Session 3A
Most Challenging Standards from The Joint Commission

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The Joint Commission’s Vision
All people experience the safest, highest quality, best-value health care across all settings.

The Joint Commission’s Mission
To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

Objectives
- Review challenging standards and strategies for compliance
  - Laws and Regulations
  - Personnel
  - Patient and Sample Identification
  - General Laboratory
  - Blood Bank
  - Clinical Records
  - Waived Testing
  - Tissue Standards
- Learn what is new at The Joint Commission

Laws and Regulations
- CLIA Certificates
- Proficiency Testing
**CLIA Certificates**

- **LD.04.01.01 EP4** Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.
- **Opportunities**
  - Put it on your calendar to do a comparison of your test menu to your CLIA certificate
  - Keep an ongoing list of new specialties/subspecialties
  - Lab Central

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**Proficiency Testing**

- **QSA.01.02.01 EP 2** For individual unacceptable proficiency testing results, the laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action sufficient to address and correct the issues identified in the investigation. These actions are documented.
- **QSA.01.02.01 EP 3** The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented.

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**Opportunities**

- Use the investigation forms from your proficiency testing providers
- The laboratory director or technical supervisor is the only required signature for review
- The attestations must be signed by the testing personnel and the laboratory director/technical supervisor
- Leading Practice Library
Personnel

- Qualifications
- Competency

Qualifications

- **HR.01.01.01 EP 1** An individual qualified to provide technical consultation or supervision and general supervision is on duty or is available whenever testing requires consultation or supervision.

- **HR.01.02.03 EP 1** The qualifications of the laboratory director of record meet the requirements set forth in federal and state law and regulation.

- **HR.01.02.05 EP 3** The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities.

**Opportunities**
- Understand the CLIA requirement for all required personnel
  
- Have a policy to verify highest level of education
- Make sure to include staff performing POCT and phlebotomists if they perform nonwaived testing
- Lab Central

Competency – Waived Testing

- **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.

- **WT.03.01.01 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.
Competency – Waived Testing

**Opportunities**
- 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
- Have two years of records available during survey
- Leading Practice Library

Competency – Nonwaived and PPMP Testing

**HR.01.06.01 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.

Competency – Nonwaived and PPMP Testing

**HR.01.06.01 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 – Nonwaived and PPMP

**Opportunities**
- Use routine quality surveillance activities to meet some of the assessment methods
- For PPMP credentialing and privileging does not count as the competency assessment
- Use annual skill fairs for POCT personnel
- Make this automated and electronic
- Verify that first year hires have assessment scheduled at 6 and 12 months
- Have two years of records available during survey
- Leading Practice Library
## Competency Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Nonwaived Testing including PPMP</th>
<th>Waived Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Use 6 methods (if applicable)</td>
<td>Use 2 of 4 methods</td>
</tr>
<tr>
<td>2. Direct observation of routine testing</td>
<td>2. Direct observation of routine testing</td>
<td>2. Direct observation of routine testing</td>
</tr>
<tr>
<td>4. Problem solving skills</td>
<td>4. Problem solving skills</td>
<td>4. Written test</td>
</tr>
<tr>
<td>5. Direct observation of instrument checks</td>
<td>5. Direct observation of instrument checks</td>
<td>5. Direct observation of instrument checks</td>
</tr>
<tr>
<td>Initial Training and Annual Assessment</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Signatures</td>
<td>Both the director/supervisor AND the employee must sign that the individual has received training and is competent prior to performing testing independently.</td>
<td>No signature required but the director/designee assesses competency</td>
</tr>
</tbody>
</table>

## Patient and Sample Identification

**NPSG EP 1** Use at least two patient identifiers when administering blood or blood components; when collecting blood samples and other specimens for clinical testing; and when providing other treatments or procedures. The patient’s room number or physical location is not used as an identifier.

**NPSG EP 2** Label containers used for blood and other specimens in the presence of the patient.

### Patient and Sample Identification Opportunities

- Perform random direct observations of staff performing sample collections
- Look in your biohazard trash containers
- Booster Pak

### General Laboratory

- **Equipment**
- **EQC**
- **Calibration Verification**
- **Correlations**
Equipment

**EC.02.04.03 EP 7** The laboratory performs preventative maintenance, periodic inspection, and performance testing of each instrument or piece of equipment. These activities are documented.

