

Preparing Inspection Documentation

Prepare to be Prepared

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Objectives

- Identify required documents
- Discuss advanced document review
- Identify most commonly cited deficiencies
- Prepare for the day of Inspection – Get it Together
- How to respond to deficiency responses
- Explain accreditation resources

Documents? What Documents??

Documents include:

- Policies & Procedures
 - Every instrument
 - Every method
 - Every process
 - Approval by Medical Director
 - Review by staff
 - Biennial Review
 - Downtime procedures



Documents include:

- Quality Plan
 - List of Quality Indicators
 - Quality Dashboard
 - Root Cause Analysis
 - Annual evaluation
 - IQCP's & biennial evaluations

Documents include:

- Proficiency Testing
 - Activity Menu
 - Attestation Pages
 - Signed by all testing personnel
 - Raw Data / Instrument Printouts
 - Final Report
 - Signed by Medical Director / Designee
 - Evaluation of Unacceptable Results
 - Evaluation of Ungraded
 - Educational Challenges / Lack of Consensus, etc.



Documents include:

- Safety Plan
 - Chemical Hygiene Plan
 - Chemical Inventory
 - Carcinogens / Acute & Reproductive Toxins
 - Spill Kits & posted instructions
 - Formaldehyde / Xylene Monitoring
 - Biological Safety Cabinets
 - Eyewash Activations
 - Safety Inspections (Medical Director Review)
 - Fire Safety Training

Documents include:

- Quality Control Records
 - Per instrument/method
 - Daily / Weekly / Monthly
 - Supervisor's Monthly Review
 - Corrective Action for outliers



Documents include:

- Instrument / Method Validations
 - Analytical Accuracy
 - Analytical Precision
 - Reportable Range
 - All validations since the last inspection
 - Others may be requested as needed
 - Summary Statement

"I have reviewed the verification (or validation) data for the performance specifications listed below for the (insert instrument/test name), and the performance of the method is considered acceptable for patient testing."

Documents include:

- Maintenance Records
 - Every Instrument
 - Centrifuges
 - Microscopes
 - Pipette Calibrations
 - Thermometers
 - Temperatures
 - Remote Monitoring
 - Daily and/or Min/Max Thermometers



Documents include:

- LIS Records
 - Director's Biennial Review of Report
 - Downtime Reports
 - Reference Intervals
 - Critical Results with read-back
 - Interface Verifications
 - Prior to implementation of an interface
 - Whenever any change is made to an existing interface that could affect the accuracy of transmission of patient results

Documents include:

- Personnel files
 - Diploma/Transcript/PSV/Licensure
 - Job Descriptions
 - Training / Competency Records
 - Delegation Documents
 - Performance assessments of delegated duties
 - Medical Directors assessment of adequacy of staff

Advanced Document Review

Inspection Models



In-Person (Traditional)

In-Person with advance document review

Virtual

Virtual with advance document review

Advanced Document Review



**ACCESS TO DOCUMENTS AND
SOPS PRIOR TO INSPECTION
INTERACTION**



**DOCUMENTS REVIEWED AND
QUESTIONS “COLLECTED”**



**ONSITE OR VIRTUAL INSPECTION
THROUGH INTERACTIONS WITH
LABORATORY STAFF**

Most Commonly Cited Deficiencies and How to Avoid Them

Top 10 Deficiencies

Checklist Requirement		CAP-wide Ranking
COM.01200	Activity Menu	1
GEN.55500	Competency Assessment	2
COM.10000	Procedure Manual	3
COM.04250	Comparability of Instruments and Methods – Nonwaived Testing	4
COM.04200	Instrument/Equipment Record Review	5
COM.30600	Maintenance/Function Checks	6
COM.01700	PT and Alternative Assessment Result Evaluation	7
COM.30750	Temperature Checks	8
COM.01400	PT Attestation Statement	9
COM.30450	New Lot/Shipment Confirmation of Acceptability	10

#1 Activity Menu

- New testing performed but not added
- Discontinued testing still on menu

T1 (Section ID: 1924573) - Activities

[Watch the Section Activities Demo](#)

ADD

MOVE/REASSIGN

REMOVE

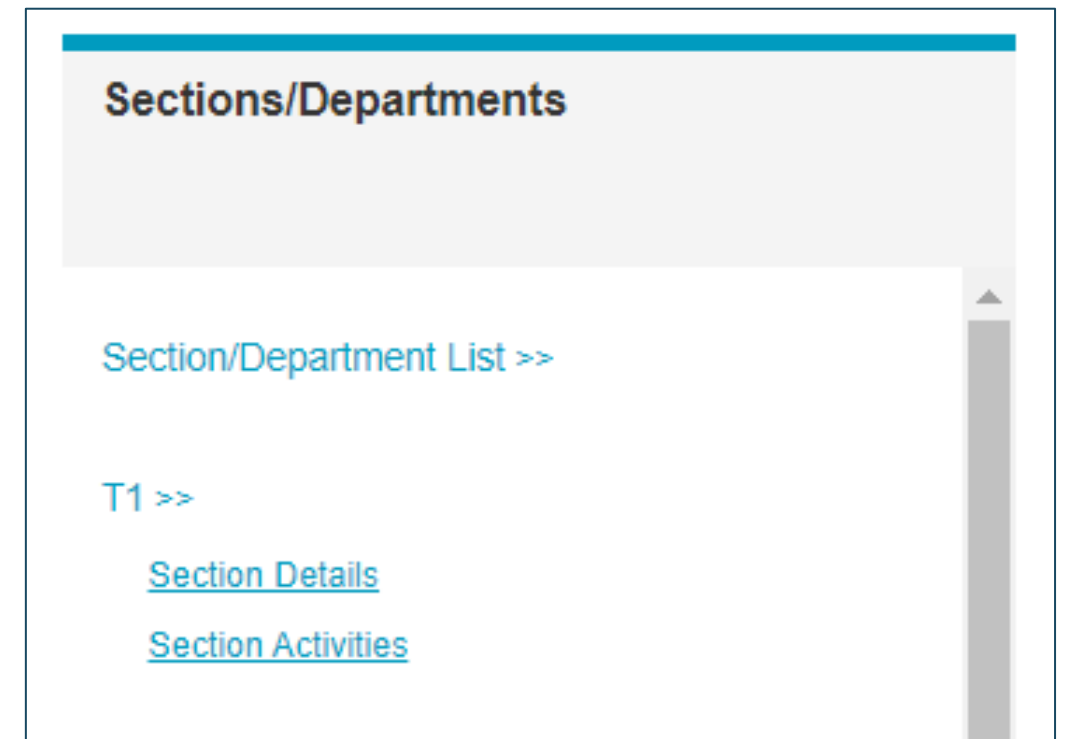
[Download CAP Master Activity Menu](#)

