How the Joint Commission Accredits Clinical Laboratories for Point-of-Care Testing
Putting the Accreditation Puzzle Together

October 14, 2010
Megan E. Sawchuk, MT(ASCP)
Associate Director
Standards Interpretation Group

Objectives
- Describe The Joint Commission POCT accreditation process
- Define ways to prepare for accreditation
- List common deficiencies

Compliance 101:
Understanding applicability is the key
Sources of confusion

- Definition of a lab test
- Exceptions
- Multiple test complexity levels
- Multiple laboratory accreditors
- Multiple healthcare accreditation programs, e.g. hospital, ambulatory, lab

Definition of a lab test

- Laboratory test = *in vitro* testing on blood, body fluids, or tissue performed for
  - Diagnosis
  - Treatment
  - General assessment of health
- Regulated by CMS' Clinical Laboratories Improvement Amendments (CLIA) [42 CFR 493]
  - Hospitals have Conditions Of Participation (CoPs)

Applicability & Exceptions

- Applies to most healthcare testing, including employee health testing
- Exceptions defined in law
  - Research (the test itself)
    - Alternatively, clinical research in which tests are performed are CLIA regulated, e.g. drug trials in which CBCs are conducted.
  - Forensic testing (legal use)
  - Employee drug testing
Exceptions based on definition

- NOT considered laboratory testing
  - Breath alcohol
  - Pulse oximeters (not to be confused with Oxicom)
  - Transcutaneous bilirubinometers
  - Ex vivo ABG & electrolyte (VIA LVM)
- Biosensor Technologies (monitors)
- Survey under equipment management plan
- FAQ on website

Biosensor Technology FAQ

Test Complexity

- Tests approved by FDA - assign test complexity
  - Waived
    - CLIA waived does NOT mean CLIA exempt
    - FDA cleared does NOT mean CLIA waived
  - Moderate
    - Includes Provider Performed Microscopy
  - High
- Test complexity determines requirements for personnel, Quality Control (QC), and inspection/accreditation
Point-of-Care Tests (POCT)

- Waived tests
  - Glucose meters
  - Urinalysis strips
  - Occult blood
  - Rapid strep screens
  - HemoCue
  - Coagucheck

- PPMP
  - Fern
  - KOH
  - Wet Prep
  - Urine Microscopic

- Non-waived
  - iSTAT
  - ABG analyzers
  - ACT analyzers
  - TEG
  - Mohs Testing

CLIA Certificate

- Must have correct CLIA certificate for testing level
- CLIA certificates commonly held in The Joint Commission accredited facilities:
  - Certificate of Waiver (CoW)
  - Provider Performed Microscopy Procedures (PPMP)
  - Certificate of Registration (CoR)
    - Moderate & high = non-waived; initial certificate for new lab
    - Certificate of Accreditation (CoA)
      - Moderate & high = non-waived; certificate after survey from accreditor, e.g. The Joint Commission
- Other CLIA certificate types
  - Certificate of Compliance (CoC)
    - Moderate & high = non-waived; certificate after lab has been state inspected

Laws & Policies

- Law – All nonwaived CLIA certificates must be inspected every two years
  - No federal requirement for inspection of WT or PPMP, therefore, no accreditation award for them
- Joint Commission policy - All components of a Joint Commission accredited organization and onsite contracted services must be accredited by ourselves or a cooperative partner
  - The Joint Commission Laboratory Accreditation Program
  - College of American Pathologists (CAP)
  - Commission on Office Lab Acc. (COLA)
  - State of Washington
Which standards apply to POCT?

First questions to ask:
- Who accredits the main laboratory?
- Who accredits the non-waived ancillary laboratory services?
  - Point of care
  - Nursing units
  - Blood gases
  - Clinics
- Who accredits the organization?

How do I know which lab services are accredited by The Joint Commission, if any?

- Laboratory application submitted to The Joint Commission
- Survey every two years led by an MT/CLS surveyor (Masters prepared or managerial background)
  - Only non-waived services can be accredited
  - Could be main lab, POCT only, or both
  - Organization could have more than one laboratory accreditor, e.g. main lab CAP, POCT The Joint Commission
- Having Joint Commission hospital accreditation does not mean the laboratory services are also Joint Commission accredited
  - Survey every three years for hospitals
  - Team of RN, MD, LSC, Administrator
  - No technical elements of testing are reviewed

If there are non-waived laboratory services accredited by The Joint Commission:

- Surveyed every two years
- Laboratory standards manual applies:
  - Nonwaived testing: All chapters apply, except WT
  - Many standards are “core” Hospital/Laboratory requirements intended to be met by or complement the organizational policies
  - Accreditation Participation Requirements (APR)
  - Environment of Care (EC)
  - Emergency Management (EM)
  - Human Resources (HR)
  - Infection Control (IC)
  - Information Management (IM)
  - Leadership (LD)
  - National Patient Safety Goals (NPSG)
  - Performance Improvement (PI)
If there are non-waived laboratory services accredited by The Joint Commission (continued):

- Standards applicability for:
  - Waived testing: APRs, NPSGs, LD.04.01.01, WT
  - Nonwaived testing: All chapters, except WT
  - Quality Systems Assessment (QSA) – 3 sections
    - Proficiency testing – all apply (QSA.01.05.01 – QSA.01.05.03)
    - Systems standards – all apply (QSA.02.01.01 – QSA.02.14.01)
    - Specialty & subspecialty – specific groups apply, listed alphabetically (e.g., QSA.06.01.01 – QSA.06.02.01 for chemistry)
  - Non-testing related activities:
    - Tissue Storage & Issuance (TS)
    - Clinical transfusion practices (QSA Transfusion Service)
    - Perioperative transfusion services (QSA Transfusion Service)

Are there Joint Commission organizational standards that apply to POCT?

- Yes. The organization standards manual applies, e.g., hospital, ambulatory, behavioral health, office based surgery, long term care, or home care
- Surveyed every three years
- Organizational standards same across all other Joint Commission accreditation programs (except waived testing for Critical Access Hospitals, defaults to CLIA)
  - Waived testing: APRs, NPSGs, LD.04.01.01, WT applies
  - Nonwaived: Other standards could be reviewed, e.g., safety, infection control, inventory management, specimen collection & transport, clinical side of transfusion medicine, tissue storage and issuance
  - No technical testing requirements would be surveyed
- Other laboratory related clinical and hospital requirements, e.g. transfusion medicine
  - Many related to Medicare’s Conditions of Participation (CoPs), e.g., 42 CFR 482.27 Hospital Laboratory Services

Waived testing on hospital survey

- Why does the hospital team review waived testing?
  - Waived POCT testing is not required to be accredited. Services outside the main laboratory are not routinely reviewed by the cooperative partners. Thus, if an organization does not have The Joint Commission lab accreditation, waived testing may never be surveyed.
Tip: Hospital standards related to blood administration

- EC.02.05.03 Emergency power for blood storage systems
- HRL.01.02.01 Special training provided for transfusion administration
- MS.05.01.01 Medical staff involved in PI activities for blood & blood use
- PC.02.01.01 Transfusions administered per law & medical staff policy
- PC.05.01.09 HIV/HCV Notification (Look back) policies
- PC.03.01.01 Transfusion administration equipment is available for operative and other high-risk procedures
- PI.01.01.01 Organization collects data on blood and blood use, and all reported and confirmed transfusion reactions
- RI.01.03.01 Informed consent process
- NPSG.01.01.01 Two identifiers used to ID patient for transfusion
- NPSG.01.03.01 Two persons verify patient ID and product for transfusion
- UP.01.01.01 Standardized pre-op verification list, including blood product availability (and other laboratory reports)

Tip: Hospital standards related to laboratory services

- HR.01.02.01 Testing personnel meet the qualifications defined in the CLIA regulations
- IC.01.02.01 Laboratory resources are provided to support infection prevention and control program
- IC.02.02.01 Cleaning and disinfection of bedside point-of-care instruments, e.g. glucose meters
- LD.04.01.01 All laboratory services have CLIA certificates and licenses required by regulation
- LD.04.03.01 Pathology and clinical laboratory services are provided (essential service) to meet patient needs
- LD.04.03.09 Performance management of contracted laboratory services; maintaining evidence of CLIA compliance for reference and contract laboratory services
- MM.01.01.01 Necessary laboratory results are available to those managing a patient’s medications

Tip: Hospital standards related to laboratory services

- MS.05.01.01 Medical staff involved in PI activities for autopsies
- MS.06.01.01 – MS.06.01.13 Credentialing and privileging of licensed independent practitioners (LIPs) providing interpretive reports, e.g. pathologists performing histopathology
- MS.08.01.01 – MS.08.01.03 Ongoing & Focused Practitioner Performance Evaluation (OPPE & FPPE); applies to the above LIPs
- NPSG.02.03.01 Reporting of critical results (clinical reporting intervals, such as nurse to physician, not those of the main laboratory)
- NPSG.03.05.01 Baseline and ongoing testing for anticoagulation therapy provided per written protocol/policy approved by medical staff
- PC.03.01.08 Surgical tissue specimen policies, e.g. gross only, exceptions to submission to pathology, specimen handling
- TS.03.01.01 – TS.03.03.01 Tissue storage and issuance (If lab oversees)
- WT.01.01.01 – WT.05.01.01 Waived Testing
Answering our original question…

Which standards apply to POCT?

