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Common Regulatory Inspection Deficiencies –

How Do I Avoid Them and What Do I Do if I Receive One

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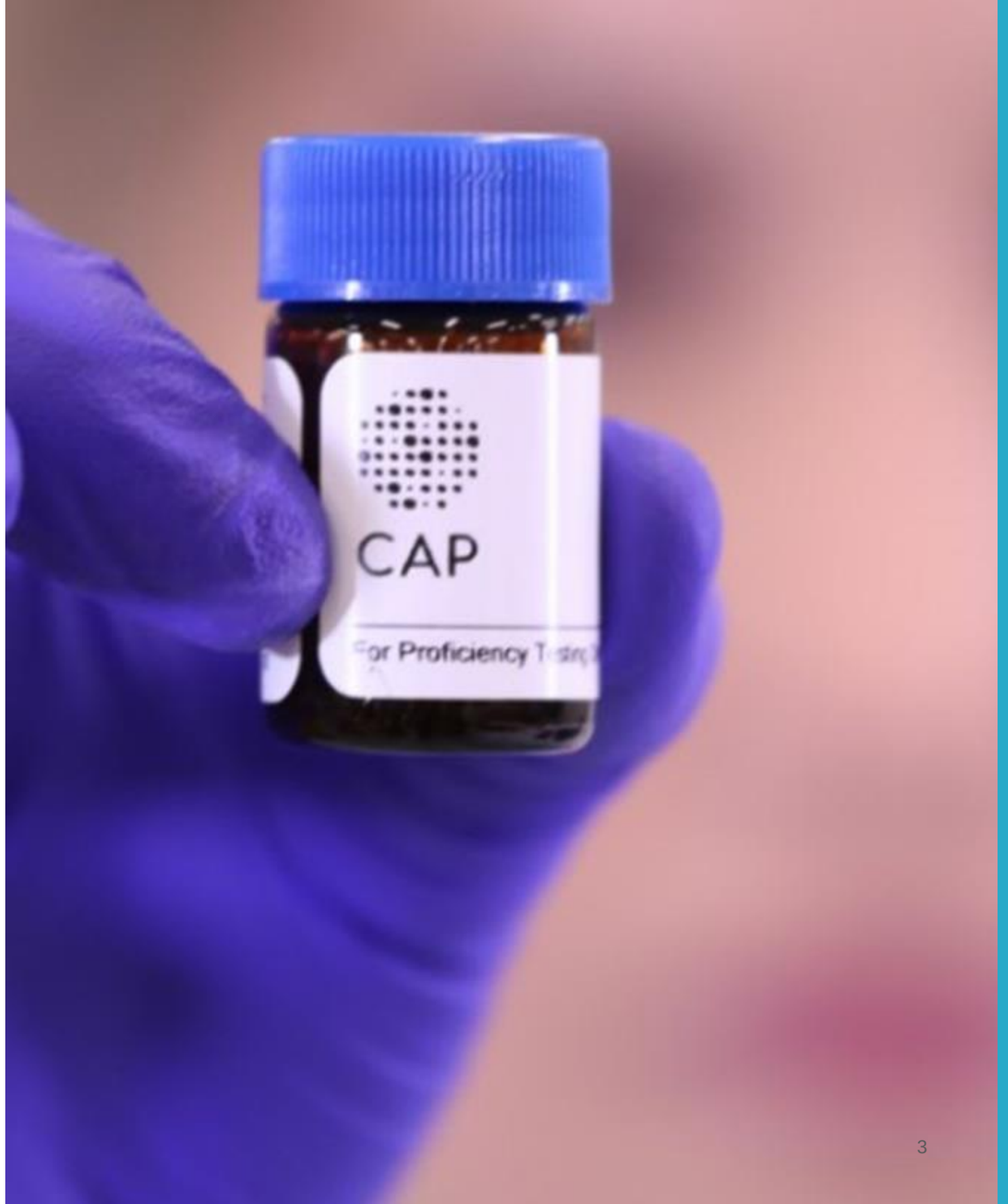
Objectives

- Q&As on most common issues in laboratories
- How to avoid deficiencies in these issue areas
- Resources Available



Proficiency Testing Evaluation

- ***Ongoing evaluation of proficiency testing (PT) and alternative assessment results with appropriate corrective action taken for each unacceptable result.***
  - **Each unacceptable PT or alternate assessment result (any result or sample not meeting defined acceptability criteria) 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
    - Correction of problems appropriate to the failure are performed in a timely manner.