1 Activity | Type: S - Scope of Service, R - Reportable Assay | [Export to Excel](#)

Activity Name ▼	Discipline ▲	Subdiscipline	Type
Glucose, whole blood, waived (glucose meter), POCT	Point-of-Care Testing	Point of Care Testing - Waived	R

#1 Activity Menu

- Laboratory's current CAP Activity Menu accurately reflects the testing performed
 - Add to new test implementation process
 - Audit Activity Menu periodically
 - Remove retired tests
 - Custom checklist generated by Activity Menu selections
 - Proficiency Testing Failures linked to menu



#2 Non-Waived Competency Assessment

- The competency of personnel performing **nonwaived** testing is assessed at the required frequency at the laboratory (CAP/US-based CLIA number) where testing is performed.
 - All variations must be included.
 - May be maintained centrally within a healthcare system but must be available upon request.



Competency Assessment Frequency

- During the first year of an individual's duties, competency must be assessed **at least semiannually** and annually thereafter.
 - Prior to performing patient testing, training must be completed and evaluated for proper test performance.
 - Training and competency assessments are separate processes.
 - Applicable to new testing personnel only.



Competency Assessment Elements

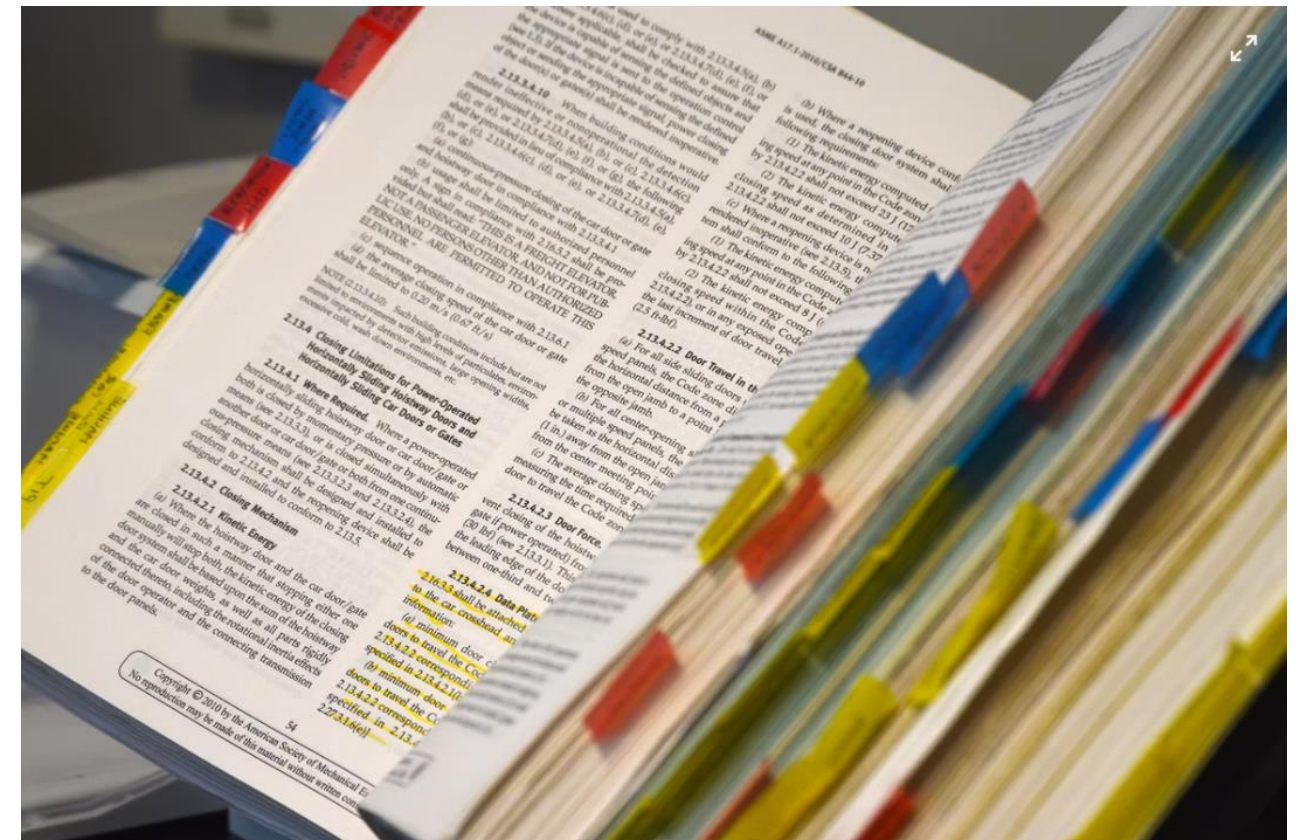
- Assessment includes all applicable **six** elements of competency for **each test system**.
 - Use laboratory activity menu to identify test systems.
 - Same analyte with two test systems (eg, automated, manual) needs separate competency assessments.
 - Multiple analytes under single test system do not need separate competency assessments (eg, chemistry panel).
 - Each test system includes assessment of
 - Pre-analytic
 - Analytic
 - Post-analytic stepsin the testing process.

