

The Joint Commission's Most Challenging Standards and What you Can Do to Maintain Compliance

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Objectives

■ Identify the top lab standards compliance issues

- Personnel
- Proficiency Testing
- Equipment
- Nonwaived Testing
- Waived Testing
- Patient Records

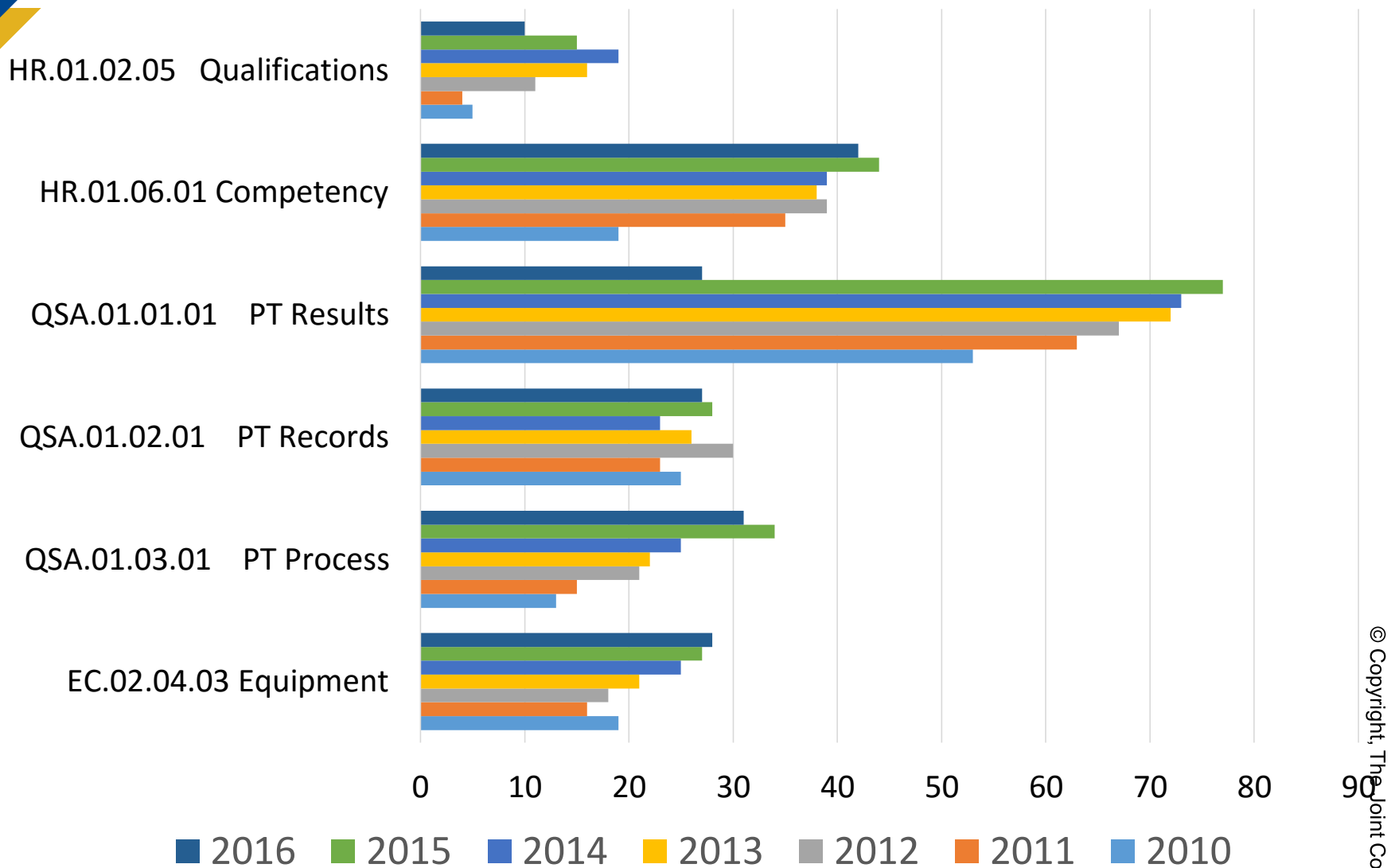


■ Implement tips to keep you in compliance

■ Create mock tracers to help with ongoing compliance

■ Identify the available Joint Commission resources

2010 -2016 Percent Noncompliance



2010 – 2016 Percent Noncompliance

QSA.02.03.01 Calibration Verification

QSA.02.08.01 Correlations

QSA.02.11.01 Surveillance

WT.01.01.01 Policies and Procedures

WT.03.01.01 Competency

WT.05.01.01 Maintains Records

DC.02.03.01 Clinical Record

2016 2015 2014 2013 2012 2011 2010

Personnel

- ▀ Qualifications
- ▀ Competency



HR.01.02.05

EP 1 When law or regulation requires laboratory service providers to be currently licensed, certified, or registered to practice their professions, the laboratory both verifies these credentials with the primary source and documents this verification when a provider is hired and when his or her credentials are renewed.

EP 3 The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities.