PT Evaluation - continued

- **Reviewing PT and alternative assessments results over time can identify**
  - Persistent bias, trends, and shifts
  - Change in system and/or process
  - Systematic error
  - Evidence of corrective action
  - Training opportunities
  - Staff competencies

Common Deficiencies - PT 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 products

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PT 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

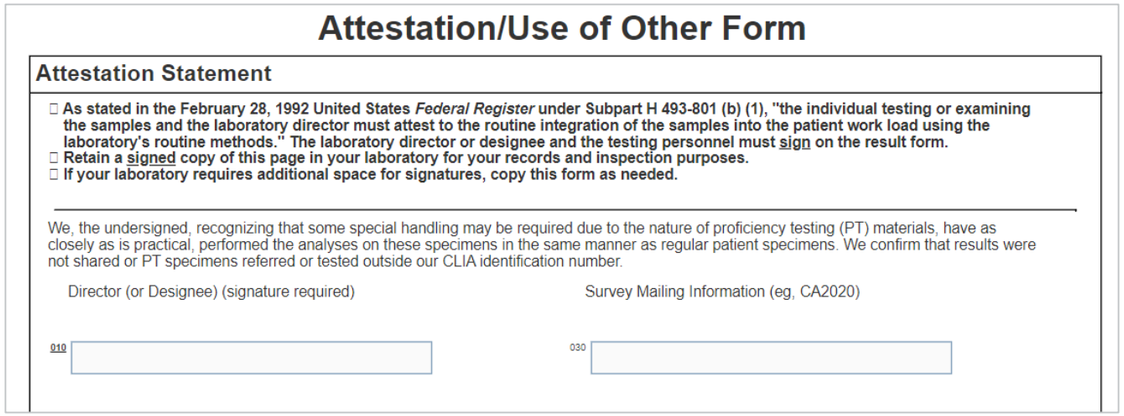
Evaluation of Possible Sources of Error

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

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.

PT Attestation Statement

- ***The proficiency testing attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.***
  - Physical signatures must be present.
    - PT results submitted electronically can have printed names but will require the physical signatures on the original attestation page.
    - Secure electronic signatures are acceptable if it is secured electronic signature



Attestation/Use of Other Form

Attestation Statement

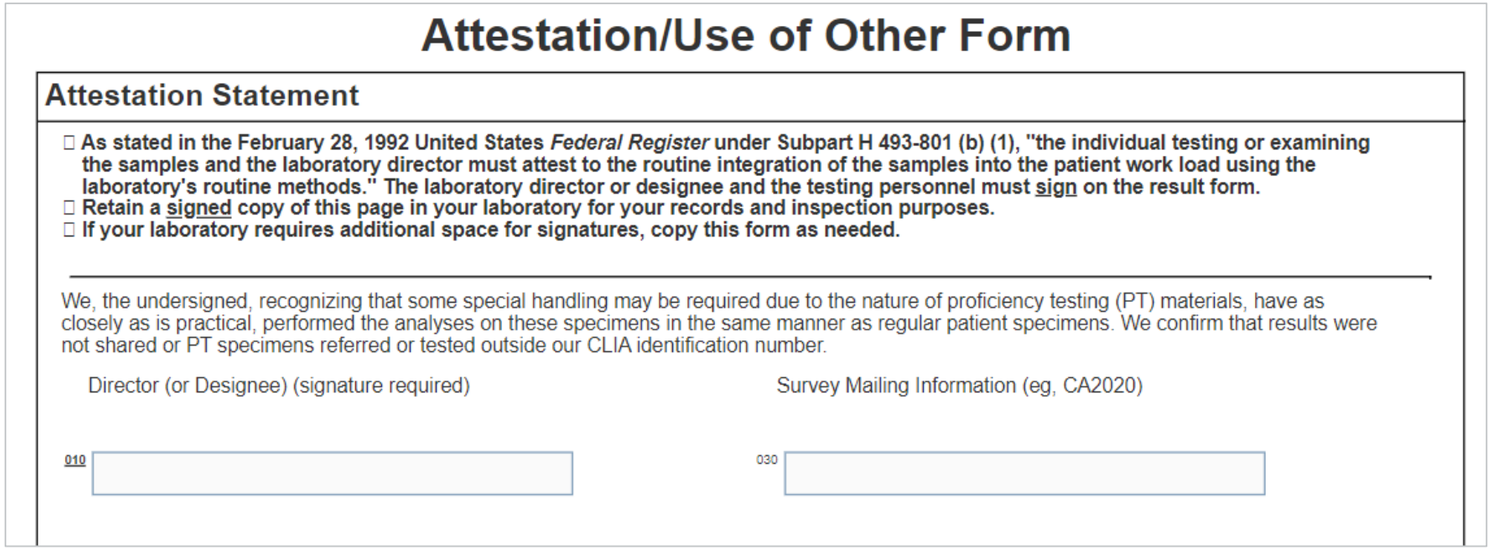
- **As stated in the February 28, 1992 United States *Federal Register* under Subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel must sign on the result form.**
- **Retain a signed copy of this page in your laboratory for your records and inspection purposes.**
- **If your laboratory requires additional space for signatures, copy this form as needed.**

