

Lab Quality Confab

**CLIA and Regulatory Readiness:
What's New, What's Coming and How
Your Lab Should Prepare**

November 4, 2015

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
 - ISO 9000:1987, 9001:2008: Quality management systems standards.
 - ISO 17025:2005: Technical standards for testing and calibration laboratories.
 - ISO 15189:2012: Specifically for medical testing laboratories.

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
- American Osteopathic Association, 142 East Ontario Street, Chicago, Illinois 60611, (312) 202-8070, www.osteopathic.org
- American Society for Histocompatibility and Immunogenetics (ASHI), 15000 Commerce Parkway, Suite C, Mt. Laurel, New Jersey 08054, (856) 638-0428, www.ashi-hla.org
- COLA, 9881 Broken Land Parkway, Suite 200, Columbia, Maryland 21046-1195, (410) 381-6581, www.cola.org
- College of American Pathologists (CAP), 325 Waukegan Road, Northfield, Illinois 60093-2750, (800) 323-4040, www.cap.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

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

*Data from 17,873 surveys, CLIA data system 12/13.

Most Common Deficiencies – CMS’s 2013 Top Ten

Top Ten Conditional Deficiencies

Description	Percent Cited*
Moderate Complexity Laboratory Director qualifications	3.7%
Successful proficiency testing participation	3.3%
High Complexity Laboratory Director qualifications	1.5%
Proficiency testing enrollment	1.4%
Analytic System (Quality Control)	1.0%
Moderate Complexity test personnel	1.0%
Technical Consultant qualifications	0.8%
Hematology	0.6%
High Complexity test personnel	0.4%
Technical Supervisor qualifications	0.3%

*Data from 17,873 surveys, CLIA data system 12/13.

Most Common Deficiencies – CAP's 2014 Top Ten

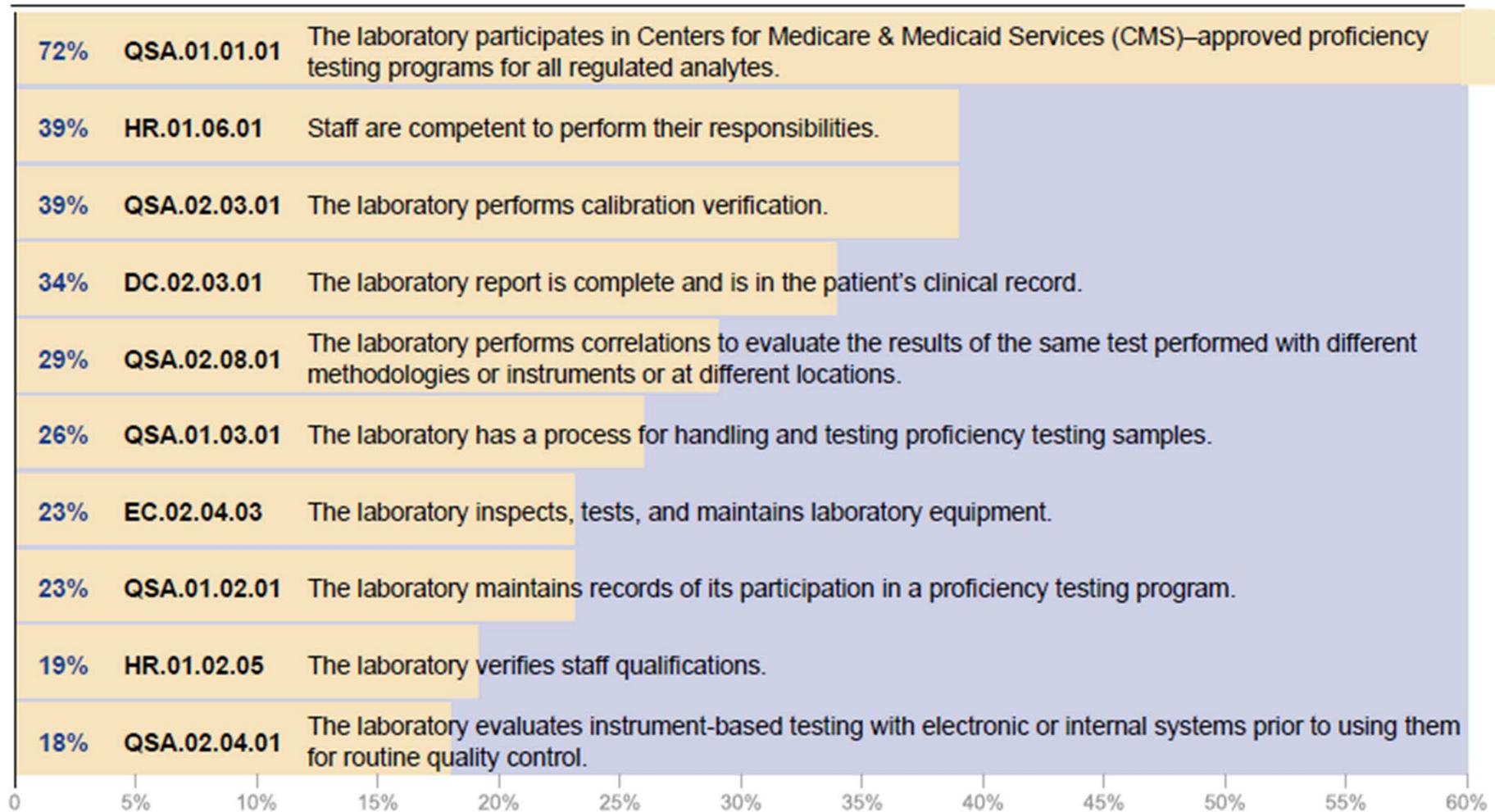
Checklist Number	Description	Percent Cited
GEN.55500	Competency records	23.5%
GEN.20375	Document control	13.9%
GEN.54400	Personnel files	7.9%
POC.06910	Personnel competency in POCT	6.9%
POC.04500	Reference intervals in POCT	6.7%
COM.01200	Accurate Activity Menu	6.2%
Various	Semiannual instrument correlation	5.4%
ANP.23410	Cryostat decontamination	4.8%
TRM.32000	Instrument preventive maintenance	4.3%
MIC.14583	Controls for direct antigen testing	4.0%