Competency Assessment – Example

Employee Name:		Sample Employee			
Date of Hire:		1/1/2018			
Period of Evaluation:		01/01/2018 - 12/31/2018			
Evaluator(s):		Sample Manager (SLM)			
Elements:					
1. Direct observation 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 testing samples					
6. Evaluation of problem-solving skills					
		Point of Care	Point of Care	Point of Care	Point of Care
Elements	Specify Instrument / Assay	Istat - Nonwaived	Glucometer (Waived)	ABL	GEM
1	Patient ID/Prep	01/08/18 SLM	02/01/18 SLM	n/a	n/a
1	Specimen Collection	01/08/18 SLM	02/01/18 SLM	n/a	n/a
1	Handling/Processing	01/08/18 SLM	n/a	01/08/18 SLM	01/08/18 SLM
1	Testing	01/08/18 SLM Accession # M123456	02/01/18 SLM MR# 111222333	01/08/18 SLM Accession # M123456	01/08/18 SLM Accession # M123456
2	Reporting Criticals	01/08/18 SLM Accession # M123456	n/a	01/08/18 SLM Accession # M123456	01/08/18 SLM Accession # M123456
2	Reporting Normals	01/08/18 SLM Accession # M123456	02/01/18 SLM MR# 111222333	01/08/18 SLM Accession # M123456	01/08/18 SLM Accession # M123456
3	Review worksheets	n/a	n/a	n/a	n/a
3	Review QC	01/08/18 SLM	01/08/18 SLM	01/08/18 SLM	01/08/18 SLM
3	Review PT results	03/15/18 SLM Sample IStat-15	n/a	03/15/18 SLM Sample ABG-16	03/15/18 SLM Sample ABG-17
3	Review PM records	03/15/18 SLM	n/a	n/a	n/a
4	Maintenance	01/08/15 SLM	02/01/18 SLM	01/08/18 SLM	01/08/18 SLM
5	Proficiency Testing	02/17/18 SLM Sample Istat-15	n/a	02/15/18 SLM Sample ABG -16	02/15/18 SLM Sample ABG-17
5	Blind Samples	01/08/18 SLM Accession # M234567	n/a	01/08/18 SLM Accession # M234567	01/08/18 SLM Accession # M234567
6	Problem Solving	Written Quiz = 100% 01/08/18 SLM	Online Quiz = 100% 01/10/18 SLM	Online quiz = 100% 01/08/18 SLM	Verbal quiz = 100% 01/08/18 SLM
Comments		Competent = yes 03/15/18 SLM	Competent = Yes 02/01/18 SLM	Competent = yes 02/15/18 SLM	Competent = yes 03/15/18 SLM

#3 Procedure Manual

- Complete procedure manual is available:
 - Paper-based
 - Electronic
 - Web-based format
 - at the workbench or in the work area
- Procedures must match practice.



#4 Comparability of Instruments and Methods – Nonwaived testing

- Non-waived methods only
- Methods within a single CAP/CLIA number
- At least twice a year
- Applies to instruments/methods producing the same reportable results (eg, manual differential vs. automated differential)
- Written procedures including acceptance criteria

#4 Comparability of Instruments and Methods – Nonwaived testing

- Missing documentation of two times per year
- Missing acceptability criteria
- Does not include all non-waived testing



#5 Instrument/Equipment Review

- Instrument/Equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.
 - Assessed at least monthly – requires:
 - Signature/initials
 - Date



#5 Instrument/Equipment Review Example

		Fill in the date the document review occurred for that month											
Department	Instrument/Testing	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
All Lab	Room Temperature Logs	02/06/22											
	Refrigerator Temperature Logs	02/06/22											
	Freezer Temperature Logs	02/06/22											
	Eye wash Logs / Shower Logs	02/06/22											
Chemistry	Instrument A maintenance logs	02/15/22											
	Instrument A QC logs	02/15/22											
	Instrument A calibration logs												
	Instrument B maintenance logs	02/15/22											
	Instrument B QC logs	02/15/22											
	Instrument B calibration logs												
	Instrument A & B Comparisons												
	Blood Gas maintenance logs	02/15/22											
	Blood Gas QC logs	02/15/22											
	Blood Gas calibration logs	02/15/22											
	PT Records	02/27/22											

#6 Maintenance/Function Checks

- Appropriate maintenance and function checks are performed.
- Records retained for instruments (eg, analyzers) and equipment (eg, centrifuges) following a defined schedule, at least as frequent as specified...
 - All instruments and equipment
 - Includes centrifuges, microscopes, temperature logs
 - Written procedure
 - Schedule specified by manufacturer
 - Documentation of performance and monthly review



#7 Proficiency Testing Evaluation

- Ongoing evaluation of proficiency testing/external quality assessment (PT/EQA) and alternative assessment results with appropriate corrective action taken for each unacceptable result.
 - Each unacceptable PT or alternate assessment result must be evaluated.
 - Investigate **each** unacceptable PT result for impact on patient sample results.
 - Major categories of investigation include:
 - **Clerical**
 - **Analytical**
 - **Procedural**
 - **Specimen handling**
 - **PT material**



Common Deficiencies and How to Avoid Them – PT/EQA Evaluation

- Missing corrective actions on failures.
- Missing documentation of review of results with codes.
- Missing documentation or evaluation of alternative assessments.
 - Alternative assessments are performed on methods/instruments that do have commercially available PT/EQA products.