HR.01.02.05

EP 6 The laboratory uses the following information to make decisions about staff job responsibilities:

- Verified licensure, certification, or registration required by law or regulation or the laboratory
- Verified education and experience



HR.01.02.05 Tips

- ✓ Understand the CLIA requirements for all types of personnel

<http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m>


- ✓ Required roles for **High Complexity Testing**: Lab Director, Clinical Consultant, Technical Supervisor (per specialty/subspecialty), General Supervisor, and Testing Personnel
- ✓ **Technical Supervisor** may have additional requirements: cytology, clinical cytogenetics, histocompatibility, histopathology – general, dermatopathology, ophthalmic Pathology, oral pathology, and immunohematology
- ✓ Required roles for **Moderate Complexity Testing**: Lab Director, Clinical Consultant, Technical Consultant (per specialty/subspecialty), Testing Personnel
- ✓ **Technical Consultant** minimum requirement is a 4 year degree and 2 years experience in the specialty – Blood gases may need someone from the lab to fill this role

HR.01.02.05 Tips


- ✓ Work with your Human Resources Department – The lab requirement is different than the hospital requirement
- ✓ Have a policy to verify the highest level of education – **Primary Source Verification of education is now acceptable**
- ✓ If using Primary Source Verification for education, then appropriate documents substantiating the education must be provided within “a reasonable time frame (the time it takes to complete the survey or within one week afterwards)”
- ✓ Make sure to include all staff performing laboratory testing
- ✓ Licensure and certification rarely replaces documentation of education
- ✓ Lab Central Connect requires identification of specific CLIA roles
- ✓ See **Standards FAQs** on qualifications and primary source verification



HR.01.06.01




EP 3 An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence.



EP 18 The staff member's competency assessment includes the following: Direct observation of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing; Monitoring, recording, and reporting of test results; Review of intermediate test results or worksheets, quality control, proficiency testing, and preventative maintenance performance; Direct observation of performance of instrument maintenance function checks and calibration; Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples); Problem solving skills as appropriate to the job

HR.01.06.01




EP 19 During the first year of employment, each staff member's competence is assessed at least semiannually for all laboratory tests he or she performs. This assessment is documented.

EP 20 After the first year of employment, each staff member's competence is assessed on an annual basis for all laboratory tests he or she performs. This assessment is documented.

COMPETENCY

HR.01.06.01 Tips

- 
- ✓ Use staff to collect the data (6 methods) for competency
 - ✓ Ensure a qualified person does the assessment
 - High Complexity: Technical Supervisor or General Supervisor
 - Moderate Complexity: Technical Consultant
 - ✓ The person doing the assessment does not have to have specific test knowledge – only experience in the specialty/subspecialty
 - ✓ Include ways to meet the 6 methods of assessment in your policy
 - ✓ Use routine quality surveillance activities to meet some of the assessment methods
 - ✓ Make employees accountable for incorporating the 6 methods into their competency – they know when they are doing some of the required tasks
 - ✓ Have employees present topics at staff meetings
 - ✓ Annual means one year from the date of the last event, plus or minus 30 days

HR.01.06.01 Tips

- ✓ PPMP is moderate complexity testing and must use the 6 methods – have a separate policy for PPMP that details the methods you will use
- ✓ Know what POCT is moderate complexity (AmniSure, ACTs, pH testing, Blood Gases) and make sure someone qualified as the Technical Consultant does the assessment
- ✓ Make this as automated and electronic as possible
 - Lab Central Connect has a competency tracker for due dates
 - Automate quizzes, scoring, and record keeping
- ✓ Verify that first year hires have assessment scheduled at 6 months ***Put this on your calendar and on their schedule***
- ✓ Have two years of records available during survey – competency assessment must be documented
- ✓ Review the forms on the **Leading Practice Library**
- ✓ See **Standards FAQs** on competency



Competency Requirements

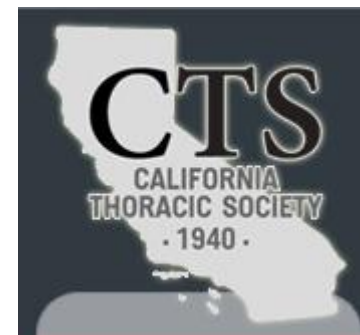
Joint Commission Requirement	Nonwaived Testing including PPMP	Waived Testing
Methods	Use 6 methods (if applicable) <ol style="list-style-type: none"> 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of QC performance by each user 4. Problem solving skills 5. Direct observation of instrument checks 6. Monitoring result reporting 	Use 2 of 4 methods <ol style="list-style-type: none"> 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of QC performance by each user 4. Written test
Initial Training and Annual Assessment	<p>Yes</p> <p>Semi-annual in the first year</p>	<p>Yes</p>
Signatures	<p>Both the director/supervisor/consultant AND the employee must sign that the individual has received training and is competent prior to performing testing independently</p>	<p>No signature required but the director/designee must assess competency</p>

WSLH *P*roficiency
*T*esting



Proficiency Testing

American
Proficiency
Institute



ACP | Medical Laboratory
Evaluation



The Joint Commission
Accreditation
Laboratory

QSA.01.01.01



EP 5 For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation.

Satisfactory Performance Criteria includes the following:

- *Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.*
- *Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing*
- *Attaining a score of 100% for ABO group and Rho(D) typing or compatibility testing*
- *Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.*
- *Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.*

QSA.01.01.01

EP 6 The laboratory's proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation.

Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, as a failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.



