Common Deficiencies Seen in Inspections

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Objectives

Identify	Analyze	Enhance
Identify the most common deficiencies	Analyze your laboratories practices and implement solutions to prevent deficiencies.	Enhance competency practices.

Why Inspections?

The Centers for Medicare and Medicaid Services (CMS) sets standards and regulates all clinical laboratory testing performed on patients in the U.S. through the CLIA.

CLIA, applies to approximately 260,000 laboratories and covers laboratory operations and the performance of laboratory-developed tests (LDT) and Food and Drug Administration (FDA)-cleared or approved tests marketed by in vitro diagnostic (IVD) manufacturers.

The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality, has the responsibility for implementing the CLIA program.

Before they can accept human samples for diagnostic testing, clinical laboratories must obtain a CLIA certificate through their state agency and be accredited by CMS or a CMS-deemed organization.

JUL.1.2018 // Source: Clinical Laboratory News

Who can certify laboratories under CLIA? Seven accreditation organizations

1. Commission on Office Laboratory Accreditation (COLA), www.cola.org
2. College of American Pathologists (CAP), www.cap.org
3. The Joint Commission (TJC), www.jointcommission.org
4. American Association of Blood Banks (AABB), www.aabb.org
5. American Association for Laboratory Accreditation (A2LA), www.a2la.org
6. American Osteopathic Association, www.osteopathic.org
7. American Society for Histocompatibility and Immunogenetics, (ASHI), www.ashi-hla.org

Where do Deficiencies fall:

- **Standard level** deficiencies describe a laboratory's failure to follow an individual requirement in CLIA regulations.
- **Condition** level deficiencies are more serious and may involve failure on multiple standards.
- CMS defines deficiencies as having **no immediate jeopardy** or **immediate jeopardy**, with the latter the most serious.
- Deficiencies in the immediate jeopardy category indicate that a laboratory's noncompliance already has or could lead to serious patient harm or death.

Examples of deficiencies:

- Phase I deficiencies require a written response indicating corrective action taken.
- Phase II deficiencies require a written response and supporting documentation demonstrating compliance. The response should explain the purpose of the documentation submitted.

Inspection readiness:

Leaders must involve the entire staff in all levels of inspection readiness—which should be part of everyday decision-making.

Decisions about staffing, equipment, reagents, controls, and other aspects of lab operations should consider the effect on a laboratory's inspection readiness.

Carrying out a self-inspection is a good place to begin to determine whether a laboratory is compliant with CLIA regulations.

Any deficiencies found—during either a mock or a real inspection—should be addressed as individual line items as well as assessed as a group to determine if the laboratory has a systemic problem.

CAP TOP 10 Deficiencies

RANK	CAP CHECKLIST NUMBER	TOTAL NUMBER OF CITATION (%)	DESCRIPTION
1	GEN.55500	1154 (29.4%)	Competency Assessment of Testing Personnel
2	COM.01200	963 (7.1%)	Activity Menu
3	COM.10000	760 (5.3%)	Procedure Manual
4	COM.04250	674 (4.8%)	Comparability of Instruments and Methods - Nonwaived Testing
5	COM.10100	606 (4.2%)	Procedure Manual Review
6	COM.30600	603 (4.3%)	Maintenance/Function Checks
7	COM.30300	602 (4.2%)	Reagent Labeling
8	COM.01700	600 (4.1%)	PT Evaluation
9	COM.04200	550 (4.0%)	Instrument/Equipment Record Review
10	COM.40000	545 (4.0%)	Method Validation and Verification Approval - Nonwaived Tests

COLA TOP 10 Deficiencies

Rank	COLA Checklist Number	Description
1	PER 5	For lack of complete competency assessments as required.
2	LDR 5	For the Lab Director not fulfilling the QC and QA responsibilities of the position.
3	PT 16	Lack of review of PT results by the Lab Director and supervisory staff.
4	LDR 4	For the Lab Director not fulfilling the PT responsibilities of the position
5	WAV 2	For not performing or documenting QC on waived testing as required by the manufacturer.
6	PER 4 C	For the Technical Consultant or Technical Supervisor not fulfilling the responsibilities of the position.
7	QC 16 -	For lack of review of cumulative QC data, either using graphing or statistical analysis, in order to assess continued accuracy and precision of quantitative methods.
8	PER 4 E	For the Testing Personnel not fulfilling the responsibilities of the position.
9	CA 2	For not performing calibration verification as required.
10	PT 4 -	For lack of twice annual split specimen analysis for unregulated analytes not enrolled in PT.

