations that previously received the HFAP Quality Review used it in conjunction with their Deficiency Report (ACHC’s Summary of Findings) to compare their performance against their Deficiency Report (ACHC’s Summary of Findings). To compare their performance against peer organizations and to proactively address issues frequently seen in other organizations. Used this way, the data becomes part of the process of continuous quality improvement and on-going survey readiness. We want to help you avoid a series of ramp up activities as your survey approaches by making ACHC Standards part of your overall quality strategy.

As always, ACHC is here as a partner in meeting your accreditation and education needs. Your feedback on this publication and on any aspect of your accreditation and education needs. Your feedback on this publication and on any aspect of your overall quality strategy.

LEADERSHIP TEAM
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Evaluating frequently-cited deficiencies offers a data-driven review of aggregate survey results for our accredited laboratories. It helps guide our efforts to provide relevant, actionable education for the organizations that look to ACHC for leadership in establishing, evaluating, and maintaining quality.

The data in this report reflect deficiencies cited on surveys performed between June 1, 2020, and May 31, 2021. This time frame reflects a period of ongoing, increased demands on the laboratory environment due to the COVID-19 public health emergency. Specifically, laboratories have managed:

- New and varying test platforms.
- High and spiking testing volumes due to increased hospital admissions.
- Additional reporting requirements for COVID-19 testing.
- Staffing shortages.

Contributing to staffing shortages is the aging demographic of qualified Medical Technologists, some of whom are retiring while others may be leaving the workforce early due to the ongoing stress presented by issues related to the ongoing PHE. With the rise of variants, it is clear that the impact of this disease on clinical laboratories will remain significant for the foreseeable future.

The ACHC Clinical Laboratory Accreditation program is fully staffed by laboratorians so we understand the day-to-day challenges that laboratories face. While it is disappointing to see that regular staff competency evaluation was a frequent deficiency (Standards 02.02.04, 03.02.03), we recognize that it is perennially challenging and problematic. Very often, required elements that are missed and result in a deficiency citation do not indicate a general disregard of the standard, but a missing component of compliance that was either misunderstood or not satisfied because the laboratory put it off to deal with urgent issues encountered in patient care. It takes great organization and attention to detail to ensure that all staff have been evaluated on all elements within the required timeframes.

Several additional deficiencies observed ([06.04.00 and 06.08.01]) also were likely results of the strain on the entire laboratory industry due to COVID-19. Staff were stretched thin to get the patient work done, so “extras” as required in these two standards were simply missed as they moved lower in the list of competing priorities.

Identifying deficiencies should not be seen as a negative. Laboratories are among the most highly regulated areas of healthcare. ACHC delivers an educational accreditation experience, including the survey itself, with the intention of providing a roadmap to close gaps in achieving consistency and accuracy in the services each laboratory provides.

Our team continues to look for ways to add value for your team. In the coming year, watch for new tools to support specific settings: hospital, MOHS, pathology, and physician office laboratories.

### TESTING SPECIALTIES

- **Chemistry**
  - Routing Chemistry
  - Urinalysis
  - Endocrinology
  - Toxicology
- **Clinical Cytogenetics**
- **Diagnostic Immunology**
  - General Immunology
  - Syphilis Serology
- **Hematology**
- **Histocompatibility**
- **Immunohematology**
  - ABO Group
  - Rh Type
  - Antibody Detection
  - Antibody Identification
  - Compatibility Testing
- **Microbiology**
  - Bacteriology
  - Virology
- **Pathology**
  - Cytology
  - Histopathology
- **Radiology**
  - Oral Pathology

### LABORATORY DEFICIENCIES

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01.04.07 Eyewash/Emergency Shower Facilities

Overview of the requirement
Approved eyewash stations/emergency showers must be provided within a 10 second travel distance from every area in which hazardous chemicals are used.

Comment of deficiencies
Most deficiencies resulted from non-ANSI-approved eyewash stations.

Frequency of citation: 19%

Examples of Surveyor findings
- Eye wash stations did not have a handle designed faucet to start the flow of water in a single motion.
- The only eye wash available was an eyewash bottle system.
- Eye wash stations were plumbed, permanent stations but lacked temperature control and a log to indicate weekly testing.

Tips for compliance
- Review ANSI standard Z358.1-2014 for design, installation, and maintenance requirements.
- Perform weekly testing of plumbed stations.
- Consider performing a risk assessment to determine if an eye wash station and/or emergency shower is required. Audit for use of corrosive chemicals as it is the use of these substances that necessitate an eye wash station.

02.02.04 Testing Personnel Competency and Evaluation

Overview of the requirement
The laboratory technical supervisor/consultant is responsible for evaluating and documenting competency of staff to perform test procedures and report results. The standard identifies required elements and intervals for competency evaluations.