QSA.01.01.01 Tips

- ✓ Review for clerical errors
 - Required changes in units of measure
 - Transposing numbers
 - < or > errors
 - Reason for not performing the test
- ✓ Put the submission date on your calendar and the lab calendar
- ✓ Have multiple people trained to submit results
- ✓ Automate reporting - investigate the capabilities to report directly from your LIS
- ✓ Investigate any score <100%
- ✓ Review performance for trends



QSA.01.02.01

EP 2 The laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action for the following:

- Individual unacceptable proficiency testing results
- Late submission of proficiency testing results (score is zero)
- Nonparticipation in the proficiency testing event (score is zero)
- Lack of consensus among all laboratories participating in the proficiency testing event (score is ungradable)

These actions are documented.

EP 3 The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented.



QSA.01.02.01

EP 4 The laboratory retains proficiency testing records for at least two years from the date of participation for the following proficiency testing events:

- Each proficiency testing result
- Test handling
- Preparation
- Processing
- Examination
- Each step in the testing
- Signed attestation statement(s) provided by the proficiency program
- A copy of the proficiency testing program report forms used by the laboratory record proficiency testing results
- Corrective action taken



QSA.01.02.01 Tips

- ✓ Documentation is required – use the investigation form provided by the PT provided or the one on our website
- ✓ Investigations must be performed when:
 - There are unacceptable results
 - Submission was late and the score is zero
 - Did not participate in the event and the score is zero
 - There was a lack of consensus and the score is ungradable
- ✓ Investigation must include potential causes and provide evidence of review
- ✓ Corrective action is performed if necessary
- ✓ Create a definition for “random error” to make the investigation meaningful

QSA.01.02.01 Tips

- ✓ Ensure policy addresses when investigations need to be done, how to complete and document the investigation and when corrective action taken must be taken
- ✓ Review attestations for all signatures
- ✓ Review of the PT provider program reports must be done by the lab director or someone who qualifies as a technical supervisor (immunohematology)
- ✓ Review PT provider program reports for proof of review
- ✓ Keep all documentation for a minimum of 2 years
- ✓ Have a consistent program for organizing the required documentation



QSA.01.03.01



EP 5 The laboratory rotates proficiency testing samples among the staff who perform patient testing.

EP 6 The laboratory's staff tests the proficiency testing samples the same number of times that they test patient samples.

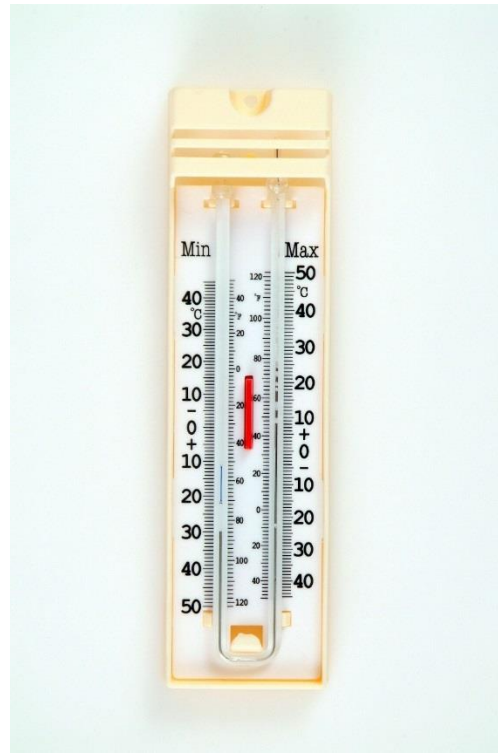
EP 7 The laboratory staff who performed the proficiency testing and the laboratory director or technical supervisor sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens.

QSA.01.03.01 Tips

- ✓ Create a schedule that includes all staff that perform the test
- ✓ Assign responsibility by sample and not by event
- ✓ Post the attestation and have staff doing the testing sign it as they complete the testing
- ✓ Ensure the Lab Director or someone who qualifies as a Technical Supervisor signs the attestation (immunohematology)
- ✓ Ensure PT is only performed on your primary instrument
- ✓ Treat PT exactly like patients
 - Don't run it in duplicate unless you do this with your patients
 - Don't run it on multiple instruments before reporting results to the PT provider
- ✓ Review paperwork for required signatures before filing



Equipment



EC.02.04.03



EP 7 The laboratory performs preventive maintenance, periodic inspection, and performance testing of each instrument or piece of equipment. These activities are documented.



EP 10 The laboratory monitors temperature-controlled spaces and equipment at frequencies established by the laboratory, using manufacturers' guidelines. The temperature is documented.

EP 13 Staff standardize scales used for phlebotomy and blood collection with a container of known mass or volume each day before use and after repairs/adjustments in order to verify that the correct volume of blood is being drawn.



EC.02.04.03 Tips

*Top
Tips*

- ✓ Create an equipment log that lists required maintenance
 - Include centrifuges, timers, pipettes, CO₂ incubators, and thermometers
- ✓ Ensure temperatures, inspections and preventative maintenance are recorded per policy
- ✓ Have multiple staff trained to take temperatures, perform alarm checks, and perform preventative maintenance
- ✓ Have the approved temperature range on the recording sheet
- ✓ Corrective action must be taken and documented when out of range or a problem is found
- ✓ Train staff on how to perform and document corrective action
- ✓ If not open 24/7:
 - There must be a way to determine if temperatures remained acceptable while closed
 - Is there a need for after hours notification of out of range temperatures?