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	030

Common Deficiencies - PT Attestation Statement

- **Signature missing**
- **Transfusion Medicine or other blood bank related PT signed by unqualified personnel**



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Survey Mailing Information (eg, CA2020)

030

Expiration Dates

- **All reagents (chemicals, stains, controls, media, antibodies, test strips, testing cartridges, etc.) are used within their indicated expiration date.**
  - **The laboratory must assign an expiration date if an expiration date is not provided by the manufacturer.**

Expiration Dates - continued

- **Procedure defining process for assigning expiration dates**
  - **Use manufacturer instructions to help build process for dates**
  - **Ensure staff understand this process and procedure**
  - **Assign to a safety audit to check for expired products**

Adverse Events

- **Several requirements around adverse events**
  - **FDA and manufacturer reporting requirements**
  - **Facility risk management reporting requirements**
  - **Adverse media attention must be reported to Accreditors**

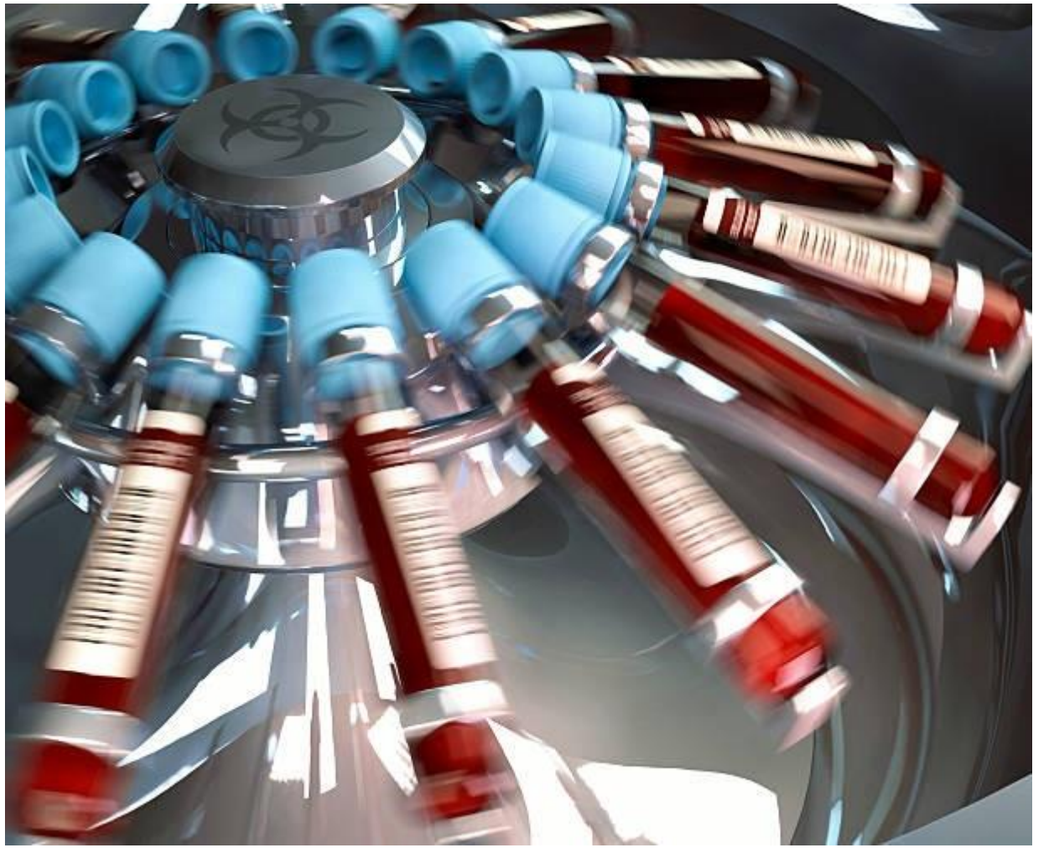
Adverse Events - continued

- Types of adverse events
  - Hematoma
  - Nausea
  - Fainting
  - Nerve damage
  - Seizure
  - Equipment failure
  - Arterial puncture complications