PT/EQA Exception Investigation Worksheet



Survey Information

Survey Name: _____ CAP No. _____
 Date Survey Received: _____ Date Analysis Performed: _____
 Date Survey Results Submitted: _____ Date Results Received: _____
 Investigation Performed By: _____
 Analyte: _____

Specimen Number	Reported Result	Intended Result/Range	Acceptable/Unacceptable
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Were the results submitted by the due date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the result correctly transcribed from the instrument read-out or report?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the correct instrument/method/reagent reported on the result form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do the units of measure match between the result form and the instrument results?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the decimal place correct?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Alternative Performance Assessment (APA) Test List



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Alternative Performance Assessment (APA) Test List

For tests for which CAP does not require proficiency testing (PT), the laboratory at least semi-annually exercises an APA system for determining the reliability of analytic testing. This form may be used to assist in compliance with the All Common Checklist requirement COM.01500.

Laboratory Name: CAP Number:

Test Name	Laboratory Section/ Department	Participating in an external PT program (list program)	Using other APA (explain below)	Evaluation Criteria for APA	Months in which APA is performed (minimum twice per year)	Comments

#8 Temperature Checks

- Temperatures are checked and recorded **each day of use** for all temperature-dependent equipment and environments using a calibrated thermometer.
 - If the laboratory is not “open” on the weekends and there is temperature dependent reagents/equipment stored in the laboratory, there must still be temperature monitoring.
 - Can use min/max thermometers.
 - Any temperatures outside of the defined ranges must have documented corrective action.



#9 PT Attestation Statement

- The proficiency testing/external quality assessment (PT/EQA) attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.
 - Secure electronic signature
 - Physical signatures

Attestation/Use of Other Form	
Attestation Statement	
<input type="checkbox"/> As stated in the February 28, 1992 United States <i>Federal Register</i> under Subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel must <u>sign</u> on the result form.	
<input type="checkbox"/> Retain a <u>signed</u> copy of this page in your laboratory for your records and inspection purposes.	
<input type="checkbox"/> If your laboratory requires additional space for signatures, copy this form as needed.	
<hr/>	
We, the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens. We confirm that results were not shared or PT specimens referred or tested outside our CLIA identification number.	
Director (or Designee) (signature required)	Survey Mailing Information (eg, CA2020)
010 <input type="text"/>	030 <input type="text"/>

#10 New Lot/Shipment Confirmation of Acceptability

- New reagent lots and shipments are checked against previous reagent lots before being placed in service.
- Examples of suitable reference materials include:
 - Positive and negative patient samples tested on a previous lot
 - Previously tested proficiency testing materials
 - External QC materials tested on the previous lot
 - Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms



Common Deficiencies and How to Avoid Them – New Lot/Shipment Confirmation of Acceptability

- No records of new lot and new shipment confirmation
- No acceptability criteria defined

