



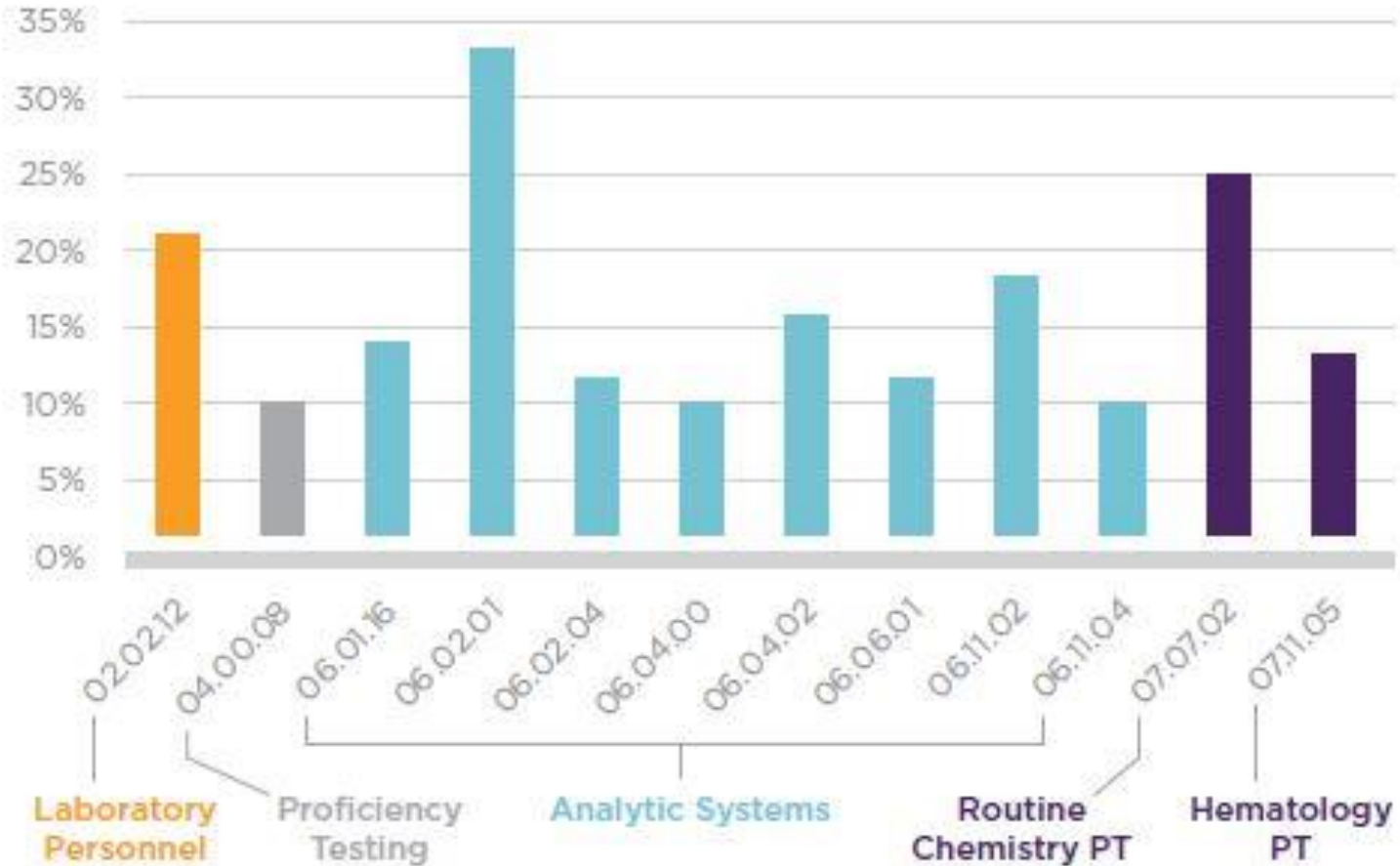
TOP LABORATORY DEFICIENCIES FROM 2017

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Surveyor/Standards Interpretation