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.

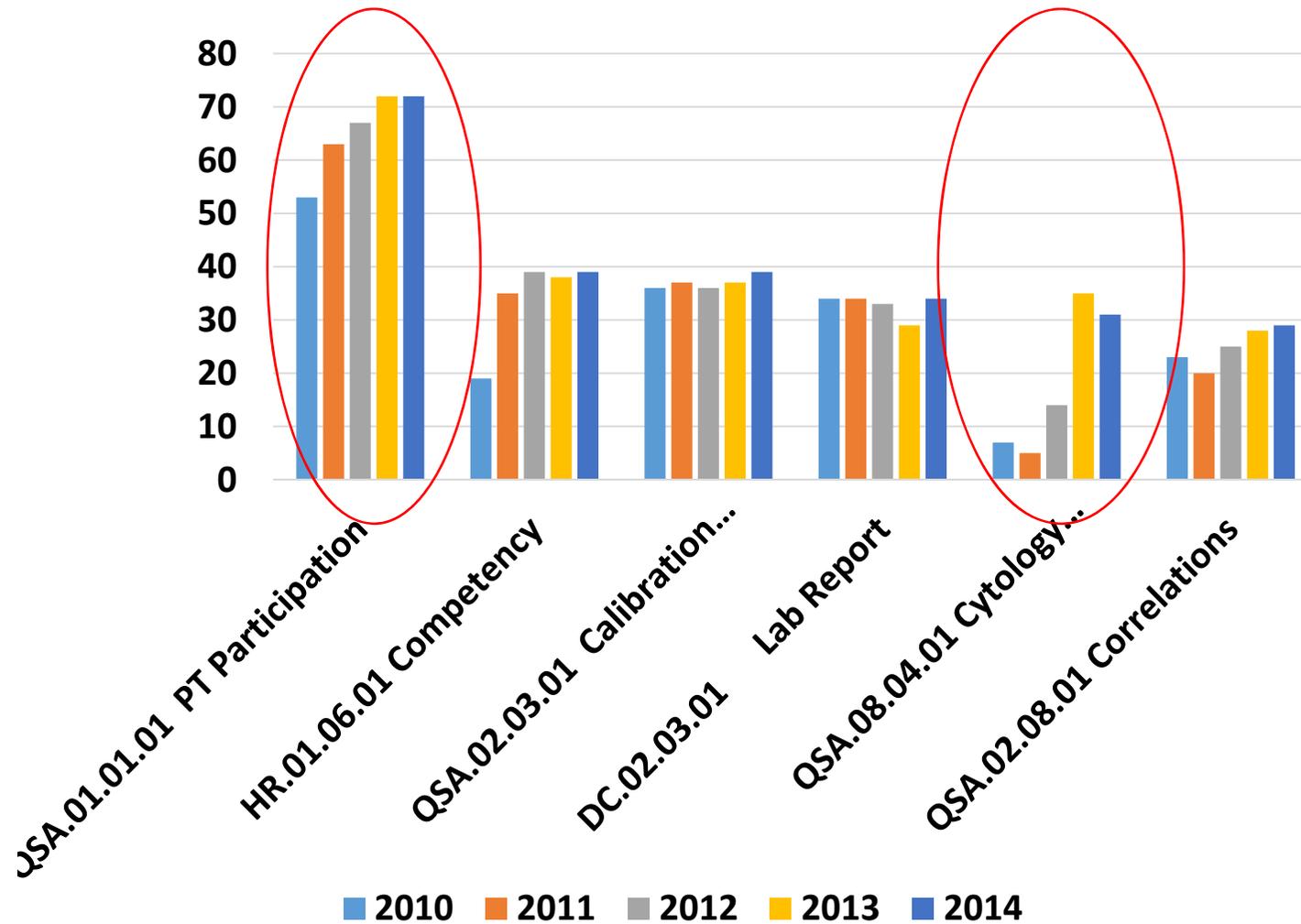
Most Common Deficiencies – Joint Commission