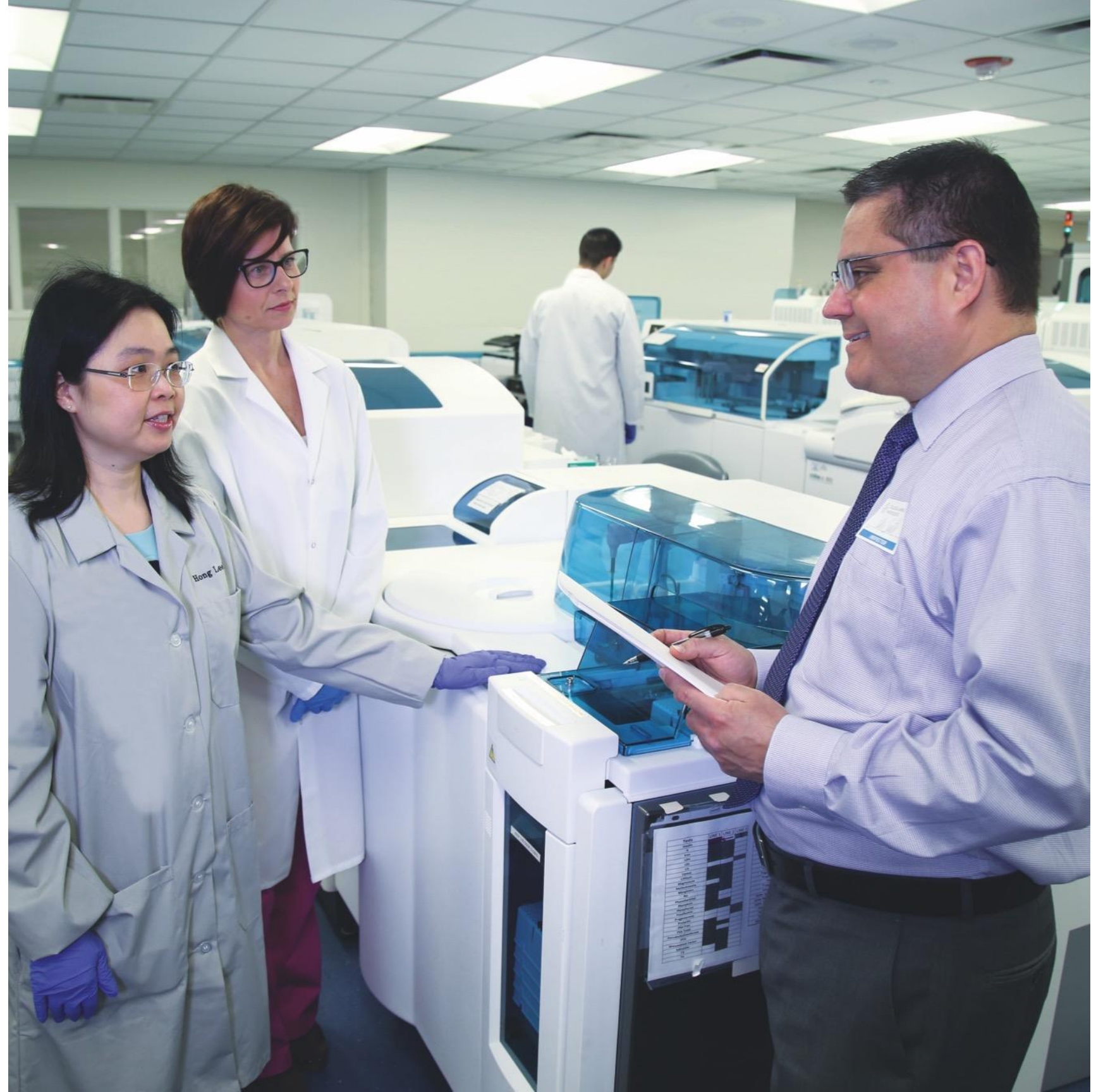


Day of Inspection

Get It Together

Introductions

- Meeting room/space for inspection team
- Introductory meeting with staff
- Brief laboratory tour



Inspection team needs

- Contact information for key personnel
- Telephone and computer access
- Office supplies in the team work area
- Badge access/escort



Documents for review



- Current activity menu
- Quality management plan and monitors
- Policies and procedures
- Proficiency testing records
- Method validation studies

Documents for Review - continued

- Current personnel roster
- Personnel files
- Initial training/competency assessments



More documents

- Quality control
- Maintenance and function checks
- Individualized quality control plans (if applicable)
- Sample laboratory reports
- Other documents as requested

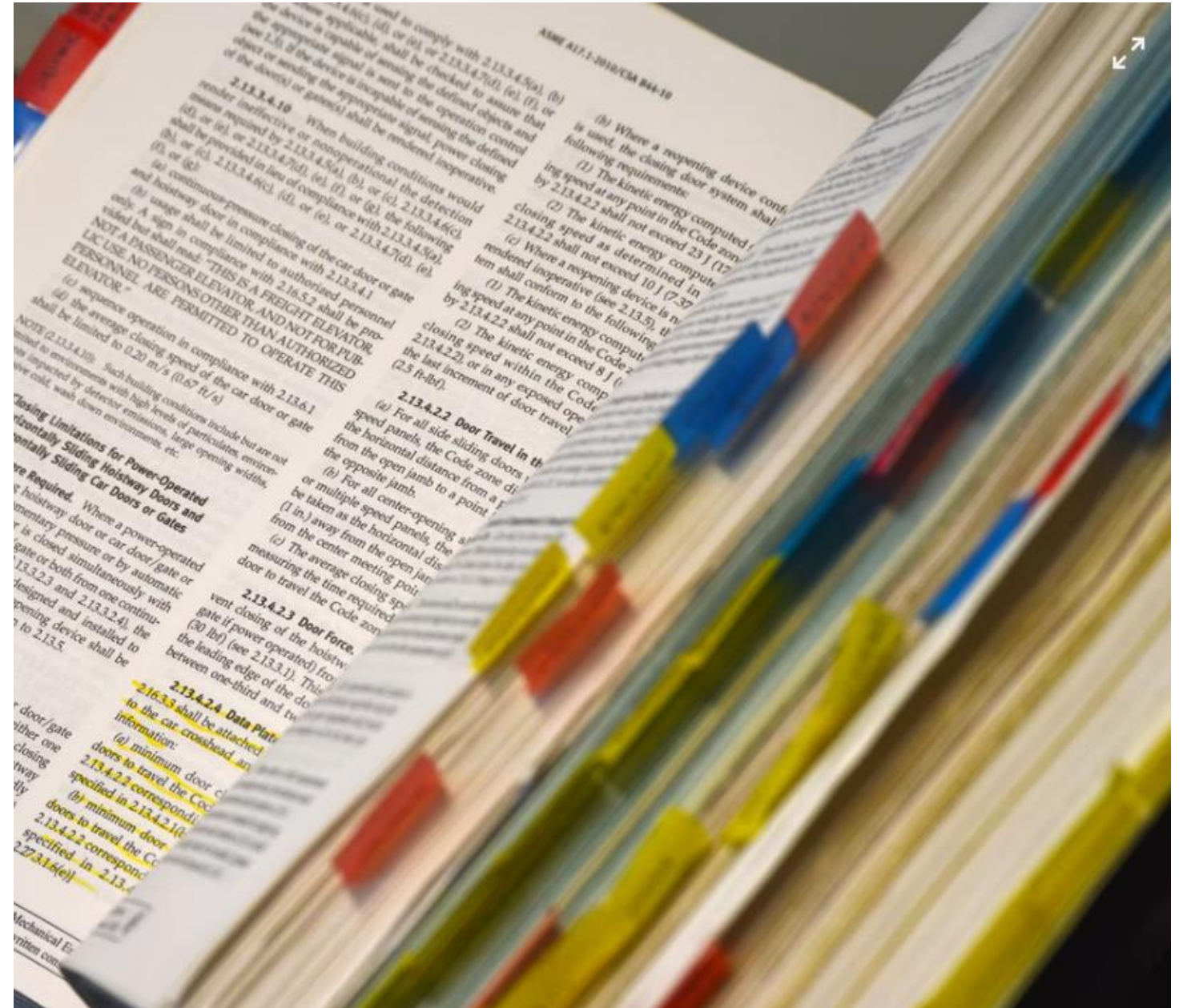
Departments to notify of the inspection

- Education personnel for point of care and transfusion medicine
- Human Resources/Employee Health
- Respiratory Therapy
- Biomedical
- Laboratory Information Systems



Strategies to Prevent Deficiencies

- Stay abreast of checklist changes.
- Conduct a thorough interim self-inspection...and correct any deficiencies.
- Focus on areas of the lab that are growing or changing.
- Make it easy for inspectors to establish compliance with checklist items.