2017 Top 12 Deficiencies





LABORATORY PERSONNEL

02.02.12 – Competency Evaluation



02.02.12

Competency Evaluation

The procedures must include, but are not limited to:

- Direct observations of test performance, including patient preparation, if applicable, specimen handling, processing and testing
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
- Direct observation of instrument maintenance and function checks
- Assessment of performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
- Assessment of problem solving skills



02.02.12

Competency Evaluation

Examples of surveyor citations:

- Checkmarks were the only indication of competency evaluation in employee records. There was no further documentation of how skills were assessed.
- Documentation of competency for personnel did not include all six elements.
- Documentation of assessment of problem solving skills was missing for seven testing personnel.



02.02.12

Competency Evaluation

Tips for compliance with this standard:

- Develop documentation that covers all 6 elements for all tests and test systems that the staff perform.
- Be prepared to demonstrate how each of the six elements is evaluated.
- Assure that the individual doing the competency assessment is qualified and has been designated by the director to conduct the assessment.
- Don't create extra work. What things do you do every day that evaluate staff competency?



PROFICIENCY TESTING

02.02.12 Attestation Statements

07.07.02 Routine Chemistry Proficiency Testing

07.11.05 Hematology Proficiency Testing



04.00.08

Attestation Statements

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

Moderate Complexity Testing The director may delegate the responsibility for signing the attestation statement to a qualified technical consultant.

High Complexity Testing The director may delegate the responsibility for signing the attestation statement to a qualified technical supervisor.



04.00.08

Attestation Statements

Examples of surveyor citations:

- Attestation statements are routinely signed by the lab manager but there is no letter of designation on file from the lab director.
- Attestation statements were not signed for various testing events.
- The attestation statements for immunohematology were signed by the administrative director who does not meet the qualifications of a technical supervisor for high complexity testing.



04.00.08

Attestation Statements

Tips for compliance with this standard:

- The director or his/her designee signs all attestation statements.
- If the director delegates responsibility for signing the attestation statements, the delegated individual must be qualified under CLIA to sign them.
- If the director delegates the responsibility for signing the attestation statements, there must be a document that clearly spells out this delegation.
- Assure that all attestation statements for immunohematology are signed by the director or a qualified technical supervisor, who must be a physician.



07.07.02/07.11.05

Chemistry/Hematology Proficiency Testing

For Proficiency Testing (PT), failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.



07.07.02/07.11.05

Chemistry/Hematology Proficiency Testing

Tips for compliance with these standards:

- Review documents submitted to the PT provider for clerical errors.
- Assure that the laboratory is reporting results in the proper unit of measure.
- Have a process to track when proficiency testing events are shipped and when results are due back to the provider.
- If you experience a problem with the proficiency testing samples, contact the PT provider for replacement samples or instructions on how to report the problem.



ANALYTIC SYSTEMS

- 06.01.16 Procedure Approval
- 06.02.01 Essential Conditions
- 06.02.04 Reagent Kit Components
- 06.04.00 Maintenance Checks
- 06.04.02 Modified System Maintenance Checks
- 06.06.01 Control Procedures
- 06.11.02 IQCP Risk Assessment
- 06.11.04 IQCP Quality Assessment



06.01.16

Procedure Approval

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.



06.01.16

Procedure Approval

Examples of surveyor citations:

- Manuals included many changes written in or attached via notes without date or signature.
- Manuals included procedures not signed by the current laboratory director.
- Procedures added January 2017 were unsigned as of March 2017.



06.01.16

Procedure Approval

Tips for compliance with this standard:

- Prior to being put into use, the laboratory director reviews 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.
- Whenever there is a change to a procedure, the change must be reviewed and approved by the director.
- Assure that all attestation statements are signed by the director or his/her designee.



06.02.01

Essential Conditions

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions. These conditions must be monitored and documented and, if applicable, include the following:

1. Water quality.
2. Temperature.
3. Humidity.
4. Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.



06.02.01

Essential Conditions

Examples of surveyor citations:

- Neither temperature or humidity were monitored with a certified instrument.
- Thermometer and humidistat were past certification expiration date.
- The laboratory did not have a policy to define water used for specific processes such as reagent reconstitution and dilutions.