Joint Commission Top 10 Deficiencies

Rank	JCHO Checklist Number	% of Citation	Description
1	HR.01.06.01	48	Staff are competent to perform their responsibilities
2	QSA.02.08.01	32	The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.
3	DC.02.03.01	31	The laboratory report is complete and is in the patient's clinical record.
4	QSA.01.03.01	31	The laboratory has a process for handling and testing proficiency testing samples
5	LD.04.05.07	29	The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining laboratory performance
6	QSA.02.10.01	27	The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.
7	EC.02.04.03	27	The laboratory inspects, tests, and maintains laboratory equipment
8	QSA.02.03.01	27	The laboratory performs calibration verification
9	QSA.01.02.01	26	The laboratory maintains records of its participation in a proficiency testing program.
10	QSA.02.04.01	25	The laboratory develops an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.

Top Laboratory Deficiencies Across Accreditation Agencies

Problems with documenting personnel competency tops the list

Competency: TOP DEFICIENCY

- See one
- Do one
- Teach one!

Case study

- Inspector asks to see competency on your newest employee
- There is training, 6 months and annual competency
- You are cited for non-compliance
- What was incorrect?

Training versus competency

Employee was trained

However must be evaluated for all 6 elements of competency **prior to reporting out any results**

Define

Competency – The ability of personnel to apply their skill, knowledge and experience to perform their laboratory duties correctly.

Assessment – Is used to ensure that the laboratory personnel are fulfilling their duties as by federal regulation.

Centers for Medicare and Medicaid Services

Training vs. Competency

Training

- Occurs before patient testing begins
- Usually once unless employee fails successful demonstration of skill to trainer and retraining required
- Does not require use of six competency assessment elements

Competency

- Occurs after independent patient testing begins
- Does require use of six competency assessment elements for non-waived testing

Training and Competency Assessment

- **Documentation of Training does not satisfy the requirement for documented Competency Assessment**.

- Many make this mistake.
- Why :

  - misunderstanding the requirement

Training Checklist

TRAINING Leukocyte Alkaline Phosphatase (LAP)
NAME:_____
DATE:_____
TRAINER:_____
Training completed:_____ by _____
I understand the procedure and feel confident to perform the testing.
Sign_____Date_ _____

Training	Trainee	Trainer
Understands the intended use of the test.		
Overview of principle of procedure		
Specimen requirements: collection and storage		
PPE requirements		
Reagent preparation		
Pull pending log and worksheet		
Additional materials required		
Review of the SOP		
Quality control samples		
Preparation of blood smear		
Storage and stability of smears		
Drying the smear		
Fixing the smears		
Staining the smears		
Using the microscope		
Identifying the granules		
Scoring the samples		
Reference range		
Recording of results		
Interpretation of Results		
Reporting results in Cerner		

New York-Presbyterian Hospital / Columbia University Medical Center
DEPARTMENT OF CLINICAL LABORATORIES

ANNUAL COMPETENCY ASSESSMENT CHECKLIST

Employee Name: Test Employee **Dept: Laboratory** **Year:** **Policy: HR-9i**

Competency Assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by the department and federal regulation.

Method of assessment:

1) direct observation;
2) observation for compliance with safety protocols;
3) periodic review of work product for compliance with standard operating procedures and applicable workload limits;
4) monitoring the recording and reporting of test results;
5) direct observation of performance of instrument maintenance and function checks;
6) assessment of test performance through testing of previously analyzed specimens, internal blind or external proficiency testing samples;
7) assessment of problem solving skills.
8) assessment of delegated functions

Evaluate the competency of staff for all tasks for which he/she is responsible. Indicate evaluation for each task as: YES (competent) or NO (not competent). Areas that the employee is not responsible will be marked NA (not applicable). If the staff is not competent, a corrective or remedial action should be initiated and documented and filed with this document.