Comment of deficiencies
Deficiencies were cited when quality control measures were not implemented and documented.

Frequency of citation: 15%

Examples of Surveyor findings
- Thermometer and hygrometer had not been checked or calibrated.
- Refrigerator used for specimen and control material storage was not being monitored.
- Log sheets were not being filled out when quality controls were tested.
- The calibration for the timer in use expired.
- Laboratory director had not signed off on the procedures.
- Comparison studies are not being performed between the clinic and the main lab as per policy for urine dipstick tests.
- External quality control is not being performed as required by the manufacturer.

Tips for compliance
- Know what testing is being done where within your organization.
- Ensure that the supervisor assigned to oversee waived testing is familiar with the ACHC standards related to waived testing.
- Ensure that for each waived test in use there is a current copy of manufacturer instructions.
- Create a comprehensive quality assurance plan to regularly monitor quality control and patient testing to ensure manufacturer instructions are being followed.

03.02.02 Waived Laboratory Supervisor Responsibilities

Overview of the requirement
The laboratory supervisor oversees operation and administration to ensure appropriate quality control and quality assurance monitoring.

Comment of deficiencies
Deficiencies were cited when quality control measures were not implemented and documented.

Frequency of citation: 15%

Examples of Surveyor findings
- Technical staff did not have all six required competency elements evaluated for each test system in the laboratory.
- Education credentials were not available for review at the time of the survey.
- Competency evaluation was not completed annually for all testing personnel.

Tips for compliance
- Create a tracking document for testing personnel that lists each test or test system.
- Ensure that all six required elements are evaluated for each test system twice in the first year and annually thereafter for all testing personnel. This is required for all moderate and high complexity testing even if it performed outside of the laboratory including point of care testing.
- Ensure that competency assessments are being completed by appropriate individuals. The initial competency must be completed by an individual qualified as a Technical Supervisor (high complexity testing) or Technical Consultant (moderate complexity testing). Annual competency assessments can be completed by General Supervisors in the high complexity testing environment.
03.02.03 Testing Personnel Competency

Overview of the requirement
The laboratory supervisor is responsible for initial training and evaluating competencies of all testing personnel.

Comment of deficiencies
The standard was cited when personnel records did not have documentation of initial training and annual competency evaluations.

Frequency of citation: 20%

Examples of Surveyor findings
- No documentation of training for laboratory testing.
- No documentation for initial orientation/training as well as annual competency assessment.
- No documented orientation, training, or competency for the use of the i-stat for testing of creatinine for CT patients.
- Training documents had not been reviewed by the laboratory supervisor.

Tips for compliance
- Assign the responsibility to the laboratory supervisor to ensure that new employee orientation and training is completed and documented for all waived testing performed. Develop a policy that describes how annual competency will be evaluated for each individual performing waived testing. This can be organization or location specific.
- Create a tracking sheet of all testing personnel to maintain documentation of evaluations and training and competency assessments.

03.02.06 Manufacturer’s Instructions for Waived Testing & 03.02.07 Quality Control for Waived Tests

Overview of the requirement
The laboratory must maintain a current copy of manufacturer’s instructions and must follow the stated instructions. The laboratory must adhere to the instructions for quality control.

Comment of deficiencies
These standards were cited when required elements of the evaluation were not documented as completed or when evaluations were not performed within required timeframes.

Frequency of citation: 03.02.06: 27% | 03.02.07: 23%

Examples of Surveyor findings
03.02.06
- The laboratory lacked procedures and/or manufacturer package inserts for the staff performing patient testing.
- Documentation showed that glucose meter control solutions and test strips were not dated when packaging was opened nor was the new expiration date noted on the solutions and strips.
- Temperature and humidity readings were not recorded to assure reagents were stored under proper conditions as indicated by the manufacturer.

03.02.07
- Logs revealed the laboratory was not following the Urine HCG test kit manufacturer instruction for external positive/negative quality controls or internal controls for tests performed.
- Documentation showed that quality controls were not conducted per manufacturer-indicated schedules or according to laboratory procedures.
- Temperature logs to monitor refrigerated materials and reagents were not maintained.

Tips for compliance
- Ensure that there is a formal procedure for each test method or that the manufacturer’s package insert is available to provide a detailed procedure for each test. Manufacturer instructions are typically found as part of the package insert available with each test kit. If test kit does not come with a package insert, these instructions should be located on the manufacturer’s web site.
- Review the manufacturer’s instructions for each test to ensure that:
  - Reagents are stored at the proper temperature.
  - Quality control material, both internal and external, is tested at the frequency required by the manufacturer and that all controls performed are documented.
  - If instrumentation is used, all maintenance is performed, as specified by the manufacturer.

