The Joint Commission Lab Program

Turning Challenges into Opportunities
The Most Common Requirements for Improvement

September 15, 2010
Welcome!

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Objectives

- Review common requirements for improvement for:
  - Non-waived testing and general laboratory standards
  - Waived testing standards
- Learn about new and revised standards for 2011
Common Requirements for Improvement
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”)

September 2010 Audio Conference
Common Requirements for Improvement
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
Common Requirements for Improvement
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
## Competency Requirements

<table>
<thead>
<tr>
<th>Joint Commission 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>
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<tr>
<td></td>
<td>1. Blind testing</td>
<td>1. Blind testing</td>
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<td>2. Direct observation of routine testing</td>
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<td>3. Monitoring QC performance (by each user)</td>
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<td>4. Written testing</td>
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<td>5. Direct observation of instrument checks</td>
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<td>6. Monitoring result reporting</td>
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<tr>
<td><strong>Initial training and annual assessment</strong></td>
<td>Yes Semiannual in 1st year</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Signatures</strong> (Requirements inadvertently reversed on March 2010 presentation)</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>Director/supervisor must sign that the individual has received training and is competent prior to performing testing independently</td>
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</tbody>
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Common Requirements for Improvement
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
Common Requirements for Improvement
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
Common Requirements for Improvement
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
Common Requirements for Improvement
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”](#)
# Equivalent QC (EQC) Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
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<th>Waived*</th>
</tr>
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<tbody>
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<td></td>
<td>QSA.02.04.01</td>
<td>WT.04.01.01</td>
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</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.
Common Requirements for Improvement
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
Common Requirements for Improvement
General laboratory standards

Standard TS.03.01.01
The organization uses standardized procedures for managing tissues.

Common challenges:
- Verifying tissue suppliers are FDA registered (renewed annually)
- Maintaining daily temperature records
- Having functional alarms for refrigerated and frozen tissues

Opportunities:
- Visit the FDA’s online database to verify tissue suppliers
- Use record keeping thermometers when not staffed daily
- Use min/max thermometers for “room temperature” products (not required for “ambient”)
Common Requirements for Improvement
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
Common Requirements for Improvement
Waived Testing

**Standard WT.03.01.01, EP 5**
- Competency for waived testing is assessed using at least two methods per person per test (see slide 13 for methods)

**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
Common Requirements for Improvement 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
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
Common Requirements for Improvement 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.
Standards update for mid-year 2011...
New & Revised Laboratory Standards

- Customer surveys conducted in fall of 2009
- Feedback indicated two primary opportunities for enhancement using existing practice guidelines
  - Add detail to more clearly define intent of existing standards
  - Incorporate new “good laboratory practice” requirements for more complex test methodologies, e.g. flow cytometry, molecular pathology, cytogenetics, microbiology, chromatography
New & Revised Laboratory Standards

- Partnered with ASCP and engaged expert panels
  - Included all levels of stakeholders, e.g. pathologists, PhDs, laboratory management, medical technologists, cytotechnologists, and other clinical laboratory scientists

- Expert panels reviewed twelve specialty areas

- Resulting work was just released for comment
  - Message sent to all list serv members
  - **Section I:** Field engagement for new and revised requirements
    - Six week comment period: September 8, 2010 to October 20, 2010
    - 10 specialty areas and general requirements
  - **Section II:** Environmental assessment for updated existing requirements
    - Three week comment period: September 21, 2010 to October 12, 2010
    - Blood Transfusion Service and Donor Center
      - Developed specific standards
      - Removed blanket reference to AABB requirements
We want your input!

Go to http://www.jointcommission.org/Standards/FieldReviews/

Section I: Open now

General Comment (All Specialty Areas)

Bacteriology/Mycobacteriology/Mycology
Blood Transfusion/Donor Center
Chemistry
Chromatography
Cytogenetics

Cytology
Flow Cytometry
Histopathology
Molecular Testing
Parasitology

Section II:

Revisit the site between September 21 and October 12 and comment on the
Blood Transfusion Service and Donor Center standards
Comment on current standards anytime!

1. Visit www.jointcommission.org
2. Hover over the “Standards” tab
3. Select “Comment on a Standard”
Resources on the Web

Centers for Medicare & Medicaid Services (CMS)
- CLIA: [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)
- CoPs: [www.cms.hhs.gov/CFCsAndCoPs/](http://www.cms.hhs.gov/CFCsAndCoPs/)

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

Food and Drug Administration CLIA Database Search

Joint Commission’s
  Frequently Asked Questions (FAQs)
- [http://www.jointcommission.org/Standards/FAQs](http://www.jointcommission.org/Standards/FAQs)
QUESTIONS????
Updates from the Executive Director
Ongoing

- Lab Focus quarterly newsletter
- Lab Stat News emails
- Lab Advantage program
  - Discounted program for bundled proficiency testing, ASCP educational programs, and Joint Commission accreditation.
  - See [www.labadvantage.org](http://www.labadvantage.org) for more information
- Pathologist survey option
Coming Soon

- Cross reference of CLSI documents related to Joint Commission standards
- Deeming process in late 2010
- eApplication for lab in 2011
- Membership with the Coordinating Council on the Clinical Laboratory Workforce (CCCLW)
Come meet with us!

- Booth 208 at ASCP in October
- Another teleconference next spring
- Upcoming CLSI-Joint Commission Teleconferences
  - “How the Joint Commission Accredits Clinical Labs for POCT”
    October 14 • 1:00–2:00 PM Eastern (US) Time
  - “POCT Challenges for End Users: Competencies—Waived vs. Nonwaived”
    - November 11 • 1:00–2:00 PM Eastern (US) Time
  - Watch for registration information on CLSI’s website
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http://www.jointcommission.org/Library/Newsletters/list_serve.htm

Lab Stat News:
qualitylabs@jointcommission.org
Contact Us

- General information:
  - Your account executive (see your organization’s secure Extranet site for specifics)

- Information on becoming accredited
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- Standards questions
  - Contact Megan Sawchuk or Cherie Ulaskas
  - Phone: 630-792-5900, Option 6
  - Online: http://www.jointcommission.org/Standards/OnlineQuestionForm/
Thank you for participating!