Roche Analyzer		1) Direct Observation	2) Safety Compliance	3) Compliance w/ SOP	4) Review test results	5) Instrument Maintenance	6) Unknown/PT Samples	7) Problem Solving	8) Delegated functions
[ ] Check If Task Is Not Applicable	Specimen requirements.	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Sample Handling and Stability	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
Assessed	Processing	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Measurement methodology	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
By:	Quality Control	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Reporting Results	[X] YES [ ] NO	[X] YES [ ] NO	[X] YES [ ] NO	[X] YES [ ] NA If YES, date of event: Accession #:	[X] YES [ ] NA	[ ] YES [ ] NA If YES, date of event _____ score: _____	[X] YES [ ] NO	
Date:	Reagent Handling and Storage	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Maintenance	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Delegated QC Review								[X] YES [ ] NA
	Delegated Staff Training								[X] YES [ ] NA
	Delegated Regulatory Tasks								[X] YES [ ] NA
	Delegated Scheduling								[X] YES [ ] NA
Radiometer ABL 800 Blood Gas Analyzer		1) Direct Observation	2) Safety Compliance	3) Compliance w/ SOP	4) Review test results	5) Instrument Maintenance	6) Unknown/PT Samples	7) Problem Solving	8) Delegated functions
	Specimen requirements.	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
[ ] Check If Task Is Not Applicable	Sample Handling and Stability	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
Assessed	Processing	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
	Measurement methodology	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
By: _____	Quality Control	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
	Reporting Results	[ ] YES [ ] NO		[ ] YES [ ] NO	[ ] YES [X] NA If YES, date of event: _____ Accession #: _____	[ ] YES [ ] NA	[ ] YES [ ] NA If YES, date of event _____ score: _____	[ ] YES [ ] NO	
Date: _____	Reagent Handling and Storage	[ ] YES [ ] NO	[ ] YES [ ] NO	[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
	Maintenance	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NO	
	Delegated QC Review								[X] YES [ ] NA
	Delegated Staff Training								[X] YES [ ] NA
	Delegated Regulatory Tasks								[X] YES [ ] NA
	Delegated Scheduling								[X] YES [ ] NA
Miscellaneous Tasks	**Task/Element**	1) Direct Observation	2) Safety Compliance	3) Compliance w/ SOP	4) Review test results	5) Instrument Maintenance	6) Unknown/PT Samples	7) Problem Solving	8) Delegated functions
Centrifuges	Operation	[X] YES [ ] NO	[X] YES [ ] NO	[X] YES [ ] NO	NA	[X] YES [ ] NA	NA	[X] YES [ ] NO	[X] YES [ ] NO
Pipettes	Operation	[X] YES [ ] NO	[X] YES [ ] NA	[X] YES [ ] NO	NA	[X] YES [ ] NA	NA	[X] YES [ ] NO	[X] YES [ ] NO

Atttestation and Signatures

"I have read the above competency assessment. I understand that by signing this statement, I agree that I have been trained in the areas noted in this assessment and I am approved to perform the tests/procedures independently. I also feel competent to perform this list of tests/procedures, and processes independently as indicated by the above assessment."

_____ _____
Employee Signature Date

_____ _____
Employee Signature / Date Supervisor Signature / Date

Requirements:

Direct observation of routine patient testing --

Monitoring the recording and reporting of test results --

Review of intermediate test results, records, and proficiency testing results --

Direct observation of instrument maintenance and function checks --

Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples --

Assessment of problem solving skills --

In God we trust, all others must provide data

- The easiest way to document problem solving is with a quiz
- It should cover the elements of specimen requirements, sample handling and stability, processing, methodology, QC and reporting results
- Case studies work very well

Suggestion:

- Create a file on each employee, in particular if they are assessed at different times of the year which is kept by them or in a central place.
- Anytime they perform a PT test a copy of results should be filed as well as any unknown samples they may run for correlation/studies
- For each test, they should file a test result they entered, which can be reviewed by the supervisor
- Any quiz or case study given should be placed in the file.
- It is a lot of work in the beginning, but much easier for the overall process
- Remember, you should evaluate competency for a specific methodology, so you don’t have to perform it for every single test, unless a test has very specific processes or interpretations

Frequency

At least semiannually during the first year the individual tests patient specimens

At least annually thereafter unless test methodology or instrumentation changes – then 6 months and annually

Prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation

Who can assess competency?

- Competency must be assessed by a supervisor (person must meet supervisor qualifications- make sure they are competency assessed as a supervisor!)
- It is no longer train the trainer
- Can another tech train people?
- Yes, as long as they are competent on that procedure- they can train
- They cannot assess competency

Who is required to have competency assessed??

- All individuals fulfilling the duties as outlined in Subpart M of CLIA regulations: (Anyone who performs testing on patient specimens)
- Clinical Consultant
- Technical Consultant
- Technical Supervisor
- General Supervisor
- Testing Personnel
- BUT ALSO:
- Managers
- Quality Managers
- Directors
- Lab attendants
- IT personnel

Frequent Warning Letter Citations

LABORATORY TESTING AND CONTROLS – 40 %

VALIDATION AND QUALIFICATION – 20 %

INADEQUATE INVESTIGATIONS – 20 %

QUALITY UNIT APPROVAL AND OVERSIGHT - 10%

DOCUMENTATION AND RECORDKEEPING - 10 %

PERSONNEL QUALIFICATIONS

- Lack of documentation in employee files is a major reason why labs are cited for deficiencies in this category.
- Most of us are good at keeping personnel files, but how many of us excel at maintaining them? Missing transcripts, diplomas, or the inability to produce a license for an employee are all considered deficiencies.

- One of the easiest ways to prevent this from happening is to first create a stepwise procedure for onboarding new employees that includes a checklist of items each of them will need to provide.
- Following this, create some sort of “bird's eye view” document or utilize automated software that allows you to see all of your employees in one spot. This gives you the ability to determine if you’re in compliance with only one glance.