EC.02.04.03 Tips

- ✓ Train staff on how to use a min/max thermometer and check competency
- ✓ Ambient temperature does not need to be monitored unless the package insert includes a range for it
- ✓ Include all testing and storage areas/equipment (morgue)
- ✓ Make sure alarm ranges are set according reagent storage requirements and alarm checks are performed as scheduled
- ✓ Include blood warmers in equipment management plan
- ✓ If temperature documentation is computerized ensure documentation is retrievable by date and time and that the records are retained for the appropriate amount of time (Tissue and blood storage must be retained for 10 years)
- ✓ Make scale checks a required documentation for therapeutic phlebotomy
- ✓ Use collection bags with graduated volume markings to eliminate the need for a scale

Nonwaived Testing

- ▶ Calibration
Verification
- ▶ Correlations
- ▶ Surveillance





QSA.02.03.01

EP 1 The laboratory has a written procedure for calibration verification that includes the following, at a minimum:

- The requirements established by the instrument manufacturer
- The number of calibration verification levels
- The type of calibration verification materials used
- The concentration of the calibration verification materials
- The frequency of calibration verification
- The acceptable performance limits for the calibration verification



QSA.02.03.01

EP 2 The laboratory tests the reportable range of results during the calibration verification process, including a minimal value, a midpoint value, and a maximum value based upon the manufacturer's directions and instrument history.

EP 3 Calibration verification is performed every six months.

Statistical Analysis and Experimental Results							
	Assigned	Mean	% Rec.	Accuracy	Linearity	R.Range	Mt
Level A	25	26.0	104.0	Pass	Pass	Pass	25
Level B	200	200.0	100.0	Pass	Pass	--	20
Level C	375	373.3	99.6	Pass	Pass	--	37
Level D	550	553.3	100.6	Pass	Pass	--	55
Level E	725	720.0	99.3	Pass	Pass	Fail	72

See User's Specifications for Pass/Fail criteria

User's Specifications		Supporting Data	
Allowable Total Error:	6 mg/dL or 10.0%	Analyst:	M
Systematic Error Budget:	50%	Date:	0
Allowable Systematic Error:	3 mg/dL or 5.0%	Value Mode:	F
Reportable Range:	20 to 810 mg/dL	Units:	n
RR-Low Range:	10.0 to 30.0 mg/dL	Lot Number:	
RR-High Range:	729.0 to 891.0 mg/dL	Comment:	E



TIPS!

QSA.02.03.01 Tips

- ✓ Semi-annual calibration verification is not required if there are three or more calibrators and the test is calibrated at least every six months
- ✓ For automated cell counters, calibration verification requirements are met if the laboratory follows manufacturer's instructions for instrument operation and the laboratory tests two levels of quality control materials each day of patient testing, provided the laboratory's quality control criteria are met
- ✓ Quality control materials, previously tested proficiency testing samples with known results, and calibration materials are acceptable to use
- ✓ Have a schedule and put due dates on multiple calendars
- ✓ Six months means six months from the date plus or minus 15 days
- ✓ Train multiple techs to perform calibration verification
- ✓ Ensure all instruments are included, chemistry, hematology, coagulation (rare)
- ✓ Calibration verification is used to set the reportable range - Set the reportable ranges to align with calibration verification
- ✓ Don't forget to include respiratory therapy and other POCT
- ✓ Must use 3 points (min/mid/max)

QSA.02.08.01



EP 1 The laboratory has written policies and procedures to perform correlations between analytes when the same analytes are tested using different methodologies or instruments or at different locations.

EP 2 The laboratory performs correlations at least once every six months. The correlations are documented.

EP 3 The laboratory defines the tolerance limits for agreement when performing comparisons of multiple instruments or different methods of the same test or assay.



QSA.02.08.01 Tips

- ✓ Correlations are limited to your laboratory and are not required for:
 - Labs providing backup testing
 - Sister facilities
- ✓ Have a schedule for periodic requirements and put it on multiple calendars
- ✓ Correlate a few samples every month
- ✓ Train multiple techs to perform correlations
- ✓ Check instruments for common analytes (Hgb on both the hematology and blood gas instruments)
- ✓ Include different methods (BB gel and tube, auto diffs and manual diffs)
- ✓ Have acceptable parameters defined in your policy and verify results are within parameters
- ✓ QC can be used as long it is the same lot number on both instruments and there is an evaluation performed
- ✓ Six months means six months from the date plus or minus 15 days

QSA.02.11.01

EP 1 The laboratory has written policies and procedures for surveillance activities that include a coordinated review of the following:

- Patient test results
- Work records
- Equipment performance testing records
- Quality control results



EP 3 The general supervisor performs or delegates to technical staff the daily supervisory review of patient results. The supervisory review is documented.

EP 5 The laboratory performs daily screening for errors in patient test results due to handwritten or manual data entry (for example, clerical errors). The daily screening is documented.



QSA.02.11.01 Tips

- ✓ Written policy must include all bullet points in EP 1
- ✓ Criteria for review should be defined. Questions to consider:
 - What requires immediate action?
 - What must be referred to a supervisor?
 - What requires a corrected report?
 - What must be reported to the Laboratory Director?
 - How and by whom are work records, equipment records, QC summaries reviewed?
 - At what frequency but no less often than monthly?
- ✓ When daily review is delegated, the policy should include how the lab director/supervisor reviews the overall surveillance performed.

