Most Common Findings From Joint Commission Surveys

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Laboratory Field Representative
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.
2010/2011 Problematic Lab Standards

The Most Common

Laboratory Observations
Objectives

- Review common requirements for improvement for:
  - Non-waived testing and general laboratory standards
  - Waived testing standards
- Learn strategies for compliance
1 - Non-waived testing

**Standard QSA.01.01.01**

The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.

**Common challenges:**
- Unsatisfactory proficiency testing

**Opportunities:**
- Set up a calendar for timely submission
- Review results for clerical errors (instrument codes, transposing results) before submitting
- Monitor data for shifts from peer means
Is it required or recommended to notify the Joint Commission of unsatisfactory performance or unsuccessful status in proficiency testing?
2 - Non-waived testing

**Standard QSA.02.03.01**

The laboratory performs calibration verification.

**Common challenges:**
- Including all non-waived instruments that have a calibration process
- Performing every 6 months

**Opportunities:**
- Ensure all instruments are included, chemistry, hematology, coagulation (rare)
- Check if calibration has three levels (cal ver not required)
- Have a schedule for periodic requirements
FREQUENTLY ASKED QUESTION

Is semiannual calibration verification required if the laboratory is performing calibration at least once every six months?
3 - Non-waived Testing

Standard DC.02.03.01
The laboratory report is complete and is in the patient’s clinical record.

Common challenges:
- Including the name and address of the testing laboratory on report
- Including the date and time of reporting on report

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”)
For the purpose of printing the name and address on a laboratory report, what is considered the testing facility?
FREQUENTLY ASKED QUESTION

We are working with our software vendor to include the date and time of reporting on our laboratory reports, as required by DC.02.03.01 EP 10. If we receive a finding on survey and are unable to get the problem fixed before our evidence of standards compliance (ESC) or measure of success (MOS) due dates, will we fail the ESC or MOS?
4 - Non-waived testing

**Standard QSA.02.04.01**

The laboratory evaluates instrument-based testing with electronic or internal systems prior to using them for routine quality control.

**Common challenges:**
- Recognizing equivalent QC systems and using Option 1 or 2
- Performing external QC (levels and frequency)

**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”](#)
<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Non-waived</th>
<th>Waived*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>QSA.02.04.01</td>
<td>WT.04.01.01</td>
</tr>
</tbody>
</table>
| Internal EQC minimums        | ABGs: 2 levels daily with one q8 hours  
All others: 2 levels once daily | At least once daily |
| Initial evaluation of internal monitoring system to determine option | **Option 1**  
Monitors entire analytical process | **Option 2**  
Monitors portion of analytical process | Not required |
| Initial parallel validation of EQC vs. external QC | 10 consecutive testing days | 30 consecutive testing days | Not required |
| Ongoing external QC - frequency | Once per calendar month & per lot and shipment | Once per calendar week & per lot and shipment | Per manufacturer instruction or lab policy |
| Ongoing external QC - levels | ABGs: 3 levels (per QSA.06.02.01)  
All others: 2 levels | | Per manufacturer instruction or lab policy |

*Use of non-waived Option 1 or 2 exceeds the standards requirements.
5 - Non-waived testing

Standard QSA.01.02.01

The laboratory maintains records of its participation in a proficiency testing program.

Common challenges:
- Retaining attestation statements
- Conducting investigation on all unacceptable challenges
- Documenting review of all events

Opportunities:
- Retain hard copy of attestations if submitting results electronically
- Investigate unacceptable challenges, even if event scores 80%
- Have lab director or technical supervisor record review all events, even if satisfactory
FREQUENTLY ASKED QUESTION

How long should we keep proficiency testing records?
6 - Non-waived testing

**Standard QSA.02.08.01**

The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.

**Common challenges:**
- Including all instruments and methods for non-waived analytes
- Performing every 6 months

**Opportunities:**
- Check instruments for common analytes, e.g. Hgb on both the hematology and blood gas instruments
- Have a schedule for periodic requirements
7 - Non-waived testing

- **Standard EC.02.04.03**
  The laboratory inspects, tests, and maintains laboratory equipment.

- **Common challenges:**
  - Monitoring temperatures and verifying alarms
  - Retaining records

- **Opportunities:**
  - Ensure temperatures are recorded and corrective action taken when out of range
  - Include blood warmers in equipment management plan
8 - Non-waived testing

Standard HR.01.06.01
Staff are competent to perform their responsibilities.