Case study

- An inspection was being conducted using a tracer audit
- Upon reviewing results performed by a long-term employee, their personnel file was being asked to be reviewed
- It was missing their qualifications and training documentation
- How do you prevent this?

Employee File

Documentation of Education (diploma or transcript)
Documentation of experience

State license if required

CLIA required roles qualifications

Orientation

Training; initial competency

If a new employee, 6 month competency assessment for nonwaived testing Nonwaived annual competency

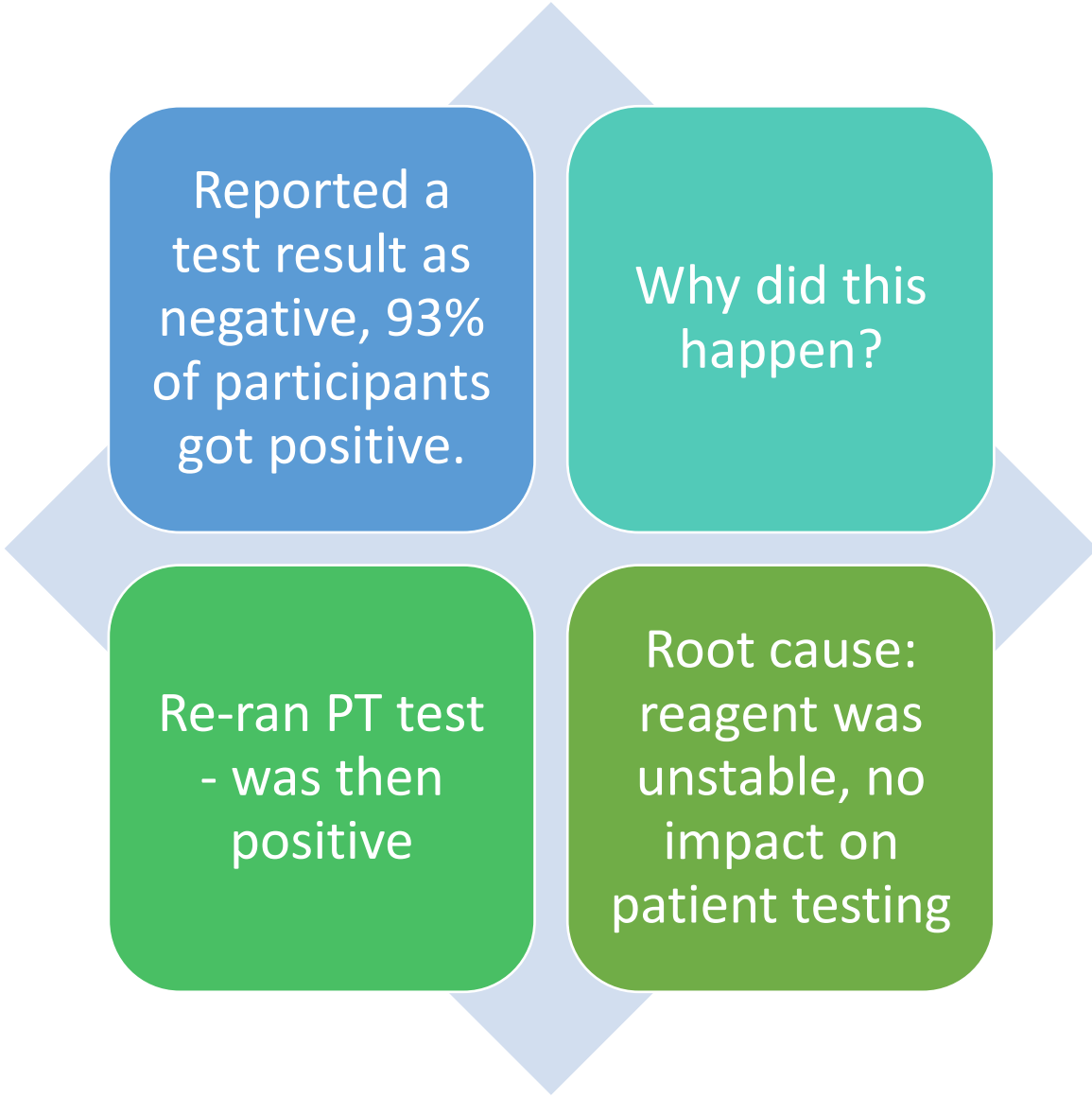
Documentation of Education (diploma or transcript)

Documentation of experience

PROFICIENCY TESTING

Records of distribution, submission, review, and responses are all things an inspector reviews	• **SUGGESTION**: Pay special attention to any surveys your lab may not have passed within the last **two** years as well as corrective action and all supporting documentation. Make sure all PT are signed off by the director.
Documentation showing that there is a fair and equal distribution of proficiency testing amongst personnel	• **SUGGESTION:** At the start of every new year make a chart with the shipping schedule for testing and rotate your personnel
Keep all survey results organized and sorted so that they may be easily retrieved if necessary.	• **SUGGESTION:** When performing PT testing, keep copies of QC and calibration for that day, as well as results of patient testing for that day, extremely helpful if you need to conduct an RCA.