Laboratory Records

- **Storage of Records**
  - **Alarm checks in blood bank**
  - **Centrifuge maintenance reports**
  - **Eye wash checks**
  - **Pre-employment health screens**

Laboratory Records - continued



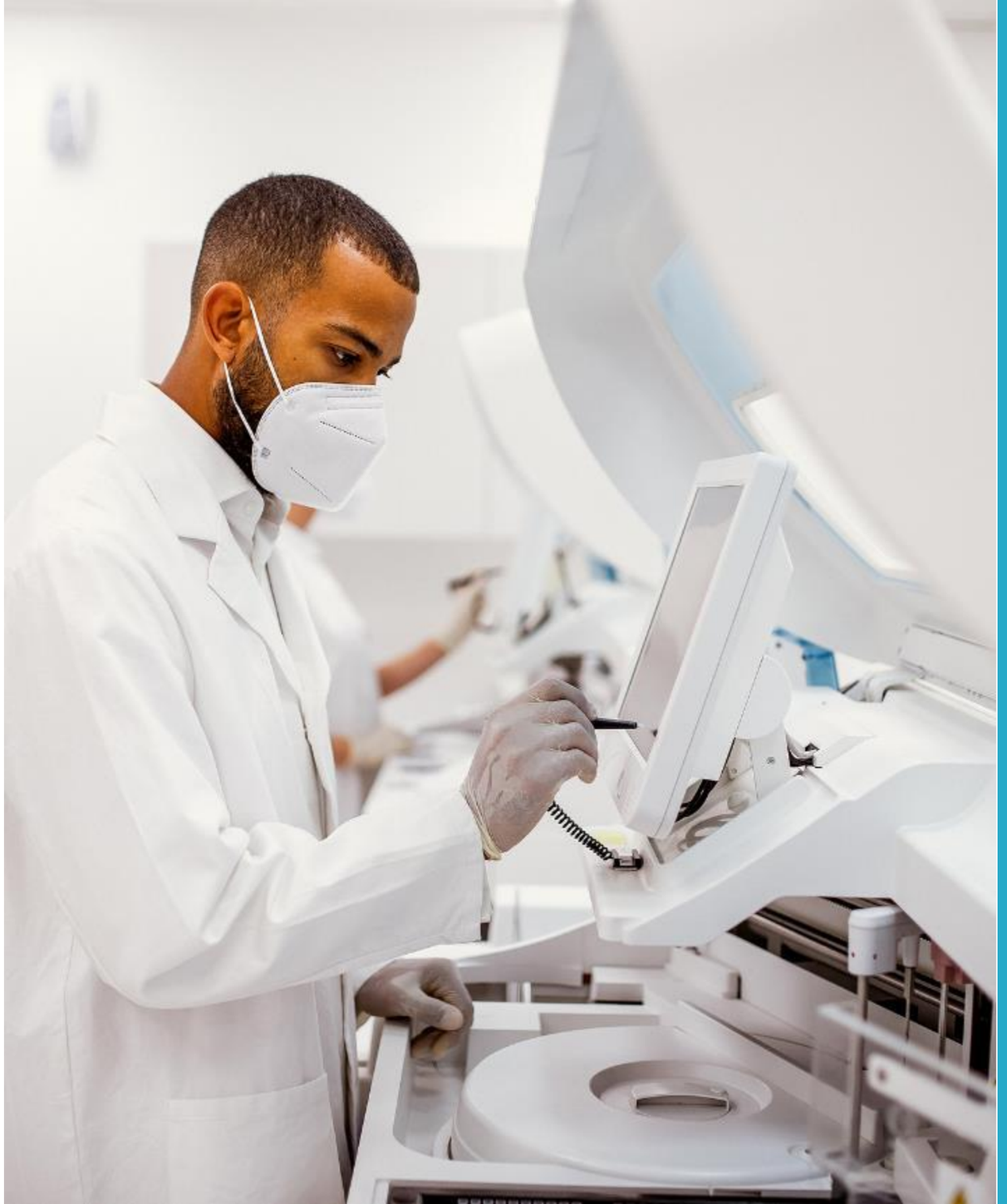
- **Storage of Records**
  - **Biomedical Engineering**
  - **Maintenance/Facilities**
  - **Human Resources**
  - **Employee Health**

