Introduction

Why this topic now/again?

- Laboratories struggle with resources, especially those related to quality/regulatory compliance.
- The regulatory/accrediting requirements continue to evolve and become more detailed even though the CLIA regulations have not changed substantially.
- Laboratories across the country continue to have difficulties meeting the requirements.
- More sophisticated testing (gene sequencing, molecular/genetic testing, laboratory developed tests) have regulatory nuances of their own.
- Expansion of the utilization of point-of-care testing.
Overview

- Even during these times when resources in the laboratory can be a limiting factor, it is possible to maintain readiness for a regulatory inspection every day.
- The keys to readiness that we will address today are:

  **Knowledge:** Of both the current standards and what may be coming next.

  **Awareness:** Where other laboratories are having problems with the standards.

  **Management:** Creating a culture of inspection readiness that results in making daily decisions with the standards in mind.
Achieving the Inspection-Ready Laboratory

Knowledge
A Brief History of the Regulatory Environment

- **CLIA (1966,1988)**
  - To ensure quality laboratory testing is performed throughout the United States, the Centers for Medicare & Medicaid Services (CMS) established the Clinical Laboratory Improvement Amendments which were enacted in 1992.
  - U.S. laboratories can elect to meet the CLIA regulations by following the requirements of one of the laboratory accrediting organizations under a CLIA Certificate of Accreditation. These organizations’ requirements are equal to or more stringent than CLIA.

- **ISO**
  - International Standards
A Brief History of the Regulatory Environment

- U.S. Accrediting Agencies
  - Started to expand into international markets and needed to use the ISO standards in countries other than the U.S.
  - Found that quality management system elements from the ISO standards provided a good framework for U.S. laboratories as well.
  - Added specific elements from ISO (i.e., document control) to their accreditation standards.
  - CLIA is the U.S. law, and laboratories providing patient testing need to adhere to all of the requirements under CLIA. However, the accrediting agencies can add to the requirements.
Agencies with Deemed Status Under CLIA

LIST OF APPROVED ACCREDITATION ORGANIZATIONS UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

- American Association of Blood Banks (AABB), 8101 Glenbrook Road, Bethesda, Maryland 20814-2749, (301) 907-6977, www.aabb.org

- American Association for Laboratory Accreditation (A2LA), 5202 Presidents Court, Suite 220, Frederick, Maryland 21703, (301) 644-3248, Fax (240) 454-9449, www.a2la.org


- Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, Illinois 60181, (630) 792-5000, www.jointcommission.org
CLSI

- "A not-for-profit membership organization, the Clinical and Laboratory Standards Institute (CLSI) brings together the global laboratory community for a common cause: fostering excellence in laboratory medicine. We do so by facilitating a unique process of developing clinical laboratory testing standards based on input from and consensus among industry, government, and health care professionals." – from the CLSI website

- CLSI resources, which can be found at its website, concerning which documents relate to each specific accreditation standard include:
  - CLSI References in the CAP Accreditation Checklists
  - CLMA Body of Knowledge 2013
  - CLSI Documents and ISO Quality Documents
  - CLSI-FDA Recognized Consensus Standards
  - CLSI-The Joint Commission Crosswalk
Additional Resources

- The following may also be helpful:
  - American Association of Blood Banks:  www.aabb.org
  - American Association of Clinical Chemistry:  www.aacc.org
  - Centers for Disease Control:  www.cdc.gov
  - Occupational Safety and Health Administration:  www.osha.gov
Achieving the Inspection-Ready Laboratory

Awareness
Question #1

- Does your laboratory have any reagents/kits where the manufacturer requirements include storage at not only a certain temperature but a defined humidity level?
Question #2

- Does your laboratory employ technical staff/supervisors/pathologists who are graduates of foreign medical programs?
Question #3

- Does your POCT program include testing that is not interfaced to your LIS?
Question #4

- Are you currently monitoring all six elements of competency for anyone performing moderate or highly complex testing?
Importance of Understanding Common Deficiencies

- The interpretation of regulatory standards, and evolution of new, improved processes for laboratories, results in periodic changes to regulatory standards.

- Because these may be changes to existing requirements, laboratories may miss these changes, resulting in deficiencies in the next inspection cycle.

- Two recent examples:
  - Documentation of staff qualifications.
  - Competency assessments.

- Both of these examples appear in the list of top 10 deficiencies for several of the agencies.