Example: Failure of a proficiency test:



Is this a correct RCA?

- Re-running a PT sample is not a root cause analysis- it is part of an RCA-
- You need to investigate and drill down as much as you can’
- Review the QC, Calibration Curve
- What impact did this error have on any patient samples run during that day?
- Was it statistically significant, but not clinically significant?
- Did you ask Why, Why, Why, Why, Why?

Common traps of an RCA

- **Three common mistakes made when approaching Problem Solving (based on assumptions):**

1) **Assuming you know what the problem is - without studying it or asking enough questions**
2) **Assuming you know how to fix the problem – without knowing what the problem really is**
3) **Assuming you know what the true cause of the problem is – without confirming it**

Five identifiable steps

- Identify the problem
- Collect data
- Identify possible causal factors- ask why, why, why, why, and why
- Identify the root cause
- Recommend and implement solutions

Root Cause Problem Solving: 5 whys?

PROBLEM STATEMENT:
The Washington Monument is deteriorating

Why is the monument deteriorating?
Because harsh chemicals are used to clean the monument

Direct Cause

Why are harsh chemicals used?
They are needed to clean the bird droppings. There are lots of birds.

WHY?

Why are there a lot of birds?
Because the birds eat the spiders. There are a lot of spiders.

WHY?

Why are there a lot of spiders?
Because the spiders eat the gnats. There are a lot of gnats.

WHY?

Why are there a lot of gnats?
Because the lights attract the gnats at dusk.

WHY?

SOLUTION: Turn the lights on 30 min later

Record Keeping

- **If it is not recorded it NEVER happened.**
- **Make a monthly chart as to what has to be reviewed/signed off each month.**
- **Thorough record keeping essential.**
  - **Creates an audit trail necessary to investigate errors.**
- **Original data CANNOT be obliterated, single line.**
- **Date and initial of changes required.**
- **NO white out or pencil is ever allowed.**
- **Document control essential as it specifies and describes the media to be used, types of documents to keep and length of time.**

DOCUMENT CONTROL

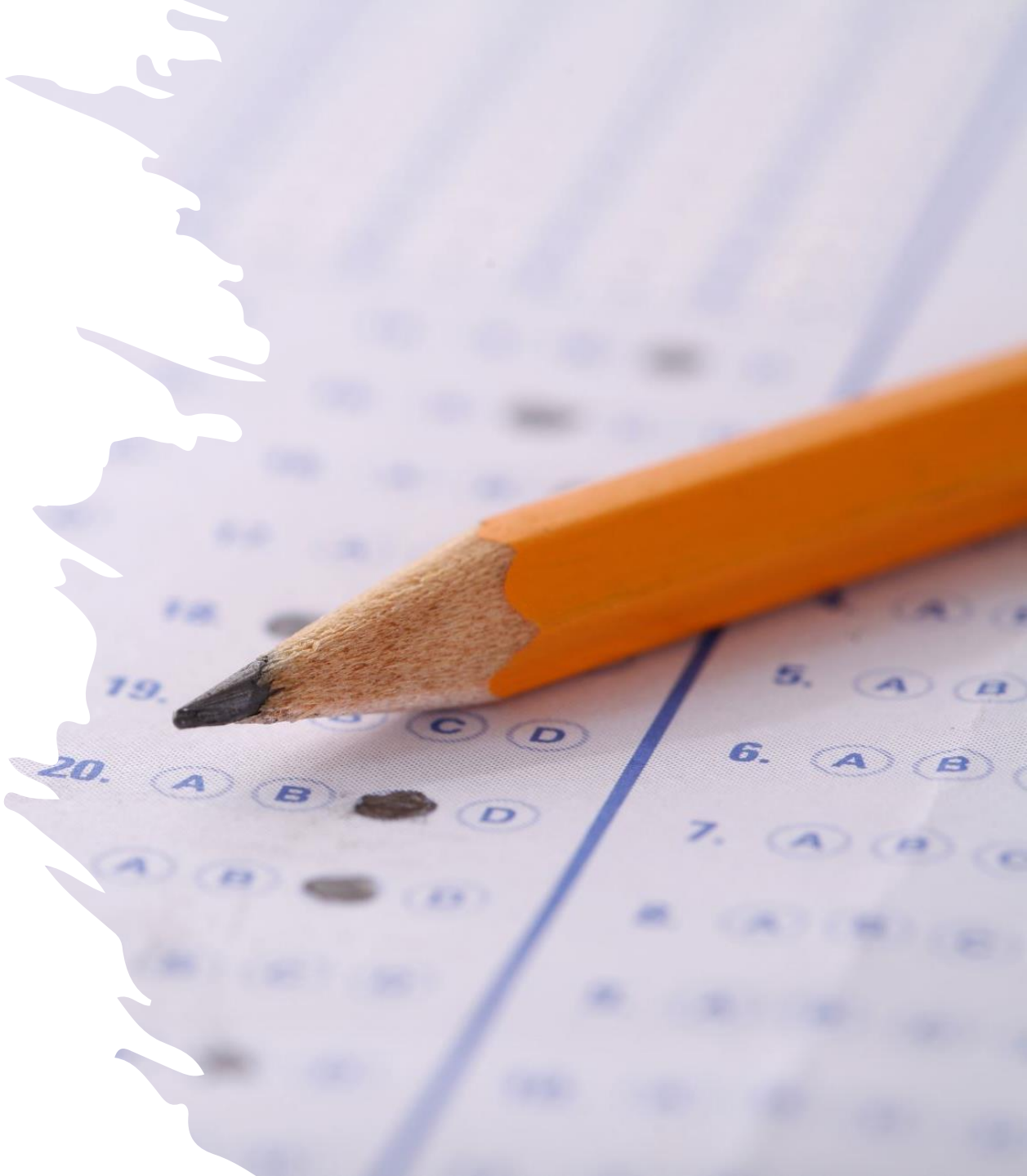
- Citations issued here include things like the lack of procedure review documentation or incomplete checklists for temperatures, maintenance, or reagents.
- Inventory control- standardize this document
- To avoid these problems, use auditing checklists and procedures part of your monthly QC review process.
- Creating a procedure review schedule (reviewing a few each month) goes a long way to ensuring each policy is reviewed and signed bi-annually without having to do them all at once.
- Don’t forget quality policies as well.