GEN.55500 Competency Assessment

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

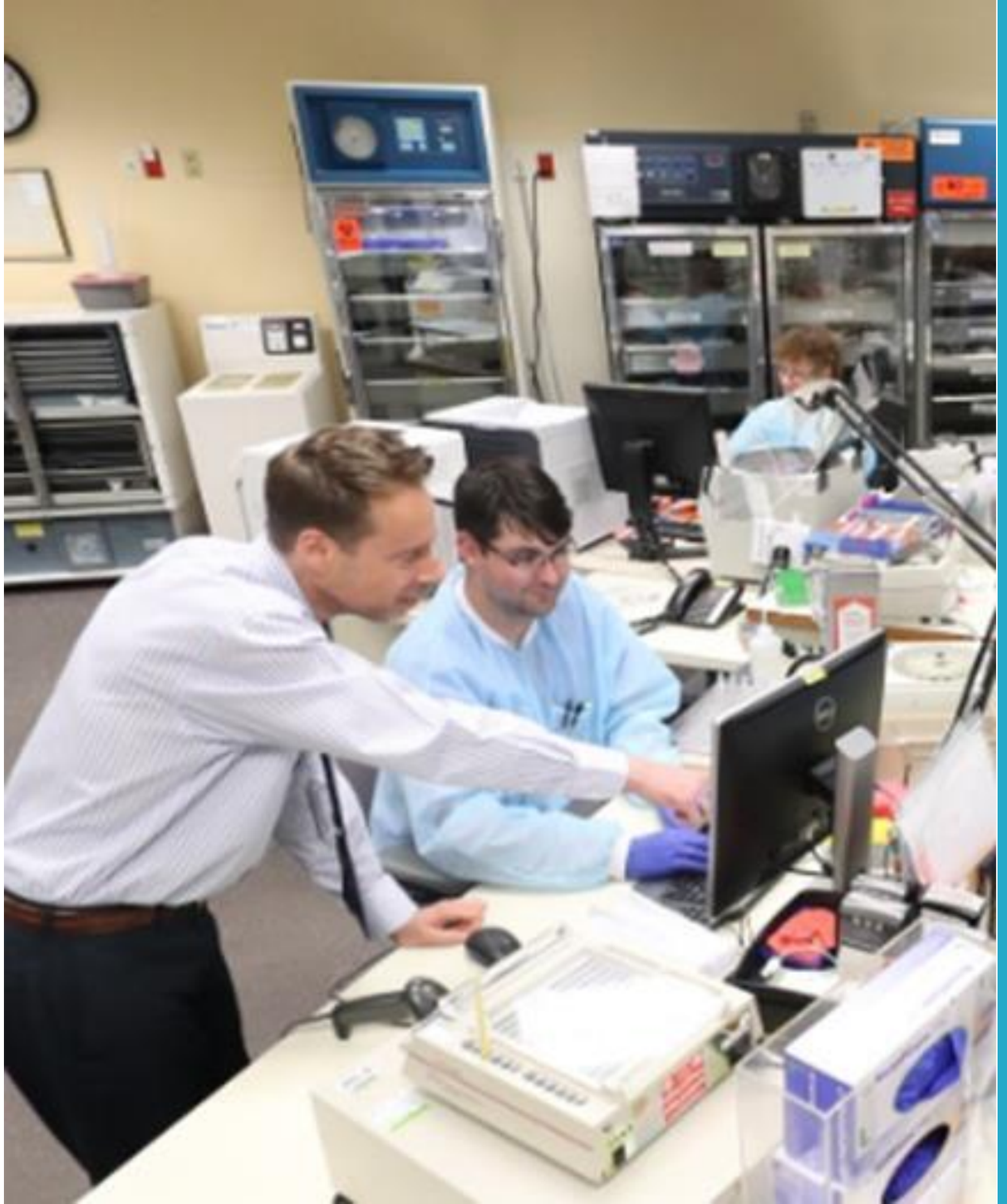
Common Deficiencies– Competency Assessments

- **Missing all 6 elements of competency at each location**
- **Personnel performing competencies do not qualify**