Common challenges:
- Including all required methods of assessment
- Assessing at required frequencies

Opportunities:
- Use routine quality surveillance activities to meet some of the assessment methods (see QSA.02.11.01)
- Verify that first year hires have assessment scheduled at 6 and 12 months
- Have two years of records available during survey
FREQUENTLY ASKED QUESTION

Is it required to use all six methods of competency assessment specified in the CLIA regulations for every non-waived test?
# 8a - Competency Requirements

## Joint Commission Requirement

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Non-waived (HR.01.04.01 &amp; HR.01.06.01)</th>
<th>Waived (WT.03.01.01)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Content</strong></td>
<td>Use all six methods</td>
<td>Use 2 of 4 methods</td>
</tr>
<tr>
<td></td>
<td>1. Blind testing</td>
<td>1. Blind testing</td>
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<tr>
<td></td>
<td>2. Direct observation of routine</td>
<td>2. Direct observation of routine testing</td>
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<td></td>
<td>testing</td>
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<td></td>
<td>3. Monitoring QC performance (by each user)</td>
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<td></td>
<td>4. Problem solving skills</td>
<td>4. Written testing</td>
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<td></td>
<td>5. Direct observation of instrument checks</td>
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<td></td>
<td>6. Monitoring result reporting</td>
<td></td>
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<tr>
<td><strong>Initial training and annual assessment</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Semiannual in 1st year</td>
<td></td>
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<td><strong>Signatures</strong></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>
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</tr>
</tbody>
</table>
1a - Waived Testing

**Standard WT.05.01.01, EP 1**

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

**Common challenges:**
- Performing QC at the required frequencies
- Documenting internal QC on each patient test and when external QC is conducted

**Opportunities:**
- Capture records using downloadable systems
- Design user-friendly manual recording forms
- Perform quality control surveillance at least monthly
1b - Waived Testing

Standard WT.05.01.01, EP 3

Quantitative test result 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.

Common challenges:
- Manually written results recorded in multiple locations

Opportunities:
- Use pre-printed adhesive labels for manual recording
- Include fields for recording results in the electronic medical record
- Use instruments that upload results into the EMR
1c - Waived Testing

Standard WT.05.01.01, EP 4

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

Common challenges:
- Maintaining the audit trail, including personnel, QC, lot numbers

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.
2 - Waived Testing

- **Standard WT.01.01.01, EP 5**
  - Current and complete policies and procedures are available for use during testing to the person performing the waived test.

- **Common challenges:**
  - Keeping procedures up-to-date

- **Opportunities:**
  - Set a reminder schedule for updating waived testing procedures (at least every three years)
  - 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
3 - Waived Testing

**Standard WT.03.01.01, EP 5**

- Competency for waived testing is assessed using at least two methods per person per test.

**Common challenges:**
- Maintaining competency for large POCT program
- Including physicians

**Opportunities:**
- Use routine quality surveillance activities to meet some of the assessment methods
- Use credentialing and privileging process for non-instrumented waived tests
4 - Waived Testing

**Standard WT.04.01.01, EP 2, 3, 4, 5**

- The organization performs quality control checks for waived testing on each procedure.

**Note:**

- Internal quality controls may include electronic, liquid, or control zone.
5 - Waived Testing

Standard WT.02.01.01, EP 1, 2

- The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate identifies the staff responsibly for performing and supervising waived testing.

**Note 1:**

- Responsible staff may be employees of the organization, contracted staff, or employees of a contracted service.

**Note 2:**

- Responsible staff may be identified within job descriptions or be listing job titles or individual names.
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  - Online: http://www.jointcommission.org/Standards/OnlineQuestionForm/
Resources on the Web

Centers for Medicare & Medicaid Services (CMS)
- CLIA: www.cms.hhs.gov/clia
- COPs: www.cms.hhs.gov/CFCsAndCOPs/

Centers for Disease Control and Prevention (CDC)
- www.phppo.cdc.gov/clia

Food and Drug Administration CLIA Database Search
- www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm
Resources on the Web

The Joint Commission
Frequently Asked Questions (FAQs)
http://www.jointcommission.org/Standards/FAQs

CLSI-Joint Commission Crosswalk
http://www.clsi.org/Content/NavigationMenu/Resources/TJC_CrosswalkWEB.pdf

Useful reference documents
http://www.jointcommission.org/assets/1/18/Lab_Reference_Documents_2_11.pdf