Suggestions for Demonstrating Compliance

Hyperlink

Hyperlink documents that demonstrate compliance

Add

Add the pertinent documents' locations with the checklist requirements

Tab

Tab procedures and documents with checklist requirement numbers

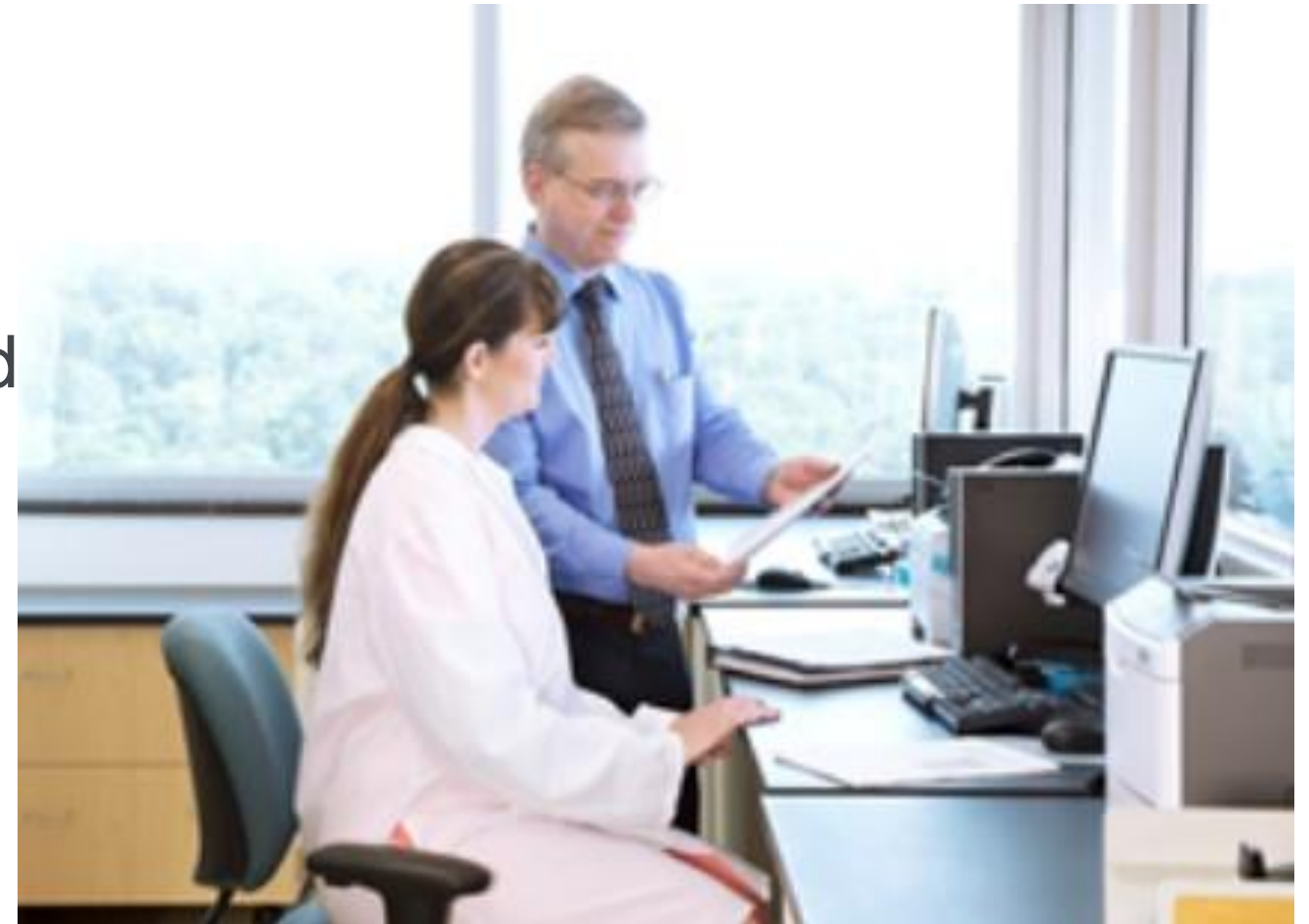
Develop

Develop a compliance manual

Deficiency Investigation Strategies

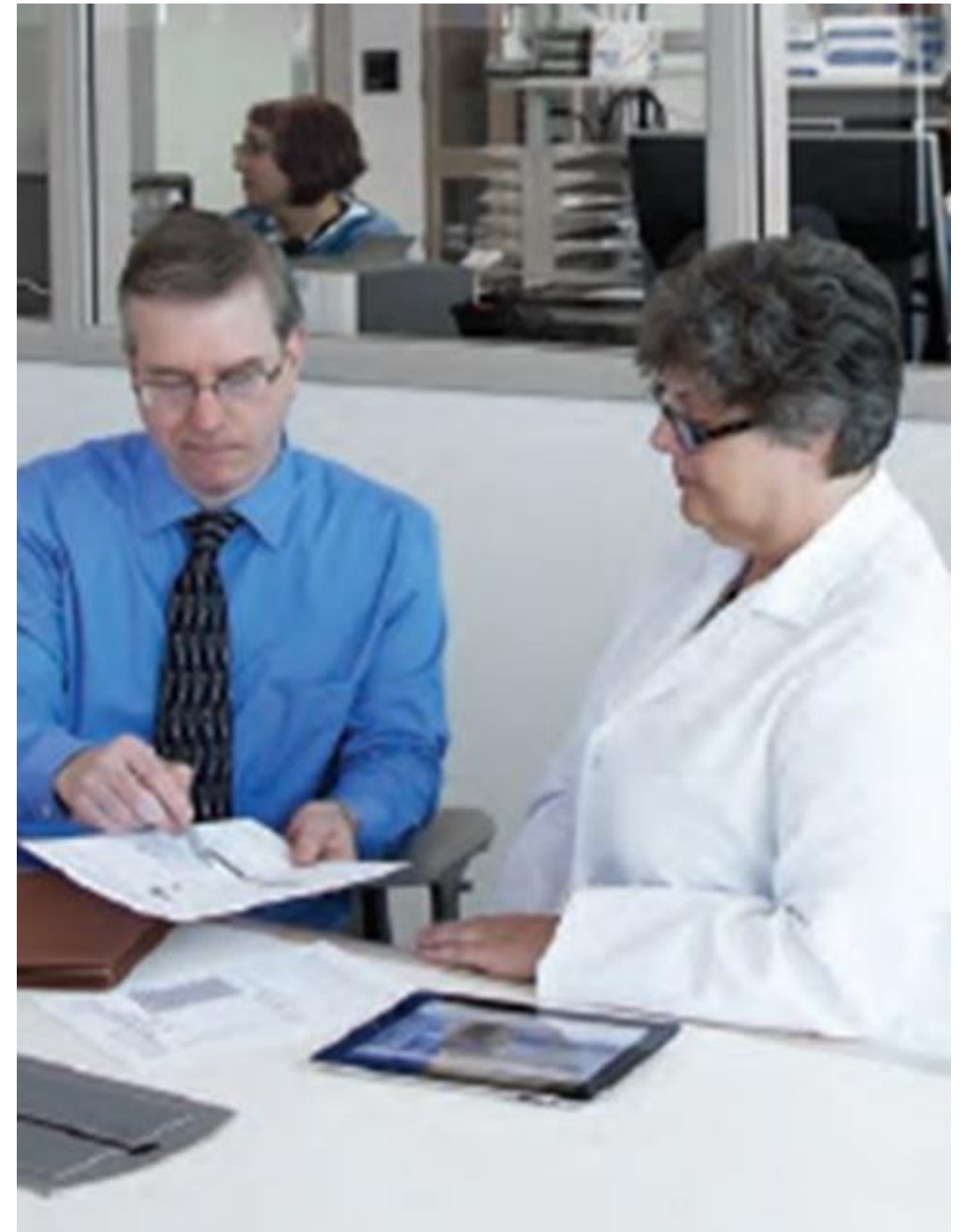
Questions to consider:

- Do lab practices completely meet the intent of the checklist requirement?