- By reviewing these lists, the laboratory can research the topics and determine if its facility’s documentation/responses still meet the requirements before its next inspection.
## Most Common Deficiencies – CMS’s 2013 Top Ten

<table>
<thead>
<tr>
<th>Description</th>
<th>Percent Cited*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper storage of reagents and specimens</td>
<td>5.4%</td>
</tr>
<tr>
<td>Analytic systems quality assurance</td>
<td>4.7%</td>
</tr>
<tr>
<td>Alternative proficiency testing if no proficiency testing available two times per year</td>
<td>4.6%</td>
</tr>
<tr>
<td>Procedure manual</td>
<td>4.1%</td>
</tr>
<tr>
<td><strong>Test reports – patient identification</strong></td>
<td>4.0%</td>
</tr>
<tr>
<td>Manufacturer’s instructions</td>
<td>3.9%</td>
</tr>
<tr>
<td>Moderate Complexity Laboratory Director qualifications</td>
<td>3.7%</td>
</tr>
<tr>
<td>Expired reagents</td>
<td>3.5%</td>
</tr>
<tr>
<td>Calibration verification</td>
<td>3.4%</td>
</tr>
<tr>
<td>Successful proficiency testing participation</td>
<td>3.3%</td>
</tr>
</tbody>
</table>

*Data from 17,873 surveys, CLIA data system 12/13.
## Most Common Deficiencies – CMS’s 2013 Top Ten

### Top Ten Conditional Deficiencies

<table>
<thead>
<tr>
<th>Description</th>
<th>Percent Cited*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Moderate Complexity Laboratory Director qualifications</strong></td>
<td>3.7%</td>
</tr>
<tr>
<td>Successful proficiency testing participation</td>
<td>3.3%</td>
</tr>
<tr>
<td><strong>High Complexity Laboratory Director qualifications</strong></td>
<td>1.5%</td>
</tr>
<tr>
<td>Proficiency testing enrollment</td>
<td>1.4%</td>
</tr>
<tr>
<td>Analytic System (Quality Control)</td>
<td>1.0%</td>
</tr>
<tr>
<td><strong>Moderate Complexity test personnel</strong></td>
<td>1.0%</td>
</tr>
<tr>
<td>Technical Consultant qualifications</td>
<td>0.8%</td>
</tr>
<tr>
<td>Hematology</td>
<td>0.6%</td>
</tr>
<tr>
<td><strong>High Complexity test personnel</strong></td>
<td>0.4%</td>
</tr>
<tr>
<td>Technical Supervisor qualifications</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

*Data from 17,873 surveys, CLIA data system 12/13.*
## Most Common Deficiencies – CAP’s 2014 Top Ten

<table>
<thead>
<tr>
<th>Checklist Number</th>
<th>Description</th>
<th>Percent Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEN.55500</td>
<td>Competency records</td>
<td>23.5%</td>
</tr>
<tr>
<td>GEN.20375</td>
<td>Document control</td>
<td>13.9%</td>
</tr>
<tr>
<td>GEN.54400</td>
<td>Personnel files</td>
<td>7.9%</td>
</tr>
<tr>
<td>POC.06910</td>
<td>Personnel competency in POCT</td>
<td>6.9%</td>
</tr>
<tr>
<td>POC.04500</td>
<td>Reference intervals in POCT</td>
<td>6.7%</td>
</tr>
<tr>
<td>COM.01200</td>
<td>Accurate Activity Menu</td>
<td>6.2%</td>
</tr>
<tr>
<td>Various</td>
<td>Semiannual instrument correlation</td>
<td>5.4%</td>
</tr>
<tr>
<td>ANP.23410</td>
<td>Cryostat decontamination</td>
<td>4.8%</td>
</tr>
<tr>
<td>TRM.32000</td>
<td>Instrument preventive maintenance</td>
<td>4.3%</td>
</tr>
<tr>
<td>MIC.14583</td>
<td>Controls for direct antigen testing</td>
<td>4.0%</td>
</tr>
</tbody>
</table>
# Most Common Deficiencies – COLA’s 2014 Top Ten

1. **Citation PER 5** – For lack of complete or current competency assessments for testing personnel and consultants.

2. **Citation WAV 2** – For not performing or documenting QC on waived testing as required by the manufacturer.

3. **Citation PT 16** – For lack of documentation of review of Proficiency Testing results by the Laboratory Director and/or laboratory staff.

4. **Citation CA 2** – For lack of documentation of calibration verification performed at required intervals.

5. **Citation LDR 5** – For the Laboratory Director not meeting the QC and/or QA responsibilities of the position.