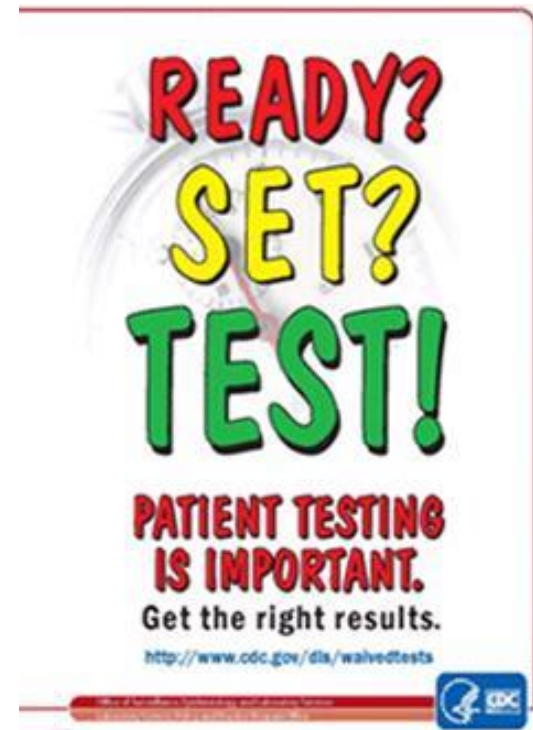
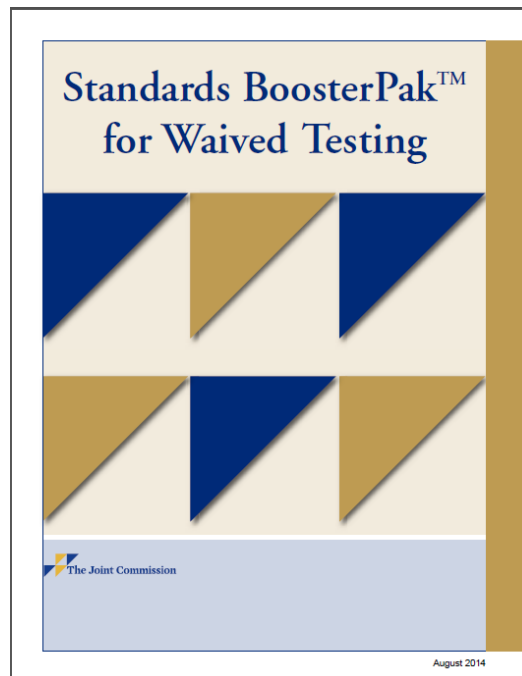
QSA.02.11.01 Tips

- ✓ As part of quality assurance, review results should be incorporated into Performance Improvement
- ✓ Results that are entered directly into the LIS are exempt from review but there should be some mechanism to periodically spot check the accuracy of the results. (Duplicate testing as part of the competence assessment process should produce results within a defined variation from the original)
- ✓ Don't forget to check the accuracy of patient results on the patient charts – not just the LIS. It is important to know that the information moved accurately from the LIS to the EMR and includes all information. **The most frequent discrepancy is that ad hoc comments do not move with the report to the EMR.**



Waived Testing

- Policy and Procedure
- Competency
- Records



WT.01.01.01

EP 2 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, establishes written policies and procedures for waived testing that address the following:

- Clinical usage and limitations of the test methodology
- Need for confirmatory testing (for example, recommendations made by the manufacturer for rapid tests) and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)
- Specimen type, collection, and identification, and required labeling
- Specimen preservation, if applicable
- Instrument maintenance and function checks, such as calibration
- Storage conditions for test components
- Reagent use, including not using a reagent after its expiration date
- Quality control (including frequency and type) and corrective action when quality control is unacceptable
- Test performance
- Result reporting, including not reporting individual patient results unless quality control is acceptable
- Equipment performance evaluation



EP 6 Written policies, procedures, and manufacturers' instructions for waived testing are followed.

WT.01.01.01 Tips

- ✓ Set a reminder schedule for updating waived testing procedures
- ✓ Outline the steps in writing for implementing a new test or changes to a test, include line items for writing the procedure and periodic review of the manufacturer's package insert for procedure updates
- ✓ Perform random direct observations outside of annual competency assessments
- ✓ Review package inserts to identify intended use, limitations, and precautions
- ✓ Review package inserts for changes with each shipment received

WT.03.01.01



EP 5 Competency for waived testing is assessed using at least two of the following methods per person per test:

- Performance of a test on a blind specimen
- Periodic observation of routine work by the supervisor or qualified designee
- Monitoring of each user's quality control performance
- Use of a written test specific to the test assessed

EP 6 Competence for waived testing is assessed according to organization policy at defined intervals, but at least at the time of orientation and annually thereafter. This competency is documented.

WT.03.01.01 Tips

- ✓ Use routine quality surveillance activities to meet some of the assessment methods
- ✓ Use credentialing and privileging process for non-instrumented waived tests
- ✓ Use annual skill fairs for POCT personnel
- ✓ Make this automated and electronic (quizzes)
- ✓ Have two years of records available during survey
- ✓ **Leading Practice Library has examples of forms**



Competency Requirements

Joint Commission Requirement	Nonwaived Testing including PPMP	Waived Testing
Methods	Use 6 methods (if applicable) <ol style="list-style-type: none"> 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of QC performance by each user 4. Problem solving skills 5. Direct observation of instrument checks 6. Monitoring result reporting 	Use 2 of 4 methods <ol style="list-style-type: none"> 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of QC performance by each user 4. Written test
Initial Training and Annual Assessment	<p>Yes</p> <p>Semi-annual in the first year</p>	<p>Yes</p>
Signatures	Both the director/supervisor AND the employee must sign that the individual has received training and is competent prior to performing testing independently	No signature required but the director/designee assesses competency

WT.05.01.01

EP 1 Quality control results, including internal and external controls for waived testing are documented.