TOP STANDARDS COMPLIANCE ISSUES FOR 2014 LABORATORY AND POINT-OF-CARE TESTING

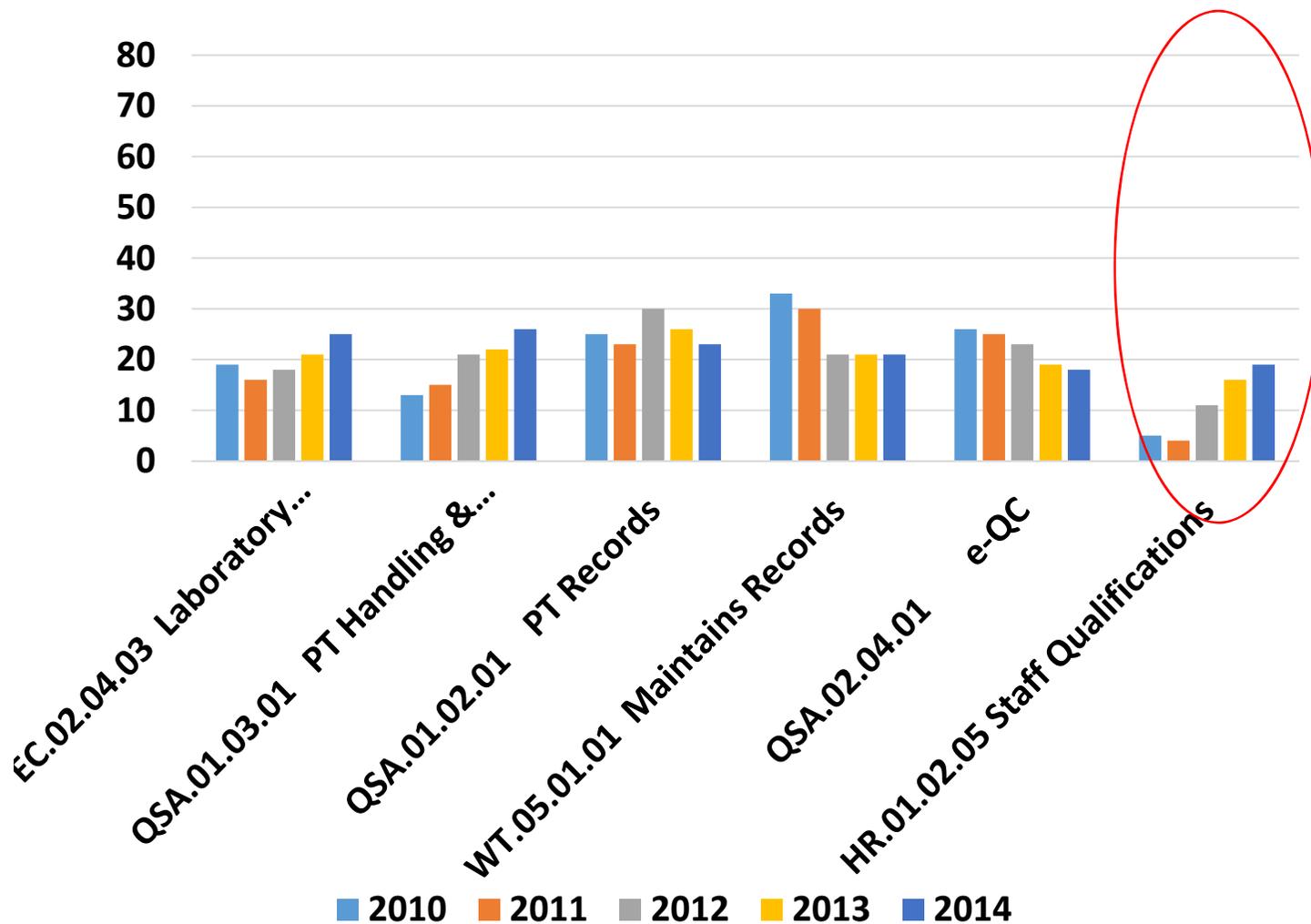


Note: The data determined for the laboratory program were derived from an average of 813 applicable surveys.

Top JC Non-Compliance Standards 2010-2014



Top JC Non-Compliance Standards 2010-2014



Common Deficiencies Comparison

	CMS	COLA	JC	CAP
Lack of documentation of staff qualifications	X	X	X	X
Incomplete competency assessments	X	X	X	X
Lack of documentation of calibration verification		X	X	X
Participation in or handling of proficiency testing	X	X	X	
Insufficient oversight by the Laboratory Director	X	X		

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

AP HR File Audit <insert date>		Hire Date	Training & Experience	Academic Degree / License or Certification	Job Description (JD)	Initial Organizational Orientation	Initial Department Competency	Formaldehyde Quiz (Safety)	6 month Competency	12 month Competency	Annual Organization	Annual Department	Visual Color Examiner	CEUs	Radiation Exposure	Incidents	Other	Overall Status	File Checked / Signed	Comments
File Organization:			Tab 1		Tab 2		Tab 3					Tab 4			Tab 5					
2	Employee #2	6/25/2012		x	Cert PA	partial	In Process	x	Due Dec				x						7/9/12	Missing Degree/Educ (eligible for certification) & Hosp orientation paperwork, update JD