6. **Citation QC 31.1** – This is a QC “transitional” citation to delineate tests for which the laboratory is currently using an EQC protocol. This transitional citation serves as written notification to the laboratory that, prior to January 1, 2016, the laboratory must either revert to the regulatory QC requirement or implement IQCP.

7. **Citation PER 3** – For lack of documentation of qualifications in the personnel record for the CLIA-required laboratory positions.

8. **Citation CA 1** – For failure to perform and/or document calibration as required.

9. **Citation QC 8** – For failure to verify by repetitive testing that assayed quality control materials meet the manufacturer’s established parameters.

10. **Citation LDR 4** – For the Laboratory Director not meeting the Proficiency Testing responsibilities of the position.
**Most Common Deficiencies – Joint Commission**

<table>
<thead>
<tr>
<th>Percentage</th>
<th>QC Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>72%</td>
<td>QSA.01.01.01</td>
<td>The laboratory participates in Centers for Medicare &amp; Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.</td>
</tr>
<tr>
<td>39%</td>
<td>HR.01.06.01</td>
<td>Staff are competent to perform their responsibilities.</td>
</tr>
<tr>
<td>39%</td>
<td>QSA.02.03.01</td>
<td>The laboratory performs calibration verification.</td>
</tr>
<tr>
<td>34%</td>
<td>DC.02.03.01</td>
<td>The laboratory report is complete and is in the patient's clinical record.</td>
</tr>
<tr>
<td>29%</td>
<td>QSA.02.08.01</td>
<td>The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.</td>
</tr>
<tr>
<td>26%</td>
<td>QSA.01.03.01</td>
<td>The laboratory has a process for handling and testing proficiency testing samples.</td>
</tr>
<tr>
<td>23%</td>
<td>EC.02.04.03</td>
<td>The laboratory inspects, tests, and maintains laboratory equipment.</td>
</tr>
<tr>
<td>23%</td>
<td>QSA.01.02.01</td>
<td>The laboratory maintains records of its participation in a proficiency testing program.</td>
</tr>
<tr>
<td>19%</td>
<td>HR.01.02.05</td>
<td>The laboratory verifies staff qualifications.</td>
</tr>
<tr>
<td>18%</td>
<td>QSA.02.04.01</td>
<td>The laboratory evaluates instrument-based testing with electronic or internal systems prior to using them for routine quality control.</td>
</tr>
</tbody>
</table>

*Note: The data determined for the laboratory program were derived from an average of 813 applicable surveys.*
Top JC Non-Compliance Standards 2010-2014

[Bar chart showing compliance levels over the years for different standards such as Participation, Competency, Calibration Verification, Lab Report, Workload, and Correlations.]
Top JC Non-Compliance Standards 2010-2014
# Common Deficiencies Comparison

<table>
<thead>
<tr>
<th>Deficiency</th>
<th>CMS</th>
<th>COLA</th>
<th>JC</th>
<th>CAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of documentation of staff qualifications</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Incomplete competency assessments</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Lack of documentation of calibration verification</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Participation in or handling of proficiency testing</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Insufficient oversight by the Laboratory Director</td>
<td>X</td>
<td>X</td>
<td></td>
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</tr>
</tbody>
</table>

Several of the top deficiencies appear on more than one of the agency lists. This indicates focus on these items by those agencies and may indicate a change in focus for that topic.
Staff Qualifications

Issues

- CLIA includes specific education/training/experience for laboratory personnel.
- Agencies discovered that some personnel qualifications were falsified.

Strategies

- The laboratory needs to provide “proof” of staff qualifications (i.e., copies of diplomas, transcripts, etc.).
- Make obtaining these documents part of the new hire process.
- Perform periodic file audits to ensure compliance.
## Audit Example

