Clinical Laboratory Evaluation Program
Part Three-Discussion and Case Studies

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Case #1- Establishment of System Specifications and the Role of the Laboratory Director
Case #1- Establishment of System Specifications and the Director’s Role

Background

A small independent laboratory in application for a permit was cited during its initial on-site survey for a deficiency of Standard QA 10 (VALSSP5) for failure to adequately validate its analytic systems. The laboratory director is a full-time pathologist at a nearby hospital; a consultant conducted all the validation studies.
Case #1- Establishment of System Specifications and the Director’s Role

Standard Cited:

Validation Sustaining Standard of Practice 5 (Validation SS5): Performance Specifications

Method validation shall be performed before a test method is used to report results; and, for methods cleared or approved by the FDA as safe and effective for in vitro diagnostic use and used unmodified, (i.e., in a manner and for indications so approved), the laboratory shall:

verify performance specifications for accuracy, precision, reportable range of test results established by the manufacturer and verify that the manufacturer’s reference interval is appropriate for the laboratory’s population.
The laboratory has not evaluated the validation data to show concordance/discordance. Method validation for the following analytes was unacceptable: sodium, potassium, chloride, calcium, total protein, urine microalbumin, folate, free T4, total iron.
Laboratory Response:

Correlations were reviewed using raw data rather than statistical analysis. Statistical analysis has now been performed.

….The laboratory submitted validation data as part of its plan of correction.
Case #1- Establishment of System Specifications and the Director’s Role

Exhibit 1: Validation Data Results

![Graph showing comparison of methods for chloride measurement]
Case #1- Establishment of System Specifications and the Director’s Role

Exhibit 2: Validation Data - Analysis

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**Regression Analysis**

<table>
<thead>
<tr>
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<th>Deming</th>
<th>Regular</th>
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<tbody>
<tr>
<td>Slope</td>
<td>0.642 (0.463 to 0.820)</td>
<td>0.526 (0.352 to 0.700)</td>
</tr>
<tr>
<td>Intercept</td>
<td>35.3 (16.4 to 54.2)</td>
<td>47.6 (29.2 to 66.0)</td>
</tr>
<tr>
<td>Std Err Est</td>
<td>2.9</td>
<td>2.8</td>
</tr>
</tbody>
</table>

95% Confidence Intervals are shown in parentheses.

**Supporting Statistics**

- Corr Coef (R): 0.7305
- Bias: -2.5
- X Mean ± SD: 105.5 ± 5.7
- Y Mean ± SD: 103.0 ± 4.1
- Std Dev Diffs: 3.9

- SubRange Bounds: None
- Points (Plotted/Total): 35/35
- Outliers: Not Tested
- Scatter Plot Bounds: None

- Slope & Intercept
  - OK

**Experiment Description**

<table>
<thead>
<tr>
<th></th>
<th>X Method</th>
<th>Y Method</th>
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<tbody>
<tr>
<td>Expt Date</td>
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<tr>
<td>Rep SD</td>
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<td>1</td>
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<td>mmol/L</td>
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<tr>
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<tr>
<td>Comment</td>
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</table>

Accepted by: ____________________________  Date: ____________

Signature
Case #1- Establishment of System Specifications and the Director’s Role

Observations

Validation results prepared by the consultant were unacceptable, yet the data analysis was signed by the laboratory director.

...A conference call was scheduled with the laboratory director and the consultant who prepared the validation data analysis, to better understand their respective roles in laboratory operations.
Case #1- Establishment of System Specifications and the Director’s Role

Dialogue

The director was asked to explain the meaning of each of the various graphs and results; to discuss what each represented in terms of a statistical analysis of the data; and to provide the laboratory’s criteria for acceptability.

....The laboratory director admitted he did not understand any of the data presented, the laboratory did not have any criteria for method performance. “The consultant takes care of all this”, he responded.
Dialogue

The consultant was asked the same questions… to explain the meaning of each of the various graphs and results; to discuss what each represented in terms of a statistical analysis of the data; and to provide the laboratory’s criteria for acceptability.

....The consultant admitted she could not answer these questions; her role is limited to preparing the data for the director’s review and it is her expectation that he interprets the data.
Case #1- Establishment of System Specifications and the Director’s Role

Dialogue

The director was then asked what would be the potential impact to patients, if tests are run on systems that are not validated properly.

….The laboratory director said he thought it would be a good idea to calculate how far the system is off, and to add that value to each patient’s result to compensate for the system error.

The consultant groaned…..
Case #1- Establishment of System Specifications and the Director’s Role

The Message

Setting laboratory specifications for system performance (as outlined in the Quality Management System Standards) is a critical function, and cannot be delegated.