- Follow The Joint Commission Organizational standards (surveyed every three years)
  - Waived testing
  - Non technical aspects related to nonwaived testing
  - Other laboratory related clinical and hospital requirements, e.g. transfusion medicine (slides 19-21)
- For non-waived testing, follow the standards of the applicable laboratory accreditor (surveyed every two years)
- For waived testing, follow the most stringent standards amongst accreditors when different (may be reviewed on either survey)

Accreditation tools:
Periodic Performance Review

- PPR Software
  - Web enabled tool via secure extranet
  - Self-assessment—non-punitive process
  - Submitted annually
  - Plans of Action / Measures of Success
- Conference Call (Optional)
  - Standards Interpretation Staff (SIG)
  - Approval of POA and MOS

Completing the PPR

- In all cases, highly recommend participating in the hospital’s PPR
  - Support the hospital’s PPR with completing WT and other laboratory related standards
- And if the laboratory services are surveyed…
  - Only by The Joint Commission
    - Complete PPR review against the applicable standards in lab manual
  - Only by a Cooperative Partner
    - Participate in the partner’s self assessment process
    - By a combination of laboratory accreditors
    - Complete PPR review against the applicable standards in lab manual
    - Participate in the partner’s self assessment process
Accreditation tools: Standards Edition

- Profile for your laboratory and organization will be built from your application
- Only the applicable standards will be displayed
  - Organizational Customized Standards (OCS)

Joint Commission Accreditation Resources & Options

- Lab Focus quarterly newsletter
  - http://www.jointcommission.org/Library/Newsletters/list_serve.htm
- Lab Stat News emails qualitylabs@jointcommission.org
- Frequently Asked Questions (FAQs)
  - http://www.jointcommission.org/Standards/FAQs
- Standards Interpretation Group
  - Phone: 630-792-5900, Option 6
  - Online: http://www.jointcommission.org/Standards/OnlineQuestionForm/
- Lab Advantage program
  - Discounted program for bundled proficiency testing, ASCP educational programs, and Joint Commission accreditation
- Pathologist survey option

Compliance Resources

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
Preparing for survey

Tips for Survey

- Know how to access needed records
- Tell the surveyor of staff who might be available only on certain days
- Encourage staff to openly participate
  - Provide off-site staff the same information as on-site staff
  - Inform POCT staff that they may be asked to participate in survey

Documents and Information

- CLIA Certificate(s)
- Test Menu and Instruments Used
- Total Test Volume for each CLIA
- Proficiency Testing records for last 6 events
- Personnel Files
  - Validation of educational requirements
  - State licenses as applicable
  - Competency Assessment Records
- Policies and Procedures
- Method verifications
- Calibration and Calibration Verification
- Quality Control Data
- Maintenance Records
- Environmental and Safety Inspections
- Performance Improvement data, analysis
Personnel Qualifications

- Retain records to demonstrate testing personnel meet the qualifications specified in CLIA at Subpart M.
- Qualification routes specify required education and experience
  - High complexity testing requires Associate’s degree or higher [42CFR 493.1489(b)(1-7)]
  - Moderate complexity testing requires high school diploma or higher [42CFR 493.1423(b)(1-4)]
- Credentials requiring advanced degrees are not sufficient to demonstrate education, e.g. MT(ASCP), CLS (NCA) or R.N. license

Patient Tracer Activity

- Patient tracers cover all specialties and subspecialties across the period from the last full survey
  - May be less than 24 months
  - Labs converting from another accreditor are reviewed for prior four months activity, except for PT which is for 24 months

Common POCT challenges
Common Challenges for Nonwaived Testing

- Common challenges:
  - Including name, address, report date and time on report
  - Monitoring temperatures and verifying alarms (records)
  - Maintaining competency (all methods and frequency)
  - Managing proficiency testing (performance, investigations, records)
  - Performing calibration verification
  - Establishing EQC systems and using Option 1 or 2
  - Correlating all nonwaived instruments and methods
  - Verifying tissue suppliers are FDA registered
  - Having functional alarms for refrigerated and frozen tissues