<table>
<thead>
<tr>
<th>AP HR File Audit</th>
<th>Hire Date</th>
<th>Training &amp; Experience</th>
<th>Academic Degree</th>
<th>License/Certification</th>
<th>Job Description (JD)</th>
<th>Initial Organization</th>
<th>Department</th>
<th>Compensation</th>
<th>Safety</th>
<th>Formedehyde</th>
<th>Qual/Safety</th>
<th>6 month</th>
<th>Competency</th>
<th>12 month</th>
<th>Competency</th>
<th>Annual Organization</th>
<th>Annual</th>
<th>Department</th>
<th>Visual Color</th>
<th>Examiner</th>
<th>C/S</th>
<th>Radiation Exposure</th>
<th>Incidents</th>
<th>Other</th>
<th>Overall Status</th>
<th>File Checked</th>
<th>Signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee #2</td>
<td>6/25/2012</td>
<td>x</td>
<td>Cert PA</td>
<td>partial</td>
<td>In Process</td>
<td>x</td>
<td>Due Dec</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td>C</td>
<td>7/9/12</td>
<td></td>
<td></td>
<td>Missing Degree/Educ (eligible for certification) &amp; Hosp orientation paperwork, update JD</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Employee #3</td>
<td>2/19/1991</td>
<td>x x</td>
<td>Cyto Prep Tech</td>
<td>x x x</td>
<td>x x</td>
<td>x x</td>
<td>x x</td>
<td>C</td>
<td>7/9/12</td>
<td>Initial orientation checklist missing</td>
<td></td>
<td></td>
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<tr>
<td>Employee #5</td>
<td>3/4/1991</td>
<td>x x</td>
<td>Histotechnologist</td>
<td>x x x</td>
<td>x x</td>
<td>x x</td>
<td>C</td>
<td>7/9/12</td>
<td></td>
<td>Rehired 5/29/12</td>
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<tr>
<td>Employee #6</td>
<td>9/8/2009, Rehired 5/29/12</td>
<td>x x</td>
<td>Histotechnologist</td>
<td>x x x</td>
<td>Due Nov</td>
<td>x</td>
<td>C</td>
<td>7/9/12</td>
<td></td>
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</tr>
<tr>
<td>Employee #8</td>
<td>6/17/2012</td>
<td>x</td>
<td>Cert PA</td>
<td>x x x</td>
<td>Due Dec</td>
<td>x x</td>
<td>C</td>
<td>7/9/12</td>
<td>Certification pending within 12 mos., update JD</td>
<td></td>
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</tr>
<tr>
<td>Employee #10</td>
<td>10/19/2009</td>
<td>x</td>
<td>Med Transf.</td>
<td>x x x</td>
<td>x x</td>
<td>C</td>
<td>7/9/12</td>
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</tr>
<tr>
<td>Employee #15</td>
<td>5/29/2012</td>
<td>x x x</td>
<td>Histotechnologist</td>
<td>x x x</td>
<td>Due Nov</td>
<td>x x</td>
<td>C</td>
<td>7/9/12</td>
<td>Missing onboarding checklist &amp; formaldehyde quiz</td>
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<td></td>
</tr>
<tr>
<td>Employee #16</td>
<td>5/7/2012</td>
<td>x x</td>
<td>Cert PA</td>
<td>x x x</td>
<td>Due Nov</td>
<td>x</td>
<td>C</td>
<td>7/9/12</td>
<td></td>
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</tr>
</tbody>
</table>

### Temps/Agency Techs

| Temp #1          | 5/7/2012 | x                     | Med Off Asst II | Co file | x x | x | 7/9/12 | |
| Temp #4          | 5/24/2012 | x                     | Cert PA         | Co file | x x | Due Nov | x | 7/9/12 | |
| Temp #5          | 4/22/2012 | x                     | Lab Proc Rep II | Co file | x x | 7/9/12 | |

### Key:
- **Pending Item**

### Note:
- Audit Findings - 33 of 37 files were complete or 89%
Employee Competency

Issues

- For moderate or high complexity testing, CLIA spells out six elements of competency that need to be addressed on each testing platform for anyone performing testing.

- New hires need to have competency checked twice in the first year and once every year after the first. All six elements need to be monitored and documented.

Strategies

- Develop a mechanism to ensure that new hires have two assessments the first year – see audit form.

- For annual assessments, some laboratories divide the six elements and address one each month.

- Make competency assessment a routine lab function.
Example – Six Elements of Competency Assessment

<table>
<thead>
<tr>
<th>Competency Elements</th>
<th>Test System</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquiring</td>
<td>Date</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
</tr>
<tr>
<td>Retrieval</td>
<td>Date</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
</tr>
<tr>
<td>Digitization</td>
<td>Date</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
</tr>
<tr>
<td>Verification</td>
<td>Date</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
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</tr>
<tr>
<td>Communication</td>
<td>Date</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
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</tr>
<tr>
<td>Organization</td>
<td>Date</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
<td>Date/Method</td>
</tr>
</tbody>
</table>

**Notes:**

- **High complexity test:**
- **Lowest complexity test:**
- **Critical test:**
- **Routine test:**
- **Special test:**