06.02.01

Essential Conditions

Tips for compliance with this standard:

- Use certified thermometers and humidistats for monitoring temperature and humidity in all locations throughout the organization where the temperature and humidity are essential conditions for accurate test results.
- Assure that certified thermometers and humidistats have not expired.
- The laboratory should have a water policy that outlines what type of water is used under what circumstances.



06.02.04

Reagent Kit Components

Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

Surveyor Citations:

- Pathology/Histology department does not have a procedure prohibiting mixing of stain kit components.
- The laboratory did not have a policy for kit procedures to ensure there was no interchanging reagents from different kit lots.

For compliance the laboratory should have either a departmental policy that states kit components will not be interchanged or, have this defined in individual test procedures.



06.04.00/06.04.02

Maintenance Checks/Modified System Maintenance Checks

The laboratory must comply with the manufacturer's maintenance recommendations for each unmodified piece of equipment and instrument. Similarly, for equipment, instruments, or test systems developed internally, a maintenance protocol must be established. This included performing scheduled preventative maintenance and unscheduled repairs as needed. Documentation is required.



06.04.00/06.04.02

Maintenance Checks/Modified System Maintenance Checks

Examples of Surveyor Citations:

- Daily cleaning and maintenance on the microtome, embedding center, and tissue processor are performed but not logged. No yearly preventative maintenance occurred for these instruments.
- Water system monthly sanitation is inconsistently performed by the biomed department with documentation missing for 2 of 12 months in 2015, 2016, and 2017.
- No preventative maintenance on the microscopes in use throughout the laboratory.



06.04.00/06.04.02

Maintenance Checks/Modified System Maintenance Checks

Tips for compliance with this standard:

- 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.



06.06.01

Control Procedures

CMS has approved a procedure which permits laboratories to develop and customize quality control procedures in their healthcare settings. This procedure is termed Individualized Quality Control Plan (IQCP). An IQCP is comprised of three parts, a risk assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. The RA is the identification and evaluations of potential failures and errors in a testing process. A QCP is a laboratory's standard operating procedure that describes the practices, resources, and procedures to control the quality of a particular test process. The QA is the laboratory's policy for the ongoing monitoring of the effectiveness of their IQCP.



06.06.01

Control Procedures

Examples of Surveyor Citations:

- Quality control procedures for the Oxicom used for oximeter testing were less stringent than the CLIA regulatory requirements but no IQCP had been developed to modify the CLIA regulation.
- Laboratory policy and manufacturer's instructions call for quality control testing on each kit for rapid streptococcal antigen but testing practice revealed external controls were testing only on every new lot number.
- Review of the technical procedures for Rapid Strep and RSV revealed that that procedures state that external QC is to be performed on each new lot number, shipment of kits and every 30 days. For Strep, the 30 day QC was not performed in June, July, August, September, October, or November of 2016 or January of 2017. For RSV the 30 day QC was not performed in September, October, November of 2016 and January of 2016.



06.06.02

Control Procedures

Tips for compliance with this standard:

- 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 when 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.



06.11.02

IQCP – Risk Assessment

The laboratory conducts RA to identify and evaluate the potential failures and sources of errors in testing systems in the laboratory's own environment. RA includes, at a minimum, evaluation of five components:

- Specimen
- Test System
- Reagent
- Environment
- Testing Personnel

The scope of RA must encompass the entire process: preanalytic, analytic, and postanalytic phases. RA activities must be documented with documentation retained for at least two years after the corresponding QCP has been discontinued. Documentation of a QCP under the specialty of Immunohematology must be maintained for ten years.



06.11.02

IQCP – Risk Assessment

Examples of Surveyor Citations:

- No documentation was available to support the RA.
- The IQCP for strep testing at this location is based on the hospital laboratory IQCP and does not address potential failures and errors specific to this testing site.
- While reviewing documentation it was difficult to determine whether all five components were included in the RA.