TIP: CLSI POCT4-A2 Point-of-care In Vitro Diagnostics (IVD) Testing

Common Challenges for Waived Testing

- Common challenges:
  - Keeping procedures up-to-date
  - Maintaining competency for large POCT program, including physicians
  - Performing QC at the required frequencies
  - Documenting internal QC on each patient test and when external QC is conducted
  - Recording reference ranges with manually written results documented throughout the patient record
  - Maintaining the audit trail, including personnel, QC, lot numbers

TIP: CLSI C30-A2 Point-of-care Blood Glucose Testing in Acute and Chronic Care Facilities

Common Challenges for POCT

- TIP: POCT Coordinators should consider whether or when it is better to:
  - Manage all POCT as one complexity (e.g. moderate) to simplify oversight
  - Manage all POCT per the FDA designated complexity level to reduce required resources

### Comparison of Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Nonwaived</th>
<th>Waived</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLIA certificate</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Establish P&amp;P</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Initial training and annual competency</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2 levels of QC each day</td>
<td>Yes 3 for Abgs</td>
<td>Yes</td>
</tr>
<tr>
<td>Reference intervals on patient chart</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Critical result reporting</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Comparison of Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Nonwaived</th>
<th>Waived</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method validation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Equivalent QC (EQC) validation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Semiannual correlation studies</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Semiannual calibration verification</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Proficiency testing</td>
<td>Yes</td>
<td>Regulated: 3x per year Nonregulated: Semiannual</td>
</tr>
</tbody>
</table>

### Competency Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Non-waived</th>
<th>Waived</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td>Use all six methods</td>
<td>Use 2 of six methods</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>Both the director/supervisor and the employee must sign that the individual has received training and is competent prior to performing testing independently</td>
</tr>
</tbody>
</table>
Equivalent QC (EQC) Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Non-waived</th>
<th>Waived*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal EQC minimums</strong></td>
<td>QSA.02.04.01</td>
<td>WT.04.01.01</td>
</tr>
<tr>
<td>ABGs: 2 levels daily with one q8 hours</td>
<td>2 levels</td>
<td>Two levels at least once daily</td>
</tr>
<tr>
<td>All others: 2 levels once daily</td>
<td>2 levels</td>
<td>At least once daily</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial evaluation of internal monitoring system to determine option</th>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measures entire analytical process</td>
<td></td>
<td>Not required</td>
</tr>
<tr>
<td>Measures portion of analytical process</td>
<td></td>
<td>Not required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial parallel validation of EQC vs. external QC</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10 consecutive testing days</td>
<td></td>
<td>Not required</td>
</tr>
<tr>
<td>30 consecutive testing days</td>
<td></td>
<td>Not required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial parallel validation of EQC vs. external QC</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>30 consecutive testing days</td>
<td></td>
<td>Not required</td>
</tr>
<tr>
<td>60 consecutive testing days</td>
<td></td>
<td>Not required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ongoing external QC - frequency</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Once per calendar month</td>
<td></td>
<td>Per manufacturer instruction or lab policy</td>
</tr>
<tr>
<td>Once per calendar week</td>
<td></td>
<td>Per manufacturer instruction or lab policy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ongoing external QC - levels</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ABGs: 3 levels (per QSA.06.02.01)</td>
<td></td>
<td>Per manufacturer instruction or lab policy</td>
</tr>
<tr>
<td>All others: 2 levels</td>
<td></td>
<td>Per manufacturer instruction or lab policy</td>
</tr>
</tbody>
</table>

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

Standards update for mid-year 2011...

New & Revised Laboratory Standards

- 2009 Customer feedback indicated two opportunities
  - 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, cytogentic, microbiology, chromatography
- Partnered with ASCP and engaged expert panels
- Resulting work released for comment
- Provide input at [http://www.jointcommission.org/Standards/FieldReviews/](http://www.jointcommission.org/Standards/FieldReviews/)
  - Section I: Field engagement for new and revised requirements (Open through October 20)
  - Section II: Environmental assessment for updated existing requirements (Closed October 12)
Comment on current standards anytime!

1. Visit www.jointcommission.org
2. Hover over the "Standards" tab
3. Select "Comment on a Standard"

What’s up next?

- Cross reference of CLSI documents related to Joint Commission standards
  - Go to: www.clsi.org > Resources > Crosswalks > The Joint Commission Crosswalk

- CLSI-Joint Commission Teleconference
  - "POCT Challenges for End Users: Competencies—Waived vs. Nonwaived" - November 11 • 1:00–2:00 PM Eastern (US) Time
  - Register online: www.clsi.org > Education > CLSI - Joint Commission webinars

- ASCP October 27-31 - Booth 208

Thank you!
QUESTIONS????