Procedures

- Standard operating procedures
- Make sure your procedures match what you are doing! Conducting an audit will ensure that everyone is on the same page.
- If you use a bench excerpt it MUST be included in your procedure
- Reference Ranges: make sure they match from the procedure, computer and downstream systems, on-line manual, and patient reports.
- Name and address of the performing laboratory on all reports

Goal of Laboratory Documents

- Bore the inspector!
- If everything is standardized, all employee files, competency assessment, procedures, and documentation it demonstrates that the laboratory has good processes in place.



CALIBRATION VERIFICATIONS

- Incomplete documentation of semi-annual calibration verifications and method correlations or incorrect methodologies being used in the “cal-ver” process top the citations in this category
- Creating a binder for each instrument can be helpful in organizing any calibration verification and/or correlation material.
- Set reminders in your email calendar for when these are next due so that they don’t get forgotten. It also helps to work with the manufacturer and network within the industry to determine appropriate testing methodologies.

Method correlations:

- Performed on analyzers every 6 months
- Have a procedure that states how many samples you will test
- As well as the statistics and acceptable limits to demonstrate the analyzers correlate.
- Remember to cover the reportable range
- Use an annual calendar that lists what tests need to be run and when they need to be run.
- Remember, these can also be used as unknowns for competency assessment.

Lot to lot validation

- Try to sequester as many reagents as possible to limit the number of lot to lot validations that you perform.
- Have a procedure that states how many samples you run, as well as what is considered acceptable.
- Use your inventory control documentation as a guide to when new lots are received and as well as when the lot to lot is performed.
- You should also perform shipment to shipment correlation.
- Have a form to make this easier, all technologists should be responsible for this