EP 3 Quantitative test results reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served.

EP 4 Individual test results for waived testing are associated with quality control results and instrument records.



WT.05.01.01 Tips



tips!

- ✓ Train staff on the difference and purpose of internal and external quality control
- ✓ Use a log that includes Quality Control results (internal and external) and lot numbers
- ✓ Make Quality Control (internal and external) and lot numbers a mandatory entry
- ✓ Review results for reference ranges – if not with the results does the staff know where to find them?
- ✓ Review reference ranges for the specific test methodology used and patient population served
- ✓ If possible seek test systems that electronically track the elements of an audit trail, e.g. patient identifier, test date, test lot number, results, QC lot numbers, QC results, testing personnel identifier



DC.02.03.01

EP 1 The laboratory report is maintained in the patient's clinical record.

EP 2 The laboratory report includes the following information: The name and address of the laboratory performing the test.



EP 10 The laboratory report includes the following information: The results of examinations and tests performed.

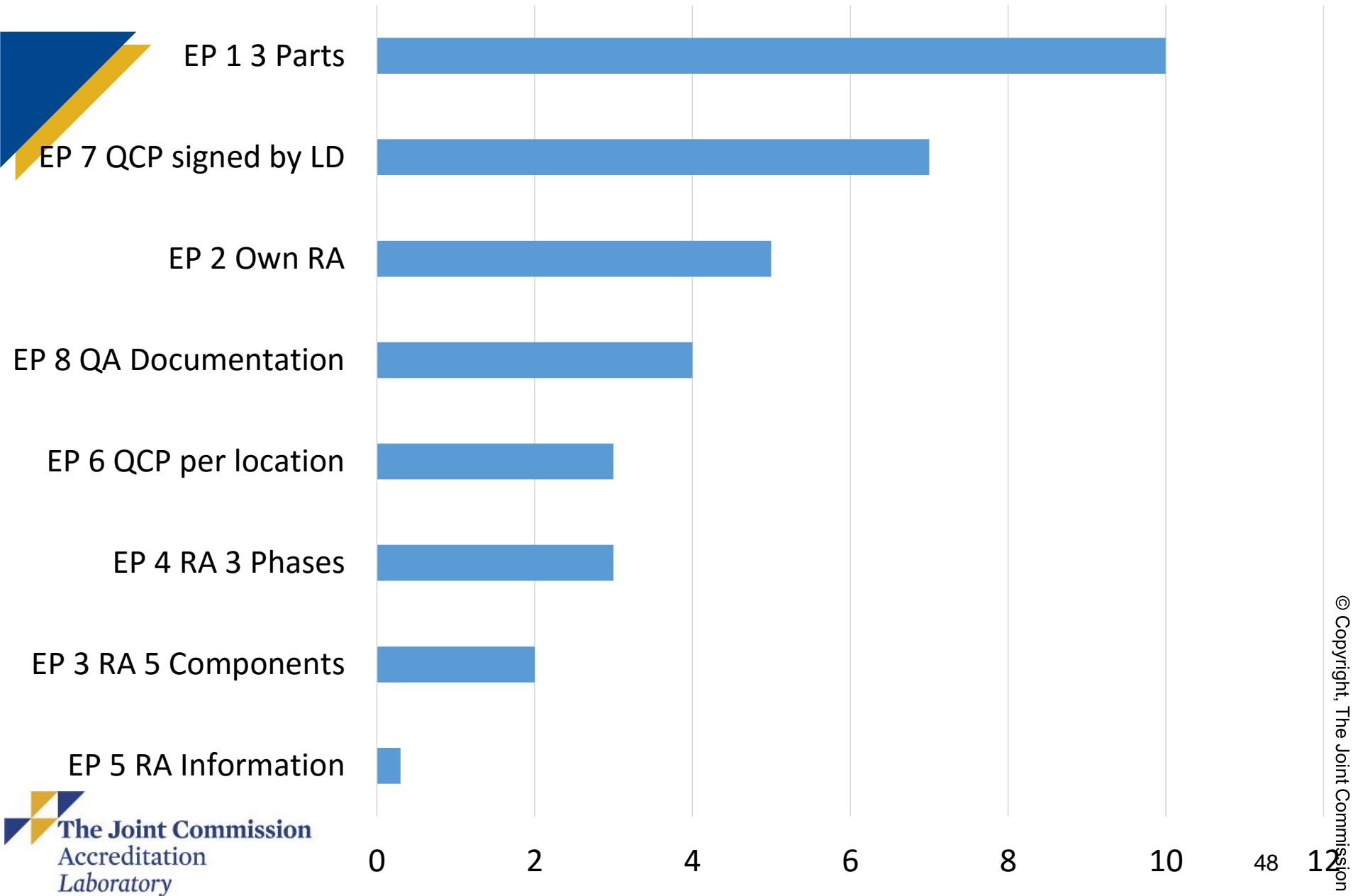
EP 14 Test reports for nonwaived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served.

DC.02.03.01 Solutions

- ✓ Review results from reference labs
- ✓ Review Frozen Section reports
- ✓ Review results from labs used when equipment is down
- ✓ Participate in hospital EMR development
- ✓ Be careful when transitioning from paper to electronic or electronic to electronic
- ✓ Look for PPMP and waived testing results
- ✓ See FAQ [“Laboratory Report Requirements in the Medical Record”](#))



2016 IQCP Percent Noncompliance



Watch Out!