...An interview with the laboratory director will be a required element of the survey process, to assess whether he or she is not actively involved in setting specifications for laboratory performance. The director can be cited for failing to discharge his or her responsibilities.
Case #1- Establishment of System Specifications and the Director’s Role

Prologue

• The laboratory director obtained training in the interpretation of statistical techniques for method validation and in establishing specifications for system performance

• The laboratory was required to conduct new validation studies and submit a plan detailing their criteria for acceptable system performance
Case #1- Establishment of System Specifications and the Director’s Role

Questions for Discussion

▪ To what extent do consultants have a role in laboratory operations?

▪ What are the responsibilities that a laboratory director can delegate? Which responsibilities cannot be delegated?

▪ What other measures can be used to assess the extent to which a laboratory director is effective and involved in laboratory operations?
Case #2-Training and Competency of Laboratory Personnel
Case #2-Training and Competency

Background

DOH Bureau of STD receives an email from a County STD Program, expressing concerns about a spike of 15 co-infected (GC and Chlamydia) individuals reported within the past six weeks (higher than the number of cases typically reported for the entire year). In each case the subject’s history is not consistent with test findings. The laboratory is contacted and insists the results are correct, however, subjects are negative when retested at another laboratory (prior to treatment). Wadsworth CLEP staff are asked to investigate.
The laboratory added a new test system for GC and Chlamydia three months prior to the spike in co-infected cases. Specimens are tested with a reagent that detects both Chlamydia and Gonorrhea. Specimens positive in the initial run are then tested with reagents specific for Chlamydia and GC.
Whenever reagents are received, the technologist discards the reagent boxes and places all the reagents for the assay in a plastic bag. I found four different lots of GC reagent and two different lots of Chlamydia reagent in use. None of the reagents were labeled with the date they were placed into use. Based on a review of test instrument findings and worksheets, it appeared that the GC specific and Chlamydia specific reagents were being used interchangeably.
Case #2-Training and Competency

Investigation Findings

It was determined through a review of worksheets that the laboratory technologist had mixed up the reagents. The screening reagent was used instead of the GC specific reagent, thus an unknown number of patients were incorrectly diagnosed with both Chlamydia and Gonorrhea.
Case #2-Training and Competency

Investigation Findings

The personnel folder of the technologist performing the assay did not contain any documentation of training or competency assessment. The laboratory manager stated that the technologist had been trained by the manufacturer but this could not be substantiated.
Case #2-Training and Competency

Standards

Quality Management System Sustaining Standard of Practice 1 (QMS SSP1): *Establishment of Specifications and Requirements*

The quality management system shall establish specifications and requirements for adequate training and competency evaluation of all staff and supervision by competent persons conversant with the purpose, procedures, and assessment of results of the relevant examination procedures.
Case #2-Training and Competency

Standards

Director Sustaining Standard of Practice 3 (DIR SSP3; incorporates director responsibilities under Part 19.3 of NYCRR) The director shall:

- Ensure that sufficient qualified personnel are employed with documented training and/or experience to supervise and perform the work of the laboratory; and

- Provide educational direction to laboratory staff.
Case #2-Training and Competency

Standards

Human Resources Sustaining Standard of Practice 3 (HR SSP3): Personnel Records

Laboratory management shall maintain records of the relevant licensure, educational and professional qualifications, training and experience, continuing education, dates of employment, and competence of all personnel.
Case #2-Training and Competency

Standards

Human Resources Sustaining Standard of Practice 7 (HR SSP7): Training

Laboratory management shall have procedures for training for all staff, and such training shall be documented.
Case #2-Training and Competency

Standards

Human Resources Sustaining Standard of Practice 8 (HR SSP8): Competency Assessment

Laboratory management shall have procedures for performing and documenting competency assessment for all staff.

The competency of staff shall be evaluated at least semiannually during the first year the individual tests patient specimens and thereafter annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual’s performance must be reevaluated to include the use of the new test methodology/instrumentation.
Case #2-Training and Competency Standards

Human Resources Sustaining Standard of Practice 8 (HR SSP8): Competency Assessment Procedures to evaluate employee competence shall include, but are not limited to:

- Direct observation by supervisory staff;
- Observation for compliance with safety protocols;
- Periodic review of work product for compliance with SOP;
- Monitoring the recording and reporting of test results;
- Direct observation of performance of instrument maintenance and function checks;
- Assessment of test performance through testing of previously analyzed specimens (internal or external);
- Assessment of problem solving skills.
Case #2 - Training and Competency