**EC.02.04.03 EP 10** The laboratory monitors temperature-controlled spaces and equipment at frequencies established by the laboratory, using manufacturers’ guidelines. The temperature is documented.

Opportunities

- Ensure temperatures are recorded and corrective action taken when out of range
- Ensure 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)

Equivalent QC

**QSA.02.04.01 EP 3** The laboratory conducts an evaluation of the electronic or internal quality control by testing external quality controls in parallel with the electronic or internal quality controls for the following: 10 consecutive days of testing for test systems that monitor the entire analytical process; 30 consecutive days of testing for test systems that monitor a portion of the analytical process. The evaluation of the electronic or internal quality controls is documented.

**QSA.02.04.01 EP 6** The laboratory performs external quality controls at the following frequencies: as defined by the evaluation (either weekly or monthly); according to the manufacturer’s recommendations; with each new lot number, shipment, or package of reagents.

**QSA.02.04.01 EP 7** The laboratory performs external quality controls at the number of levels specified by the specialty and subspecialty requirements (for example, blood gases require three levels of quality control). The external quality control results are documented.
Equivalent QC

**Opportunities**
- Evaluate all non-waived test systems with internal, automated, or alternative QC systems (10 or 30 day evaluation)
- Establish external QC frequency based on evaluation
- Read CLIA Brochure #4 "Equivalent Quality Control Procedures"

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<tr>
<th>Joint Commission Requirements</th>
<th>Nonwaived</th>
<th>Waived</th>
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<tr>
<td><strong>Internal EQC minimums</strong></td>
<td>ABGs: 3 levels daily with 1 level every 8 hours</td>
<td>At least once daily</td>
</tr>
<tr>
<td></td>
<td>All others: 2 levels once daily</td>
<td></td>
</tr>
<tr>
<td><strong>Initial evaluation of internal monitoring system to determine option</strong></td>
<td>Option 1: Monitors entire analytical process</td>
<td>Option 2: Monitors portion of analytical process</td>
</tr>
<tr>
<td><strong>Initial parallel validation of EQC vs. external QC</strong></td>
<td>10 consecutive testing days</td>
<td>10 consecutive testing days</td>
</tr>
<tr>
<td><strong>Ongoing internal QC frequency</strong></td>
<td>Once per calendar month and per lot per shipment</td>
<td>Once per calendar month and per lot per shipment</td>
</tr>
<tr>
<td><strong>Ongoing external QC levels</strong></td>
<td>ABGs: 3 levels (per QSA.06.02.01)</td>
<td>All others: 2 levels</td>
</tr>
</tbody>
</table>

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.

**QSA.02.03.01 EP 3** Calibration verification is performed every six months.

**Opportunities**
- Ensure all instruments are included, chemistry, hematology, coagulation (rare)
- Calibration verification must cover the reportable range
- Have a schedule for periodic requirements
- Semi-annual calibration verification is not required if there are three or more calibrators and the test is calibrated at least every six months
Correlations

- **QSA.02.08.01 EP 2** The laboratory performs correlations at least once every six months. The correlations are documented.

- **Opportunities**
  - Check instruments for common analytes, e.g., Hgb on both the hematology and blood gas instruments
  - Have acceptable parameters defined
  - Include all instruments and methods for nonwaived analytes
  - Have a schedule for periodic requirements

Blood Bank

- **Policies and Procedures for blood transfusion service**
- **Policies and Procedures for transfusion related activities**

Blood Transfusion Service

- **QSA.05.01.01 EP 4** The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology conducts an annual review of the policies and procedures of the blood transfusion service. The annual review is documented.

- **QSA.05.01.01 EP 5** The transfusion service director has oversight of policies, processes, and procedures related to the blood transfusion service, including blood administration.

- **Opportunities**
  - Annual policy and procedure review cannot be performed by a designee
  - The annual policy and procedure review must be documented
  - Blood administration policy and procedures must be included in the annual review
Transfusion Related Activities

**QSA.05.18.01 EP 7** The organization follows its policy and procedures that guide the monitoring of the patient and the reporting of suspected transfusion related adverse events during blood and blood component administration.

**Opportunities**
- Perform random direct observations to ensure vital signs are being taken according to policy
- Become involved in the training
- If electronic, create an online class to review administration and suspected transfusion reactions
- Audit charts

Clinical Record

**DC.02.03.01 EP 2** The laboratory report includes the following information: The name and address of the laboratory performing the test.