- Still using EQC for blood gases performed outside the lab
- Forgetting about moderate complexity kit tests
- Not realizing you need IQCP for microbiology for:
 - Media QC
 - Streamlined QC for organism identification
 - Weekly QC for antimicrobial susceptibility
- IQCP not implemented (completed but not signed by lab director) and performing QC at a frequency less than CLIA requirements
- IQCP did not take into consideration all testing locations
- Not understanding that the Risk Assessment is used to determine the type and frequency of quality control used
- Being part of a system and using the primary lab's Risk Assessment as their own
- Not setting aside time to work on IQCP






Mock tracers may be the secret to unannounced survey success

Tracer Methodology

- Up to 60% of the survey activity
- Patients are the framework
- Follows the experience of care
- Usually begins with a test result
- Includes preanalytics and postanalytics
- Involves multiple staff, the patient, and even family to learn details about an individual's health care experience
- Review specialties and subspecialties for a 2 year period
 - 13 – 24 months
 - 6 – 12 months
 - Within the last 6 months



The Purpose of Mock Tracers

- 
- Evaluate the effectiveness of policies and procedures
 - Engage staff in looking for opportunities to improve processes
 - To be certain compliance issues have been addressed



purpose

Skill set for Mock Tracers

Ask Good Questions

- Simple questions in succession
- Encourages staff to share information
- Use observations of the surrounding
- Use responses

Analysis and Organize

- Plan a mock tracer
- Report results
- Follow up



Interviewing Techniques

- Speak slowly and carefully
- Set your interview subject at ease: use mirroring
- Use I statements
- Ask open-ended questions
- Pause before responding
- Listen attentively
- Listen actively
- Manage your reactions to difficult situations
- Always thank your interview subjects



Mock Tracer Checklist and Timeline

✓	Planning and Preparing for the Mock Tracer	
	Step 1: Establish a schedule for the mock tracer	Month 1
	Step 2: Determine the scope of the mock tracer	Month 1
	Step 3: Choose those playing the roles of surveyors	Month 1
	Step 4: Train those playing the roles of surveyors	Months 1 and 2
✓	Conducting and Evaluating the Mock Tracer	
	Step 5: Assign the mock tracer	Month 2
	Step 6: Conduct the mock tracer	Month 3
	Step 7: Debrief about the mock tracer process	Month 3
✓	Analyzing and Reporting the Results of the Mock Tracer	
	Step 8: Organize and analyze the results of the mock tracer	Month 4
	Step 9: Report the results of the mock tracer	Month 4
✓	Applying the Results of the Mock Tracer	
	Step 10: Develop and implement improvement plans	Months 5 - 7

Starting Points

Common starting points for tracers

- Lab Developed Tests
- Critical results
- Emergency release
- Suspected transfusion reactions
- Positive blood cultures
- Autopsies
- Special procedures/stains
- Point of care testing
- Frozen sections
- Low volume tests
- Proficiency Testing results



Documents Reviewed

Documents reviewed

- Instrument maintenance records, calibration verification, quality control, correlations
- Policies and procedures
- Employee evaluations, training, competency and qualifications
- Blood utilization review
- Process improvement
- Patient medical records
- Waste disposal records
- Tissue storage records



Examples of Questions

- What processes and procedures do you have in relation to POCT?
- What oversight responsibility does the laboratory have in relation to POCT?
- What process exists for STAT tests?
- How are results communicated?
- How do you receive an order for POCT?
- How do you ensure correct patient identification before drawing a sample?
- What is your hand washing policy?
- What kind of training and competency do you provide for staff members who conduct POCT?
- What methods do you use to assess competency for waived/nonwaived/PPMP testing?
- Will you show me the temp logs for your storage refrigerators?
- What is the process for testing that cannot be completed onsite?
- What communication processes do you have in place for receiving and reporting critical results?



Examples of Questions

- ▶ How do you ensure the privacy of test results?
- ▶ What documentation do you have in relation to instrument maintenance?
- ▶ What kind of documentation do you maintain for quality control, calibration, calibration verification, and correlations?
- ▶ What routine documentation do you have in place in the laboratory?
How do you monitor for completeness?
- ▶ What kind of monitoring do you do with regard to waived testing and how is that documented?
- ▶ How do you document testing?



Example of Questions

- What is your process for maintain quality control?
- What data and analysis have you done on the incidents of transfusion reactions?
- What initial assessment do you do on new transfusion patients?
- Who is responsible for checking inventory supplies?
- How do you interact with others in the laboratory?
- What participation do you have on organization wide committees?
- How are you monitoring for the effective integration of the laboratory into the Hospital?
- How do you verify patient identification?
- How do you label patient samples?