- Was the policy/procedure being followed as written?
- Was there a record of review and/or corrective action when applicable?



Deficiency Investigation Strategies, cont'd

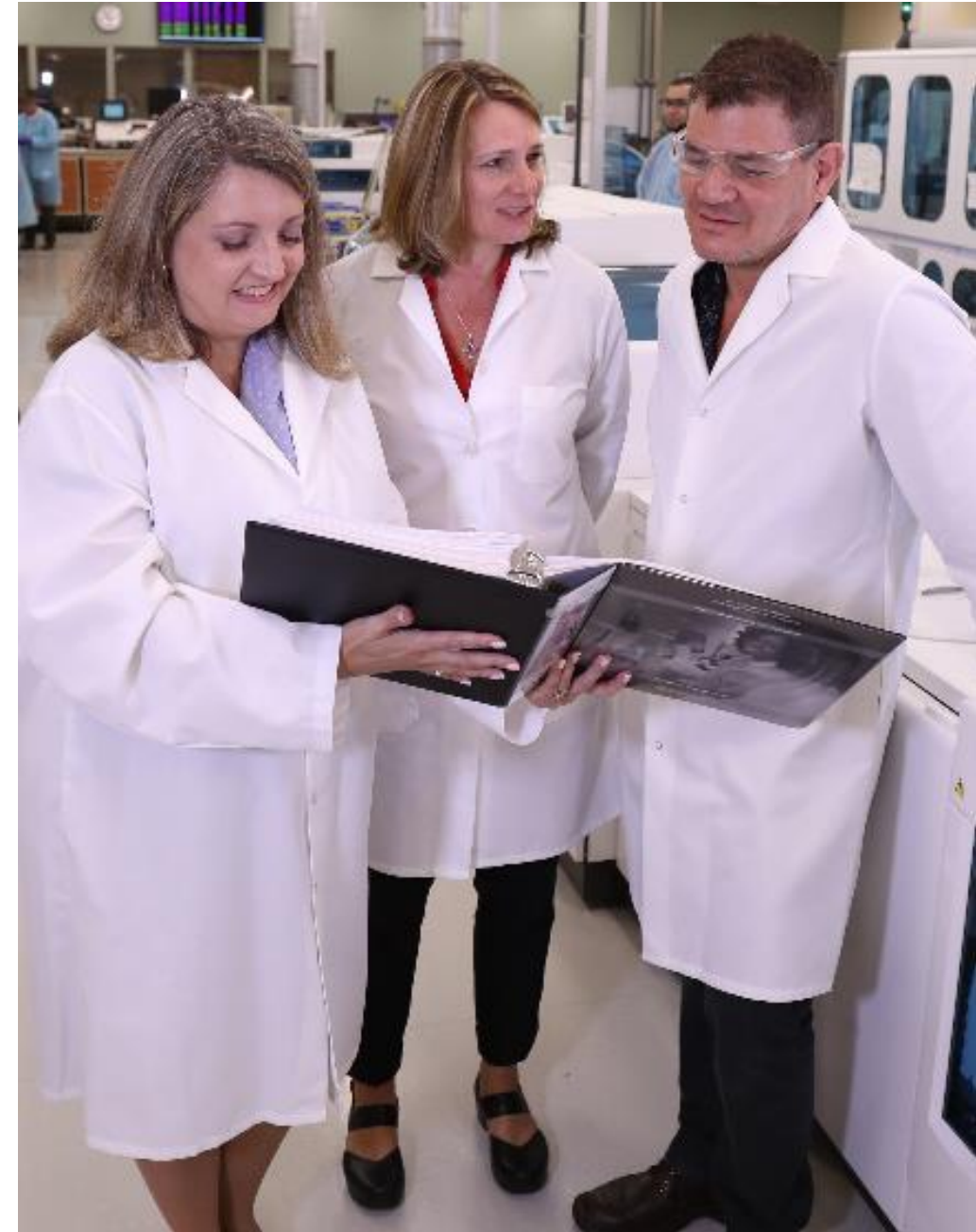
- Did testing personnel receive appropriate comprehensive training and competency assessments applicable to their job responsibilities?
- Was the appropriate documentation in place at the time of inspection but the inspector missed reviewing it?