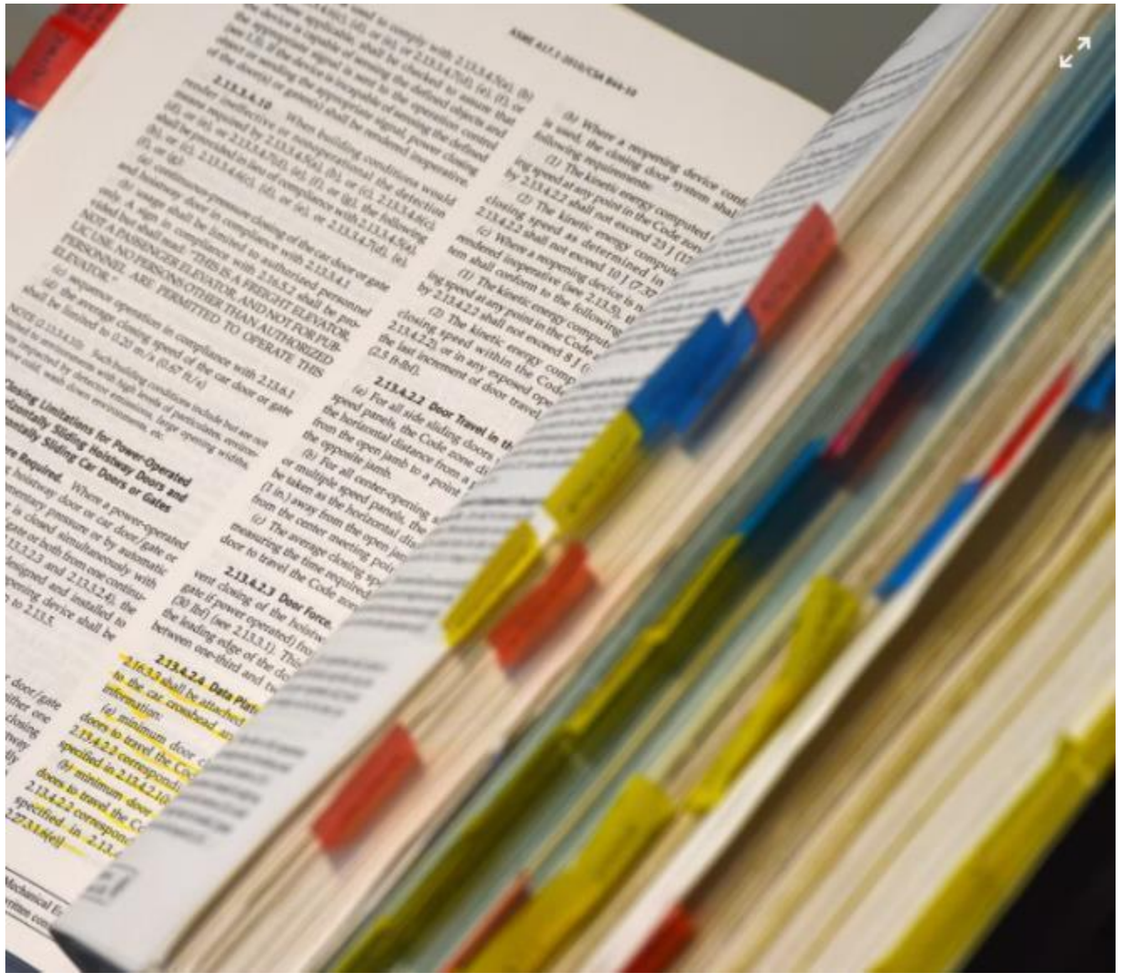
Carryover

- **Purpose**
  - Ensure automatic pipetting mechanisms do not introduce material into the next sample
- **How to perform**
  - Follow manufacturer instructions
  - Run a High, low/blank, high, low/blank



Strategies to Prevent Deficiencies

- Stay abreast of checklist changes
  - Download new checklists at least annually
- Conduct a thorough interim self-inspection…and correct any deficiencies
  - Utilize laboratory staff to conduct self inspections
  - New eyes have new perspectives



Strategies to Prevent Deficiencies - continued

- Focus on areas of the lab that are growing or changing
  - Use the checklists or standards when adding new testing
  - Standardize processes for validation/verification of new tests
- Make it easy for inspectors to establish compliance with checklist items
  - Organization is critical

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

Inspection Models

- In-Person (Traditional)
- In-Person with advance document review
- Virtual
- Virtual with advance document reveiw

What is a Virtual Inspection?

UTILIZES LIVE STREAMING TECHNOLOGY TO “PERFORM” THE INSPECTION

SET UP AN INSPECTION SCHEDULE

ORGANIZE ELECTRONIC MEETINGS FOR DOCUMENT SHARING AND PROCESS REVIEW

IT TAKES WORK!

Either of those “With Advance 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

Advanced Document Review Questionnaire

***Review Option**

Laboratory will upload relevant documents to be shared with the inspection team in advance of the inspection. Update

***Questionnaire**

***Do you use any individualized quality control (IQCP) plans?** Update

Yes

***In the last 2 years, have you implemented any new tests, instruments or methods in your laboratory?** Update

Yes

***Does the laboratory perform any Laboratory Developed Tests (LDT) or modified FDA cleared/approved tests?** Update

No

PROCEED TO ATTACH DOCUMENTS >>

Accreditation Resources

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

Application/Reapplication Process

Accreditation Manuals/ Retention Guidelines

Laboratory Webinars

Focus on Compliance

Laboratory Inspection Preparation Course

Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox

PT Compliance Notice (PTCN)

Checklist Resources

Accreditation Checklists

Checklist Requirement Q & A

Quality Management

IQCP Toolbox

External Resources

Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox

Everything you need to know about PT/EQA.