PROFICIENCY TESTING

04.02.05 Unsuccessful Performance by Analyte

Overview of the requirement
For a specific analyte or test, if two or more consecutive events are unsatisfactory, the analyte/test is deemed unsuccessful.

Comment of deficiencies
The standard was cited when analytes had consecutive testing events with unsuccessful performance.

Frequency of citation: 16%

Examples of Surveyor findings
04.02.06
- Laboratories had unsuccessful performances for the following analytes:
  - Total Protein (BF) 2020-1 67% 2020-2 67%
  - Procalcitonin 2019-1 67% 2019-2 0%
  - DDimer 2020-1 50% 2020-2 0%
  - CSF/BF Microscopy 2020-1 67% 2020-2 67%
  - Urine Sediment 2019-2 67% 2020-1 67%
  - TSH 2019-2 40% 2020-1 40%

Tips for compliance
- Conduct a complete investigation all proficiency testing results that are less than 100%. Initial issues may be first evident with a score of 80%.
- Do not use “unexplained” as a reason for the failure. Investigate the cause. Initial failures become repeat failures if only cursory initial investigations are completed.
- Ensure that test results are submitted by the program due dates.
ESSENTIAL CONDITIONS

06.02.01 Essential Conditions

Overview of the requirement
Laboratories must define conditions for proper storage of reagent/specimens, test system operations, and results reporting.

Comment of deficiencies
Deficiencies were cited when instruments were not certified or monitored, documentation was not maintained as per policy, and corrective action not taken when necessary.

Frequency of citation: 19%

Examples of Surveyor findings
- No certified temperature and humidity instrument, nor a log to keep temperature and humidity digital monitors for temperature/humidity were not calibrated or checked by staff.
- No written water quality policy.
- Policy indicates cultures to be checked for microbial growth performed monthly; documentation shows missing checks.
- Humidity logs show levels below the established criteria; no corrective action documented.

Tips for compliance
- Ensure that all temperature and humidity monitoring equipment have in date calibrations.
- Educate staff on the importance of documenting corrective actions taken to correct out of range temperature or humidity readings.
- Develop a system to ensure that each temperature/humidity log is reviewed on a regular basis, at least monthly, so that lapses are identified, and appropriate corrective action measures taken. Be sure to document all review activities.
- Develop a policy to define what type of water is used for specific purposes. What is tap water used for? What is reagent grade water used for? What is water obtained from the Millipore system used for?

06.04.00 Maintenance Checks

Overview of the requirement
Equipment, instrument, or test system maintenance is performed as defined by the manufacturer on at least the frequency specified by the manufacturer.

Comment of deficiencies
Deficiencies were cited when maintenance was not performed or appropriately documented.

Frequency of citation: 20%

Examples of Surveyor findings
- Document review showed that maintenance checks on equipment or instruments were inconsistently performed.
- A maintenance log was not maintained.

Tips for compliance
- Develop a list of tests that require comparison testing.
- Develop written procedures for performing comparison studies that includes criteria for evaluation and acceptable performance.
- Develop a calendar/schedule to ensure that the comparison studies are completed twice each year.
- If correlations fail to meet the acceptable performance as outlined in the organization’s policy, be sure to take and document any corrective actions.

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 laboratory must compare results at least twice annually and review against written criteria for acceptable variation in test values.

Comment of deficiencies
Deficiencies were cited for failure to perform comparison studies.

Frequency of citation: 20%

Examples of Surveyor findings
- Comparison studies were not performed between automated and manual differentials twice per year.
- Comparison studies were not performed on all I-Stat meters for back up chemistries using the ChemB+ cartridge for glucose, BUN, creatinine, sodium, potassium, TCO₂, chloride.
- Studies had been completed as required for the routine chemistry tests, but there were gaps in the correlation studies for the therapeutic drugs, ETOH, ammonia, CRP, and AIC.
- A comparison study between the Quick Vue serum HCG and the Vitros 5600 was not performed every six months.

Tips for compliance
- Develop a list of tests that require comparison testing.
- Develop written procedures for performing comparison studies that includes criteria for evaluation and acceptable performance.
- Develop a calendar/schedule to ensure that the comparison studies are completed twice each year.
- If correlations fail to meet the acceptable performance as outlined in the organization’s policy, be sure to take and document any corrective actions.

We’re here to help.
To learn more, visit our website at achc.org, call us at (855) 937-2242, or email customerservice@achc.org.
ACHC OFFERS MORE, SO YOU CAN OFFER MORE TO YOUR PATIENTS