Investigation Strategies: Path to Corrective Actions

If the laboratory answered “no” to any of the questions on the previous slides, the laboratory should:

- Investigate the cause of the deficiency
- Implement corrective actions



Responding to Deficiencies

Deficiency Response: Types of Appropriate Documentation



New or revised policies and procedures with appropriate review and approval



Sections of policies and procedures that have been underlined or highlighted



Quality control, calibration, maintenance, temperature records, etc

Documents? What Documents??

Accreditation Resources



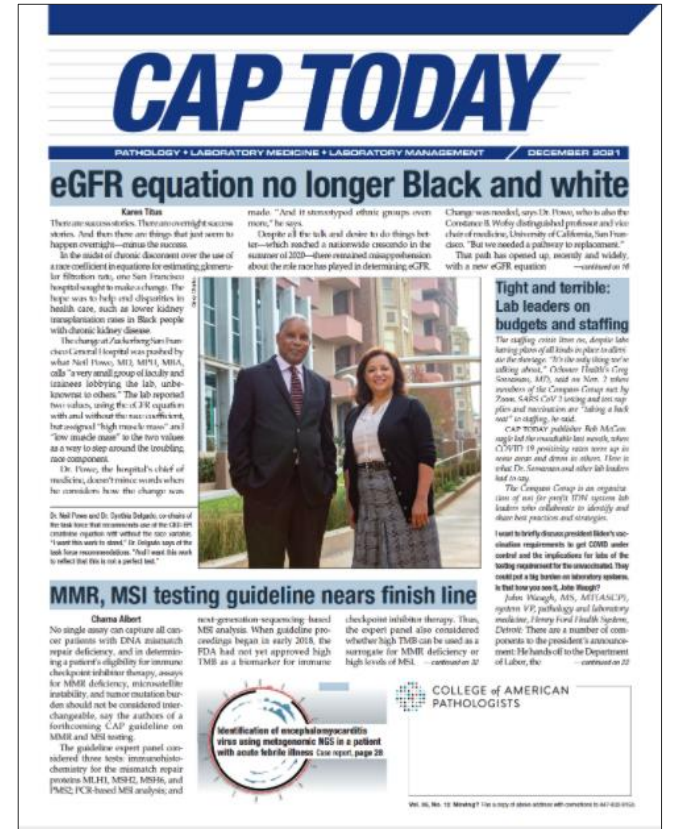
Expanded Accreditation Resources

- Revised and expanded online resources
- New content includes:
 - A series of Checklist Q&A's written by technical specialists
 - An informative multi-module course, *Laboratory Inspection Preparation: Getting Ready for Your First Inspection*
- Everything is fully searchable to find what you need quickly.

CAP's e-LAB Solutions Suite is available at any time for accreditation questions.

CAP Resources to Keep Up-to-Date

- CAP Today
- e-Alerts
- Online Inspector Training – Team Member/Team Leader
- CAP Accreditation Resources Repository
- Educational webinars – Focus on Compliance Series



Focus on Compliance

This library of past webinars focuses on timely compliance topics.

2021

- ▶ **CAP Accreditation During the COVID-19 Crisis: A Novel Approach**
Focus on Compliance (FOC) webinar that addresses the COVID-19 pandemic and its impact on CAP accredited laboratories.
 - Presentation Slides (PDF)
 - Question & Answers (PDF)
 - Toolkit (ZIP)
- ▶ **Responding to Deficiencies: Clear, Concise, and Complete Compliance**
Focus on Compliance (FOC) webinar that addresses responding to deficiencies.
 - Presentation Slides (PDF)
 - Question & Answers (PDF)
 - Toolkit (ZIP)
- ▶ **Preanalytical Errors: Taking the Garbage Out**
Focus on Compliance (FOC) webinar that addresses preanalytical errors.
 - Presentation Slides (PDF)
 - Question & Answers (PDF)
- ▶ **Focus on Compliance Webinar Laboratory Safety: Think Outside the Cabinet**
Focus on Compliance (FOC) webinar that addresses safety in the laboratory. Learn how to improve compliance with safety requirements.
 - Presentation Slides (PDF)
 - Question & Answers (PDF)
 - Toolkit (ZIP)
- ▶ **2021 CAP Accreditation Checklist Updates: Changes that Matter**
Focus on Compliance (FOC) webinar that addresses 2021 checklist updates and changes.
 - Presentation Slides (PDF)
 - Question & Answers (PDF)
 - Toolkit (ZIP)
- ▶ **Building a Quality Management System (QMS) for Your Laboratory: Moving on Up to the QMS Side**
Focus on Compliance (FOC) webinar that addresses building a quality management system (QMS).
 - Presentation Slides (PDF)
 - Question & Answers (PDF)



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