3	Employee #3	2/19/1991		x	Cyto Prep Tech	x	x	x			x	x	x					C	7/9/12	
5	Employee #5	3/4/1991		x	Histotechnologist	x	x	x			x	x	x					C	7/9/12	Initial orientation checklist missing
6	Employee #6	9/8/2009, ReH 5/29/12		x	Histotechnologist	x	x	x	Due Nov		x		x					C	7/9/12	Rehired 5/29/12
8	Employee #8	6/17/2012		x	Cert PA	x	x	x	Due Dec		x		x					C	7/9/12	Certification pending within 12 mos., update JD
10	Employee #10	10/19/2009		x	Med Transcrip		x	x			x	x	x					C	7/9/12	
15	Employee #15	5/29/2012	x	x	Histotechnologist	x	x	x	Due Nov										7/9/12	Missing Initial Onboarding & Color paperwork
16	Employee #16	5/7/2012		x	Cert PA	x	x	x	Due Nov				x					C	7/9/12	Missing onboarding checklist & formaldehyde quiz
Temps/Agency Techs																				
1	Temp #1	5/7/2012		x	Med Off Asst II	Co file	x	x					x					C	7/9/12	
4	Temp #4	5/24/2012		x	Cert PA	Co file	x	x	Due Nov				x					C	7/9/12	
5	Temp #5	4/22/2012		x	Lab Proc Rep II	Co file	x	x					x					C	7/9/12	

KEY: Pending Item

NOTE: Audit Findings - 33 of 37 files were complete or 89%

Management Review	Auditor: insert auditor's name	Signature: _____	Date: _____
	Reviewed By: QA	Signature: _____	Date: _____
	Section Manager	Signature: _____	Date: _____
	Laboratory Director	Signature: _____	Date: _____