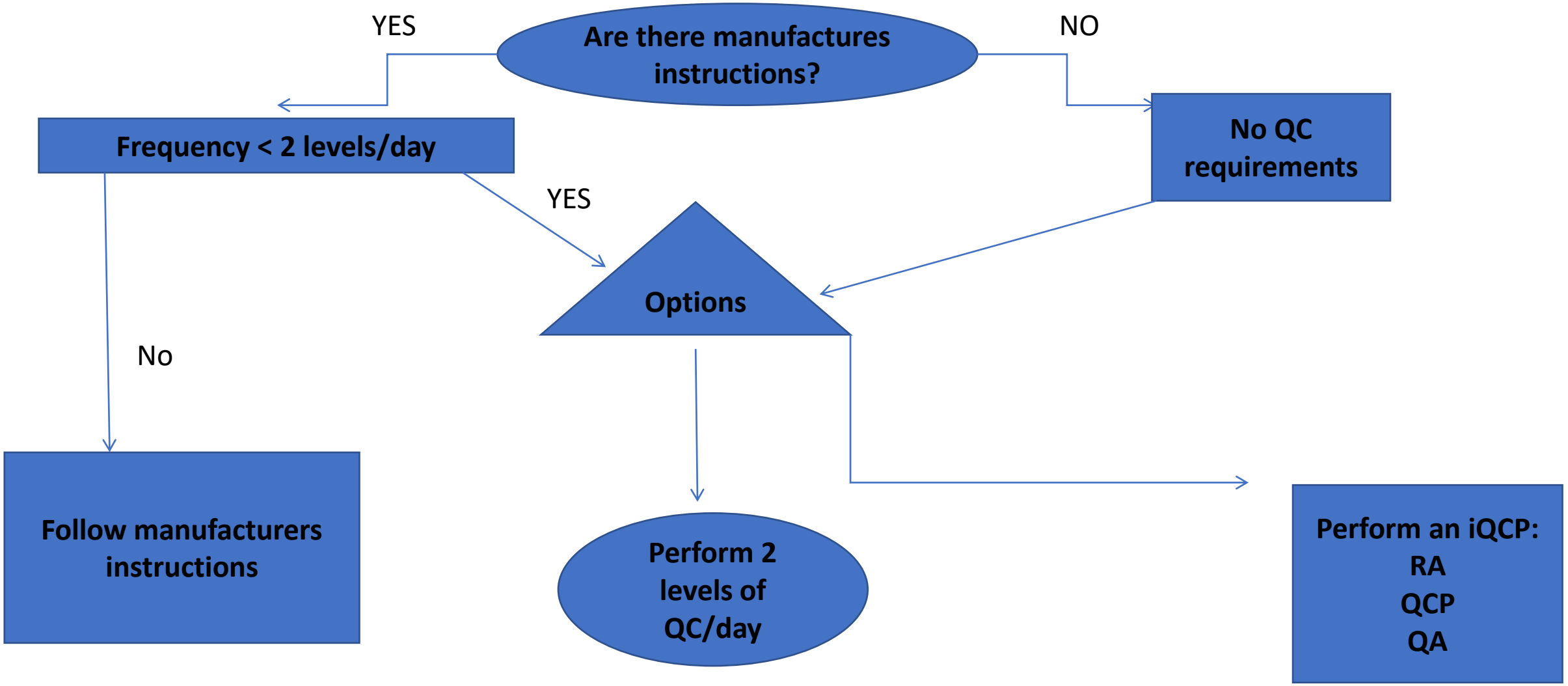
Individualized Quality Control Plan (iQCP)

- What do I need this for?
- A Laboratory Developed Test
- Many POC tests- or run 2 levels of controls daily, but each unit is considered an individual test
- Tests that do not have a kit including QC from the manufacturer
- You need to demonstrate stability of the assay, storage conditions, testing conditions, how you will conduct proficiency testing

Quality Control

- Make sure that QC is reviewed and signed off by a supervisor as well as the director.
- Have a strong QC procedure that includes what rules you will use and it reflects what you are doing in the laboratory
- Included in the QC procedure is how you handle a change in statistics; when do you adjust the reference range? Do you investigate if it is a true shift, or random error? What QC is accepted when you are establishing a reference interval?
- Do you run QC 20 times, or do you use the manufacturer's range and evaluate after 30 days? Must be stated in the QC procedure.

Considerations for iQCP



Inspection readiness

What to do, how to do it!

System tracer audit:

- It is important to remember that tracers can be used to follow an entire process or system, and your goal should be to determine if there are any gaps or potential missteps.
- Focus on issues of particular concern for laboratories and process: e.g. patient identification, quality control, and communication of critical test results. May use when looking at QI failures
- Tracer of past testing activity, particularly if a pattern of near-miss reports or quality control problems with a particular test have been observed. When failing a proficiency test.

Joint Commission on Accreditation of Health Care Organizations The Joint Commission: The Source, September 2010, Volume 8, Issue 9

What do you need:

- Pre-analytical review of:

- Temperature logs
- Sample receipt logs
- Sample rejection logs
- Policies and procedures for:
  • Sample or patient identification verification
- Sample collection, handling, and transportation
- Sample receipt, preparation, and storage
- Sample acceptance and rejection criteria

Analytic

- Review of:
- Instrument runs
- Reagent and standard logs
  Instrument/equipment maintenance logs
  Proficiency tests
- Failed runs

- Policies and procedures for
- Testing and examinations
  Results review and follow-up
- Critical values
- Method verification and validation
- Quality control requirements; type, frequency, and corrective action for out of range QC
- Calibration and calibration verification

Post Analytical

- Non-conforming events/corrective actions
- Report completeness
- Turn-around-time
- Corrected reports

- Policies and procedures for:
- • Result release
- • Report preparation and delivery
- • Sample archiving and management
- • Sample storage and disposal requirements
- • Demographic and results corrections (corrected reports)