**Competency Elements:**

1. Client observation of routine patient test performance, including, as applicable, patient identification and preparation, specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of recordable test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Review of performance of instrumental maintenance and function
5. Assessment of test performance through testing previously analyzed specimen, external blind testing samples or external proficiency samples
6. Evaluation of patient testing skills

**Technical Aspects:**

- **Accuracy:**
- **Precision:**
- **Reproducibility:**
- **Sensitivity:**
- **Specificity:**

**References:**

- [Chi Solutions, Inc.](https://www.chisolutions.com)
- [Additional Resources](https://www.nist.gov)

**Review:**

Reviewed by: __________ Date: __________
Calibration Verification

Issues

- Records of performance either not available or incomplete.
- Methodology unacceptable.
- Documentation not reviewed with acceptance signature by Laboratory Director or designee.

Strategies

- Master list of all needed calibration verifications.
- Network within industry and/or contact vendors to assess methodology.
- Periodic audit of compliance and documentation completeness.
Proficiency Testing

Issues

- Some laboratories are missing PT for certain tests.
- Alternative PT needs to be performed and monitored when necessary.
- All PT issues need to be addressed, and the Laboratory Director needs to be aware/involved in the analysis.

Strategies

- Review test menus periodically (annually at a minimum) to ensure enrollment in PT.
- Develop alternative PT when needed.
- Ensure follow-up on an PT issues by the Laboratory Director.
Laboratory Director Responsibilities

Issues

- CLIA specifically spells out the responsibilities of the Laboratory Director.
- Any failure to meet CLIA requirements can lead to citation of the Laboratory Director as well.

Strategies

- Ensure that the Laboratory Director understands his/her responsibilities. Educational programs are available for new directors.
- Ensure proof of the Laboratory Director’s involvement in laboratory activities (i.e., signatures, meeting minutes).
- Document delegation of responsibilities by the Laboratory Director.
Achieving the Inspection-Ready Laboratory

Management
“All documentation/reviews up-to-date for PT, competency, procedures, etc. Personnel competency assessments up-to-date, documentation of highest level education for personnel available. Also would help to take a look at the list of top ten deficiencies and make sure the laboratory is in compliance.”

CMS – Karen Dyer, Acting Director, Division of Laboratory Services
“Write down where you have documented accreditation compliance for each requirement, because it is all too easy to get ‘inspection-day amnesia.’”

Denise Driscoll, CAP Director, Laboratory Accreditation Program & Regulatory Affairs
Quote – COLA

“Being *inspection-ready* comes from a culture of quality that is observed throughout the survey cycle.”

Kathy Nucifora, COLA Director of Accreditation
Quote – Joint Commission

“Embed standards into everyday work.”

Stacy Olea, Joint Commission, Executive Director
Laboratory Accreditation Program
Additional Advice from the Experts

- Utilize the available resources and tools – you do not have to be a member to access some of the information!

- Focus on three important laboratory processes:
  - Quality Assessment.
  - Training and Competency.
  - Involvement of the Laboratory Director.

- Educate everyone on the standards; provides extra eyes on the processes.

- Use “Tracer Methodology” developed by the Joint Commission (see following slides) to check periodically for compliance with standards.
Conduct Monthly Mock Tracers

http://www.jointcommission.org/tracer_methodology_101/
Laboratory Tracer Strategies

- Focus on issues of particular concern for laboratories and process interfaces with clinical staff.
- Consider your laboratory’s past testing activity as a starting point.
- Select the medical record of a patient who received multiple laboratory tests, including tests performed at point-of-care sites.
- Instead of one person conducting the tracer, consider walking through one as a group.
- Don’t forget to consider the beginning and end of a process, not just the outcome.
## Mock Tracer Tracking Worksheet: The Laboratory Tracer

Use this worksheet to record notes and areas of concern that you identify while conducting your organization’s mock tracers. This information can be used to highlight a good practice or to determine issues that may require further follow-up. “Yes” or “no” indicates whether the staff member interviewed during the tracer answered the question correctly.