06.11.02

IQCP – Risk Assessment

Tips for compliance with this standard:

- The laboratory should identify the data and timeframe used for the Risk Assessment (RA).
- The laboratory needs to be able to produce the data used in the RA. In addition, the laboratory must have a way to retain the data used in the RA for two years beyond the retirement of the IQCP.
- The data used in the RA must be data specific to the site where testing is being performed.
- Assure that all 5 elements are addressed in the RA.



06.11.04

IQCP – Quality Assessment

The laboratory must establish a review system for the ongoing monitoring of the effectiveness of their IQCP. The monitoring should include, but is not limited to, the following components: testing personnel, environment, specimens, reagents, and test system. Reevaluation of the QCP should be considered when changes occur in any of the above components.



06.11.04

IQCP – Quality Assessment

Examples of Surveyor Citations:

- While the IQCP written detail includes monitoring on a weekly, monthly, and annual basis, there is no evidence that the data is further evaluated in the QA report.
- The laboratory has not incorporated Quality Assessment into the IQCP.
- No system has been established to verify effectiveness of the written IQCPs.



06.11.02

IQCP – Quality Assessment

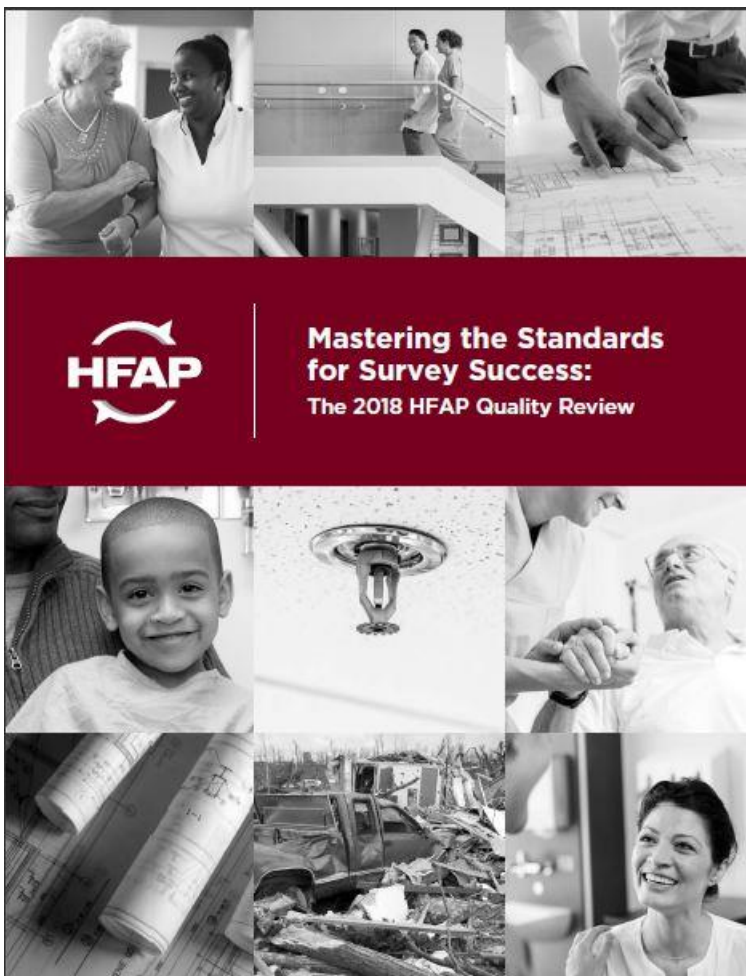
Tips for compliance with this standard:

- The laboratory should conduct the appropriate data review as defined in their IQCP to determine the effectiveness of their plan.
- The laboratory should document all Quality Assessments completed.
- If there is a PT failure for a test with a reduced quality control frequency due to an IQCP, there must be a corresponding Quality Assessment for that test or test system to evaluate and address the reason for the failure. Also, the laboratory should determine if any other patient results could have been at risk.



Additional Resource

The full report is available at:
www.hfap.org.





THANK YOU

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