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

MedStar Health Laboratory Associate Personnel Competency Assessment Tracking Form ANATOMIC PATHOLOGY-HISTOLOGY

Associate Name: _____ Year: _____

Type of Competency	Method	of	Assessment
<input type="checkbox"/> Initial	PT: Proficiency Testing	QC: Quality Control Review	Q: Quiz
<input type="checkbox"/> 6 month	RR: Results Review	PSE: Occurrence Report Review	BS: Blind Sample Testing
<input type="checkbox"/> Annual	WR: Worksheet Review	CR: critical Result Report	
<input type="checkbox"/> Re-training			

Competency elements:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples
6. Evaluation of problem-solving skills

Notes: *denotes High complexity test

blacked out boxes=waived test

Department/Area	TEST SYSTEM	Competency Elements						Competent to Perform Y/N
		1	2	3	4	5	6	
Histology	Specimen Processing	Date	Date/Method	Date/Method	Date	Date/Method	Date/Method	
	Accessioning							
	Grossing / Prosecting							
	Routine Specimens							
	Special Procedures							
	Autopsy							
	Equipment Use and Maintenance							
	Embedding							
	Biopsy							
	Routine							
	Dermatology							
	Microtomy							
	Automated Microtome							
	Biopsy blocks							
	Routine blocks							
	Frozen Section							
	Manual Microtome							
	Biopsy blocks							
	Routine blocks							
	Frozen Section							
	Staining							
	Routine H&E - Automated							
	Routine H&E - Manual							
	Special Stains - Automated							
	Special Stains - Manual							
	Immunohistochemistry (IHC)							
	Immunofluorescence							
	In-Situ Hybridization							
	Automated IHC							
	cooker							
	Digestion							
	Antigen Retrieval Dako - Low pH							
	Antigen Retrieval Dako - High pH							
	Pre-dilute antibodies							
	Concentrate antibodies							
	Manual IHC							
	cooker							
	Digestion							
	Antigen Retrieval Dako - Low pH							
	Antigen Retrieval Dako - High pH							
	Pre-dilute antibodies							
	Concentrate antibodies							

(form cont.)

Slide Distribution								
Slide & Requisition Reconciliation								
Verification of Daily Work								
Pathology Office								
Transcription								
Sendout Procedures								
Consultations - In-coming								
Consultations - Outgoing								
Maintenance/Filing								
Quality Systems								
Procedure Review								
Equipment Maintenance								
QC Documentation								
Occurrence Reporting								

Based upon successful completion of this competency assessment, the employee named above is deemed to be competent to perform unsupervised patient testing for any area marked "Y".

Any area marked "N" will require re-training per applicable SOPs followed by a competency re-assessment.

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

Quote – CMS

“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**

Quote – CAP

“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

The screenshot shows the homepage of The Joint Commission website. At the top left is the logo for The Joint Commission. To the right are links for 'Log In | Request Guest Access', 'Contact Us | Careers | JCR Web Store | Press Room', and 'Forgot password? | Log In Help'. A search bar with a 'Go' button is also present. Below the header is a navigation menu with tabs for 'Accreditation', 'Certification', 'Standards', 'Measurement', 'Topics', 'About Us', and 'Daily Update'. The main content area features a 'Topic Details' section with a breadcrumb 'Home > Topic Details' and social media sharing options for Twitter, Facebook, Google+, Share, and Print. A 'Sign up for News and Alerts' box is on the left. The main article is titled 'Tracer Methodology 101 - The Laboratory Tracer', dated August 30, 2010, with a 'Download This File' button. The text describes laboratory tracers as unique for evaluating processes rather than just patient contact. The footer contains contact information, copyright notice for 2015, and social media icons.

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

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.

Tracer Team Member: _____ Tracer Patient or Medical Record: _____
 Staff Interviewed: _____
 Unit or Department Where Tracer Was Conducted: _____

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

Access this entire two-page worksheet at
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

- **Individualized Quality Control Plan (IQCP) – CMS collaborating with CLSI (EP23-A, *Laboratory Quality Control Based on Risk Management, October 2011*) and CDC to educate laboratories.**
- **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!

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