THE JOINT COMMISSION RESOURCES



IQCP Resources

Joint Commission Connect™

- Perspectives Articles (March 2014, July 2015)
- IQCP PowerPoint & Risk Assessment Template
- Leading Practice Library: IQCP examples



Lab Focus publications (Aug/Sept 2015; February 2016)

Submit a question to Standards Interpretation

<https://web.jointcommission.org/sigsubmission/sigquestionform.aspx>

Vendors

CMS

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

ASM website for microbiology examples

<http://clinmicro.asm.org/index.php/lab-management/laboratory-management/445-iqcp-iqcp>

Resources for Tracers

Publications from JCR

- *Tracer Methodology*
- *More Tracers*
- www.jcrinc.com

Survey Activity Guide (SAG)

Tracer Methodology 101 The laboratory Tracer

<http://www.jointcommission.org/assets/1/18/the%20Laboratory%20Tracer-September%202010-The%20Source.pdf>



Laboratory Accreditation Program

<http://www.jointcommission.org/accreditation/laboratory.aspx>

Lab Focus publications

Educational resources

Resources for accreditation

Resources for pathologists

Standards information (FAQs, submit a question)

Proficiency Testing information

Lab Advantage™

Laboratory Accreditation Program

Laboratory Services

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We've added new lab standards resources!
[View](#) the standards sampler, requirements and Q&As

Seeking Page

- Interested in Laboratory Accreditation? [Learn more.](#)

Educational Resources

- Information on previous teleconferences, CLIA resources, news, articles, and more. [View resources.](#)

Standards Information

- Access prepublication standards, FAQs, and the Standards Online Question Form. [View more.](#)

Resources for Accredited Customers

- Access the Survey Activity Guide, Online Publicity Kit, standards online question form and more. [View resources.](#)

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Joint Commission Resources


Ebola Preparedness



- Standards by Program Related to IC and EM for Ebola Situations

Laboratory Accreditation Standards Information

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The laboratory standards are NOT available on this website. The standards are available in [print and electronic E-dition formats](#) and can be purchased from Joint Commission Resources. Standards are posted here in prepublication and field reviews for comment.

Standards Resources



- [Facts about Joint Commission standards](#)
- [Challenging Standards for the Initial Survey of Office Based Pathology Laboratories](#)
- [Teleconference on Standard IC.02.04.01 \(Non-Acute\)](#)

Standards FAQs

- [Tabletop Drills](#)
->Revised 11/24/2008
- [Primary Source Verification](#)
->Current 4/27/2015
- [Competence of Independent Practitioners to Perform Waived Tests](#)
->Current 4/17/2014

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National Patient Safety Goals



- [Facts about the National Patient Safety Goals](#)
- [2015 National Patient Safety Goals Presentation](#)
- [Laboratory Services: 2015 National Patient Safety Goals](#)

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Forms

- [Standards Online Question Form](#)



Have a standards or regulatory question?

[Submit your question here.](#)



Requirements

- [Joint Commission Requirements](#)

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For Joint Commission accredited and certified organizations: If you have access to The Joint Commission Connect, [login](#) and select the "Contact Us" in the upper right hand corner to submit your question. If you use the form below, be sure to follow the three steps to identify your organization. This will allow us to track and prioritize customers' questions.

Joint Commission accredited? ☐ No ☒ Yes

Health Care Organization Information

Complete the three steps below. In step 3, only health care organizations accredited/certified by The Joint Commission are included in the list. Step 3 is required if you selected Yes, you are accredited.

Step 1. Select the state/country: Step 2. Select the city: Step 3. Select the health care organization: *

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Select Accreditation/Certification Manual or Health Care Setting *

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Enter Subject * (Limited to 50 characters)

Please enter your question here * (Limited to 4000 characters)

Please submit only questions that apply to the associated Manual/Chapter in each form. You may select "Submit & Add New Question" for questions regarding an unrelated topic. Your contact information above questions will be prepopulated on the form for these additional submissions.

Joint Commission Connect™

<https://customer.jointcommission.org/TJCpages/TJCHomeEmpty.aspx>

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IQCP information

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The Joint Commission Connect

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Individualized Quality Control Plan

Laboratories have two years to adopt new CMS quality control option

On January 1, 2014, the Centers for Medicare & Medicaid Services (CMS) began a two-year education and transition period for the Individualized Quality Control Plan (IQCP), a new quality control option for clinical laboratories. The IQCP Interpretive Guidelines, published by CMS on August 16, 2013, outline a risk assessment model for establishing a quality control frequency that will replace the current Equivalent Quality Control (EQC). EQC must be phased out by January 1, 2016. The education and transition period provides an opportunity for laboratories to learn about and implement IQCP. Laboratories that choose not to participate in IQCP must follow all Clinical Laboratory Improvement Amendments (CLIA) quality control regulations for nonwaived tests. For details see:


[IQCP website](#)

[CMS Survey and Certification letter Published August 16, 2013](#)

[IQCP FAQ](#)

Additional IQCP Resources

- [Joint Commission Perspectives](#)
- [Understanding IQCP for the laboratories](#)
- [Risk Assessment Example](#)





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Standards BoosterPaks™

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- [Credentialing and Privileging in Non-Hospital Settings](#)
- [Waived Testing](#)
- [Use of Restraint and Seclusion for Organizations Using Joint Commission Accreditation for Deemed Status](#)
- [Management of Hazardous Waste in Health Care Facilities](#)
- [Environment of Care](#) (EC.04.01.01, EC.04.01.03, EC.04.01.05)
- [Sample Collection](#)
- [Suicide Risk](#) (NPSG.15.01.01)
- [Safe Medication Storage MM.03.01.01](#)
- [Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation \(FPPE/OPPE\)](#)

FAQs about the BoosterPak

What is a BoosterPak?

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Additional Resources

[Measuring Hand Hygiene Adherence: Overcoming the Challenges](#)[Providing a Safer Environment for Health Care Personnel and Patients through Influenza Vaccination](#)[Guiding Principles for the Development of the Hospital of the Future](#)[More](#)

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Summary



Questions



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