1.Escalation Process for PT/EQA Event Failures

Escalation process for PT unsatisfactory, unsuccessful, or repeat unsuccessful events.

Escalation Process for PT Failures of Regulated Analytes (PDF)

PTCN Exception Code List (PDF)

Refer to this document to review exception code definitions that appear on your PT Compliance Notice (PTCN)

2. PT/EQA Result Failure Investigation

Guidance documents to review PT failures.

PT Exception Investigation Worksheet (Word)

Review of Patient Results in Response to a PT Failure (PDF)

Reinstatement Process in Response to a Cease Testing Notification (PDF)

Guidance document for laboratories directed to cease patient testing for an analyte/subspecialty due to repeat unsuccessful proficiency testing (PT) performance, which includes performing a Root Cause Analysis.

4. PT/EQA Do's and Don'ts

Frequently asked questions related to PT compliance including preventing interlaboratory communication.

PT Compliance FAQs (PDF)

Preventing Interlaboratory Communication (PDF)

5. Alternative Performance Assessment

Alternative performance assessment toolbox and test list.

Alternative Performance Assessment Toolbox (PDF)

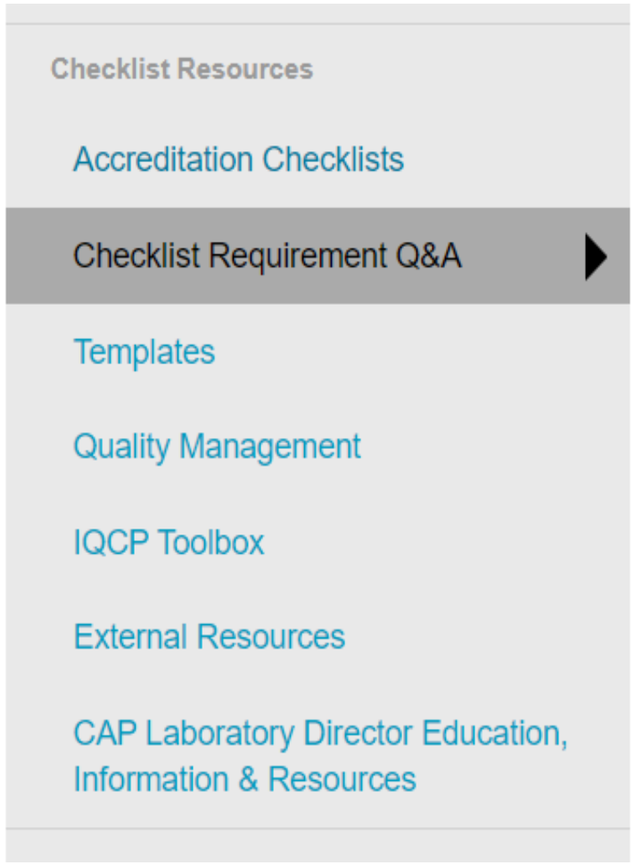
Alternative Performance Test List (Word)

Newly Expanded Accreditation Resources

- **Revised and expanded online resources make it easier to find the answers you seek.**
- **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.

Checklist Q&As



Chemistry and Toxicology

Cytogenetics

CYG.50000 (PDF)
Section Director/Technical Supervisor Qualifications; The cytogenetics laboratory has a qualified physician or doctoral scientist as section director/technical supervisor.