**DC.02.03.01 EP 10** The laboratory report includes the following information: The results of examinations and tests performed.

**DC.02.03.01 EP 12** The laboratory report includes the following information: The date and time the test results were generated as a final report. The date and time cannot be changed on copies of the report that are made at a later date.

Clinical Record

**Opportunities**
- Review results from reference laboratories
- Verify the reporting date and time is on at least one version of the laboratory report in the patient’s permanent medical record (see Lab Focus 2009 Issue 4)
- Participate in hospital EMR development (see FAQ “Laboratory Report Requirements in the Medical Record”)

Waived Testing

**Policies and Procedures**

**Records**
Waived Testing Policy and Procedures

**WT.01.01.01 EP 6** Written policies, procedures, and manufacturers’ instructions for waived testing are followed.

**Opportunities**
- 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

Waived Testing Records

**WT.05.01.01 EP 1** Quality control results, including internal and external controls for waived testing are documented.

**WT.05.01.01 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.

**WT.05.01.01 EP 4** Individual test results for waived testing are associated with quality control results and instrument records.

Opportunities
- Use a log
- 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.

Tissue Standards

**TS.03.01.01 EP 3** The organization confirms that tissue suppliers are registered with the U.S. Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.

**Opportunities**
- Use software to manage your tissue program
- Must be documented every year the supplier is used
- FDA list of registered establishments:
Resources on the Web

- The Joint Commission Frequently Asked Questions (FAQs)
  http://www.jointcommission.org/Standards/FAQs
- CLSI-Joint Commission Crosswalk
  http://www.jointcommission.org/accreditation/laboratory_educational_resources.aspx
- Useful reference documents
  http://www.jointcommission.org/assets/1/18/Lab_Reference_Documents_2_11.pdf

Joint Commission Updates

Laboratory Program
- Enhanced Intracycle Monitoring pilot is in process
  - Allows a focused review of standards compliance with Joint Commission SIG staff in a non-punitive environment
  - Will integrate PT results as a metric for discussion
  - Expect to roll out broadly in 2013

Survey Enhancements
- Corporate survey option for systems
  - Dedicated surveyors learn the system in an organizational designed orientation
  - A summary of individualized findings presented along with observations of best practices
  - Can be onsite or by phone conference depending on preference
Pathologist Surveyors

- Additional pathologists surveyors have been trained and are available by request
  - Can request pathologist only for anatomical pathology only practices

Center for Transforming Healthcare

- Formed in 2009 to find solutions to pressing health care issues identified by CEOs
- Uses DMAIC principles to analyze and identify root causes which vary by institution
  - One size does not fit all for persistent issues!
- Projects include:
  - Hand hygiene
  - Hand off communications
  - Wrong Site surgery
  - Surgical Site infections (with ACS)
  - Safety Culture
- Solutions database available from Joint Commission to enter your own data and perform your own project to improve care

Lab Central

- New customer portal that improves accreditation:
  - Allows organizations to organize files in one place to make surveys more efficient
  - Surveyors can review data before the survey to get better snapshot of organization
  - Data available for ICM discussion with SIG
  - Provides a place for private document management
- Current projection is summer implementation for initial voluntary use
ThinkLab’12/Most Challenging Standards from The Joint Commission

Joint Commission Educational Support

- Leading Practice Library
- Past audio conferences recordings on web site
- Articles from Joint Commission publications on web site
- CLIA forms on website
Other Joint Commission Resources

Center for Transforming Healthcare
http://www.centerfortransforminghealthcare.org

Other educational resources
http://www.jointcommission.org/accreditation/laboratory.aspx

Come see us at Booth 431!!

Contact Us

- General information
  - Your account executive (see your organization’s secure Extranet site for specifics)
- Information on becoming accredited
  - Contact Jennifer Rhamy
  - Phone: 630-792-5754
  - Email: jrhamy@jointcommission.org
- Standards questions
  - Phone: 630-792-5900, Option 6
  - Online: http://www.jointcommission.org/Standards/OnlineQuestionForm/
- Surveyor /Survey comments or question
  - Contact Stacy Olea
  - Phone: 630-792-5785
  - Email: solea@jointcommission.org

Questions

It’s QUESTION TIME!!

Thank you for attending Session 3A: Most Challenging Standards from The Joint Commission

Please remember to fill out your session evaluation!