Other documents:

- LDT: method validation
- Procedure
- Day of testing:
- Technologist: Training, initial competency, 6 months and year
- Quality control
- Standard curve
- Lot to lot validation
- Reagents
- Patient result report
- Chart report
- Check reference range:
- Procedure, result report, on line manual
- Proficiency testing
- IQCP

Checklists to use:

Laboratory Controls	Yes	No	NA	Observations/Recommendations
Are there an assay validation, re-validation and limited validation process outlined in a SOP?				
Is there a written procedure for repeat testing or invalidating lab data? Is there a repeat decision tree?				
How are results that fail specifications investigated or non-conformances investigated?				
Are there validated methods and acceptance criteria for each test method?				
Is there a SOP for significant figures?				
Is there a SOP that outlines good documentation practices?				

General Audit: Quick Hit Audit

				QUICK HIT CHECKLIST		
Department:						
Task		Test	Comment	Action	Sign	Date
Expired reagents:						
Storage of supplies (18")						
Reagent labeling; expiration						
Temperature & Maintenance logs						
Inventory control logs						
Lot to lot validation						
Centrifuge calibration vs protocol						
Calibration of centrifuge timers						
Reference range verification:						
documented in SOP						
posted in LIS						
on-line manual						
6 month correlations						

Linearity versus reportable range					
Proficiency test: write up					
Signed; educational challenge					
educational challenge					
Personnel file new employee					
Initial training; initial competency					
6 months					
1 year					
License/Diploma					
CE credits					
Resume					
Hire date					
access to job description					

	NYH Lab Quality System Essential (QSE)	Observed	Not Observed	Comments	Evidence of Compliance from Prior Findings?
5.6	Timely reporting of routine and critical values				
a.)	Does the laboratory routinely monitor the turn around time for defined procedures?				
b.)	If applicable, does the laboratory routinely monitor conformance to benchmarks for reporting of critical value reporting?				
c.)	If applicable, does the laboratory routinely monitor conformance to benchmarks for reporting of life altering values?				
d.)	As applicable, ask to see an example of critical value documentation in a patient report. Are the following elements documented: the name of the care provider receiving the result(s); the time and date of the communication; and the identification of the testing person who called?				
5.7.2	Results Review Program				
a.)	Are results reviewed by the appropriate personnel prior to being released?				

Typical Checklist for Equipment

#	Checks	Observations Y / N / NA	Comments
1	Is there a system to have a unique code for each piece of equipment		
2	Are the equipment placed in a environment as per its need and is there a status log available ?		
3	Are there SOPs which define the calibration and maintenance of the equipment ?		
4	Are calibration and maintenance schedules adhered?		
5	Is there are a check on equipment suitability after a modification? Do such modifications go through a change control process? Is there a mechanism to capture history of the equipment		
6	Is there a system to indicate defective equipment ?		

Template Audit Report

Audit Number :

Date(s) of audit :

Scope of Audit :

Executive Summary :

Lead Auditor :

(Sign / Date)

Department :

Auditors :

Type of Audit :

	Non-conformance	Classification	Agreed Corrective and Preventive Action	Responsibility / Date	Status Open / Closed

Head Quality (Sign/Date) :

How do you answer/investigate a deficiency?

- Deficiency: controls from a kit were placed in an independent jar, not labeled with an expiration date
- Noticed that our peroxide, and alcohol did not have expiration dates
- Phase II deficiency; needed to be answered
  - What measures would be put in place to prevent this from happening
  - Reagents were always being checked, was this just an outlier?
- Visually, reagents were being checked, occasionally we would find an out of date reagent
- Used a red dot to designate almost out of date.
- Needed to investigate; conduct a purposeful audit

Visual inspection

- Reagents were always within their expiration, labeled correctly and stored correctly.
- After the citation, a source document verification was performed for all procedures and reagents:
- What was being done?
- What was in our procedure?
- What was in the manufacturers' insert?

What was found?

- What was in the manufacturers' insert?

  GOLD STANDARD

- What was in our procedure?
- Sometimes was a little different; usually perform an annual alignment comparing to the package insert in case anything has changed
- What was being done?
- Reagents were being reconstituted and kept for longer than stated by the manufacturer-

Result of Audit

Updated reagent procedure to include all reagents and source document alignment

Posted and laminated at each station the correct reagent handling, storing etc

Monthly audited all reagents, expiration and actions

All technologists were re-trained, documented and reminded of the ramifications of not following SOP’s

Conclusion

- Keeping up with regulations is overwhelming
- Staying inspection ready is part of a quality system
- Starting is the hardest part, but engaging everyone in the process is important
- Having a good quality management system in place can help keep laboratories on track
- Understanding how to implement processes to find, correct and prevent errors will result in improved patient outcomes.