Cytopathology

Director Assessment

Checklist Q&As - continued

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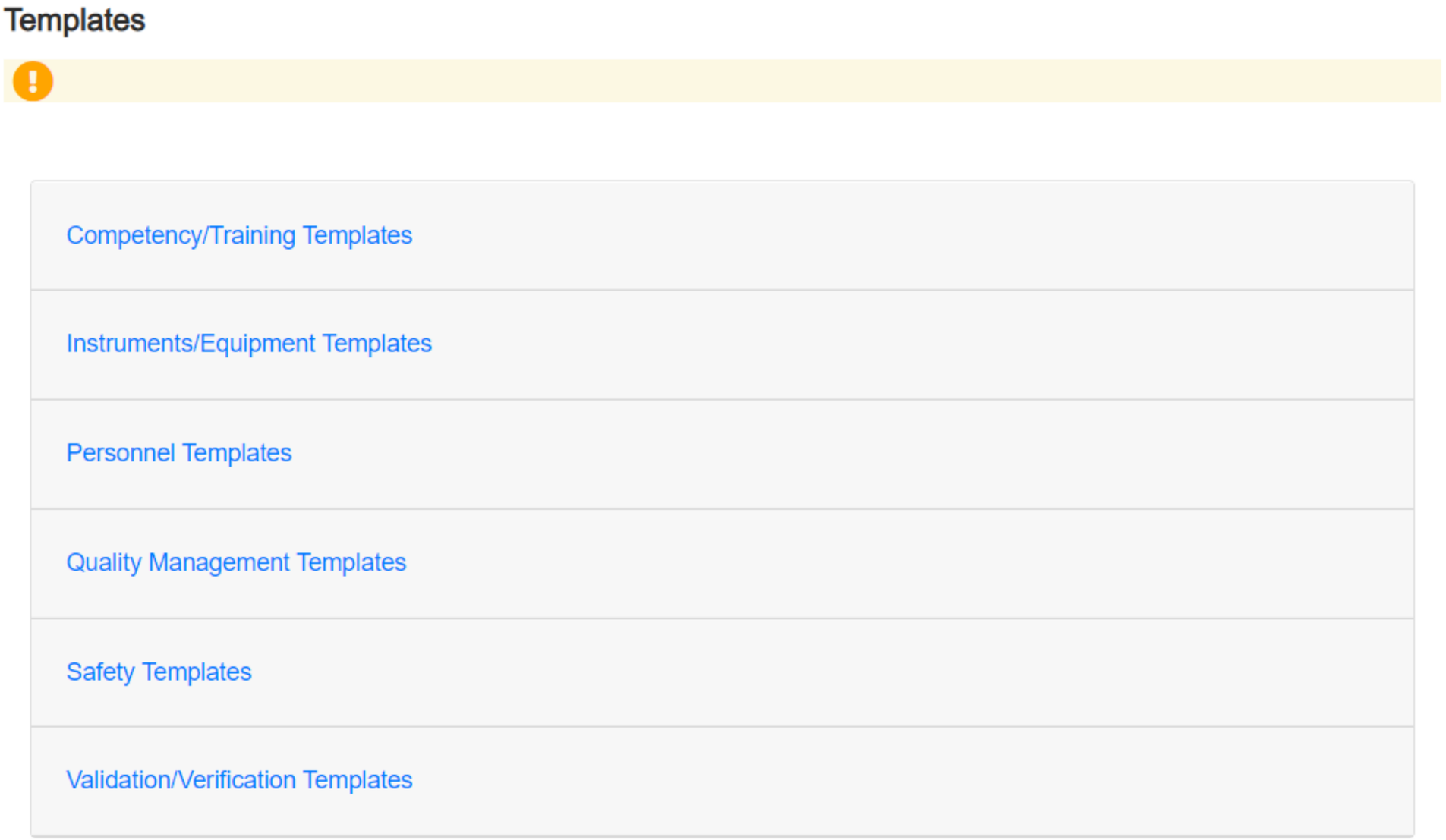
Checklist Requirement – DRA.11400	
Question -	**Answer -**
Does this mean the medical director must physically be present at the site and perform the assessment themselves or are they able to sign off on an assessment done by another employee?	The medical director must be physically present to assess the laboratory safety environment but would be able to have assistance in performing the assessment.

Templates



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											

Example Temperature Log

EXAMPLE: Refrigerator Temperature Log

Refrigerator name:	Month/Year:
Responsible supervisor:	**ACCEPTABLE RANGE: 2-8C**

<0																														
1																														
2																														
3																														
4																														
5																														
6																														
7																														
8																														
9																														
>10																														
Date	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Tech initials																														

Instructions:
1. Record current temperature by placing an X in the appropriate box.
2. Record your initials in the appropriate box.

Corrective Action: Document Below
1. Investigate the reason for the out of range temperature.
2. If deviation from the acceptable range persists, adjust the temperature dial, and check the temperature again in one hour.
3. **Take action if recorded *temperature* is *outside* the acceptable range. Contact supervisor and move items to another refrigerator.**

Date/Time	Temp.	Corrective Actions Taken	Repeat Temp.	Initials

Document further occurrences on the back.

Reviewed by and date: _____

“If it’s not documented, it didn’t happen.”

Every Regulatory Agency Inspector

Questions

- Please email accred@cap.org

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