<table>
<thead>
<tr>
<th>Tracer Team Member:</th>
<th>Tracer Patient or Medical Record:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Staff Interviewed:</td>
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<td></td>
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<tr>
<td>Unit or Department Where Tracer Was Conducted:</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>TRACER QUESTIONS</th>
<th>YES</th>
<th>NO</th>
<th>FOLLOW-UP NEEDED</th>
<th>COMMENTS OR NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe your laboratory process to handle transfusion reactions.</td>
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<tr>
<td>What training and orientation have been provided to laboratory staff to handle transfusion reactions?</td>
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<tr>
<td>What data and analysis have you done on the incidence of transfusion reactions in your organization?</td>
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<tr>
<td>What measures have you introduced, if any, to reduce the incidence of transfusion reactions?</td>
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<tr>
<td>What initial assessment do you perform for new transfusion patients?</td>
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<tr>
<td>What were the specimen collection requirements for the tests performed for this tracer patient?</td>
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<tr>
<td>Where were they collected?</td>
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<tr>
<td>What process did you follow for preparing blood units for this patient’s transfusion in an outpatient setting?</td>
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<tr>
<td>What instructions did you provide to this tracer patient?</td>
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<tr>
<td>What is your laboratory’s policy for ordering a stat procedure?</td>
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<tr>
<td>How do you verify orders for laboratory testing?</td>
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<tr>
<td>How do you determine who is authorized to give those orders?</td>
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<tr>
<td>What is your quality control process? When is corrective action required?</td>
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</tr>
<tr>
<td>What is your quality control process for the basic metabolic panel?</td>
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</tbody>
</table>

[Access this entire two-page worksheet at http://www.jcrinc.com/common/PDFs/Pubs/Periodicals/The-Source/TheSource0910-MockTracerTrackingForm_LaboratoryTracer.doc.](http://www.jcrinc.com/common/PDFs/Pubs/Periodicals/The-Source/TheSource0910-MockTracerTrackingForm_LaboratoryTracer.doc)
Additional Advice

- Keep responses as simple as possible to answer the question.

- Remember the reason behind the standard. Example: Fire Safety.

- Ensure that what is written in the policies and procedures matches what is actually being done in the laboratory. Example: QMS.

- When in doubt about a particular standard and your lab’s response, call and ask. The agencies have staff available to answer your questions.
Achieving the Inspection-Ready Laboratory

Future Developments
Hot Topics to Watch


- Laboratory-Developed Tests (LDTs) – Awaiting final FDA guidance.

- Proficiency Testing Regulations – CMS collaborating with CDC.

- Waived Testing – Competency of non-laboratory personnel performing high complexity testing (e.g., glucose meters).

- From CMS – Fecal occult blood regulation, which is in the final stages of clearance. This regulation adds the words “non-automated” to the fecal occult blood test on the waived list.
Future Developments – CAP Checklists

CAP anticipates a July 2015 release, pending CMS review and approval. Changes/additions will include:

- Individual Quality Control Plans (IQCP) (CMS has reviewed and approved CAP’s plan).
- Specimen labeling for primary and secondary specimens.
- Use of third-party verification (credential verification organization) for personnel records for educational qualifications.
- In vivo microscopy.
- Laboratory-developed tests (LDTs).
Future Developments – COLA

- Recently implemented standards for IQCP, waived testing, mass spectrometry, Laboratory Director continuing education, and direct access to test results.

- With IQCP transition period ending December 31, 2015, laboratories need to discontinue any EQC protocols and implement either the regulatory QC requirements or IQCP.

- Once FDA provides guidance on laboratory-developed tests (LDTs), will make sure standards are in line with them.

- Also planning additional standards specific for expanding and emerging technologies (e.g., mass spectrometry and time of flight methodologies along with molecular pharmacogenomics).
Achieving the Inspection-Ready Laboratory

Pulling It All Together
Keys to Readiness

Knowledge Of both the current standards and what may be coming next

Awareness Where other laboratories are having problems with the standards

Management Creating a culture of inspection readiness that results in making daily decisions with the standards in mind
Achieving the Inspection-Ready Laboratory

Q&A
Special Acknowledgement

The following individuals provided feedback/information for today’s presentation:

- **CMS** – Karen Dyer, Acting Director, Division of Laboratory Services
- **CAP** – Denise Driscoll, Director, Laboratory Accreditation Program & Regulatory Affairs
- **COLA** – Kathy Nucifora, Director of Accreditation
- **Joint Commission (JC)** – Stacy Olea, Executive Director, Laboratory Accreditation Program
- **Lucia Berte**, Laboratories Made Better!
- **Marianne McGucken**, MedStar Health
Q&A

THANK YOU FOR ATTENDING!

Nora L. Hess, MBA, MT(ASCP), PMP
Senior Consultant,
Operations Management
Chi Solutions, Inc.
(734) 662-6363, ext. 505
nhess@chisolutionsinc.com

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