Standards

Guidance - Training and Competency Assessment

Personnel must be trained and their competence assessed in the performance of laboratory specific procedures and protocols. Training by manufacturers or through attendance at external training programs, while a valuable component of a laboratory training program, cannot be substituted for training programs based on an assessment of the individual’s duties, background and skills.
Case #2-Training and Competency

Standards

Guidance-Training and Competency Assessment

Training and competency programs should be documented and include the following elements:

- Defined objectives;
- Identification of training methods;
- Identification of training materials;
- Criteria to assess effectiveness.
Case #2-Training and Competency

Survey Practices

Training and competency assessments will be evaluated for *Degree of Compliance* with the Standards and Guidance

Score of 0=Practice does not exist or does not meet intent
Score of 2=Practice does not meet minimum requirements
Score of 3=Practice meets minimum requirements
Score of 4=Practice exceeds minimum requirements
Personnel must be trained and their competence assessed in the performance of laboratory specific procedures and protocols

Score = 0

Not acceptable—does not meet intent of standard
Case #2-Training and Competency

Includes some laboratory specific procedures and protocols but objectives, methods and assessment criteria are not defined.

Score = 2
Does not meet minimum requirements.
### Case #2 - Training and Competency

Includes laboratory specific procedures and protocols, has a minimal definition of objectives and methods, includes criteria to assess effectiveness.

Score = 3

Meets minimum requirements.

<table>
<thead>
<tr>
<th>ANALYZER</th>
<th>EMPLOYEE</th>
<th>REVIEWED BY</th>
<th>COMMENTS</th>
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<td>Operat. &amp; Princ</td>
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<td>Troubleshooting</td>
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<td>Reagent Prep</td>
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</table>
Case #2-Training and Competency

Competency program has a detailed SOP, includes a pre and post test, evaluates laboratory specific procedures and protocols using a variety of methods, has detailed objectives, includes defined criteria to assess effectiveness.

Score = 4  Exceeds minimum requirements
Case #2-Training and Competency

Prologue

- The laboratory was required to conduct a complete investigation and notify any other clients that may have been affected.
- The laboratory was required to conduct an audit of its practices for training and competency assessment.
- Administrative action was taken against the laboratory owner and director.
Case #2-Training and Competency

Questions for Discussion

- Would this incident have occurred if the technologist had been properly trained and his competency assessed?

- What are some of the other deficiencies in laboratory practice represented by this example?

- What other steps could the laboratory have taken to prevent this occurrence?
Case Study # 3
Single Use Test Device QC Schemes
Case #3: Single-Use Test Device QC Schemes

Clinical Laboratory Standards of Practice


The NYSDOH requirements for the quality control of single-use test devices were developed to:

- allow alternatives to each day of use QC using external QC materials;
- meet or exceed minimum requirements established under CLIA; and,
- embody consensus guidelines being developed by CLSI.
# Equivalent Quality Control Procedures

**Clinical Laboratory Improvement Amendments (CLIA)**

## Table 1 Equivalent QC options for eligible test systems

<table>
<thead>
<tr>
<th>Equivalent QC Option</th>
<th>Test System Description</th>
<th>Evaluation Process: Internal Monitoring Systems*</th>
<th>Test Two Levels of External Controls</th>
<th>Equivalent QC Procedure Testing Frequency</th>
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</thead>
<tbody>
<tr>
<td>Option 1</td>
<td>Test Systems with Internal Monitoring System that Checks ALL Analytic Components</td>
<td>Daily testing with acceptable results</td>
<td>Results acceptable for 10 consecutive testing days</td>
<td>Testing external controls at least once per calendar month and daily testing by the internal monitoring system*</td>
</tr>
<tr>
<td>Option 2</td>
<td>Test Systems with Internal Monitoring System that Checks SOME Analytic Components</td>
<td>Daily testing with acceptable results</td>
<td>Results acceptable for 30 consecutive testing days</td>
<td>Testing external controls at least once per calendar week and daily testing by the internal monitoring system*</td>
</tr>
<tr>
<td>Option 3</td>
<td>Test Systems WITHOUT Internal Monitoring System</td>
<td>N/A</td>
<td>Results acceptable for 60 consecutive testing days</td>
<td>Testing external controls at least once per calendar week</td>
</tr>
</tbody>
</table>

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* Internal monitoring system checks must be performed in accordance with the manufacturer’s instructions, but not less frequently than daily.
Laboratory QC Protocols Based on Manufacturer's Risk Mitigation Information and the Laboratory's Environment; Proposed Guideline
Quality Control Sustaining Standard of Practice 2 (QC SS2): Single-Use Test Devices: Error detection capabilities through function checks (integrated or procedural controls) cannot be presumed. The laboratory must have documentation from the device manufacturer that pertains to:

- the analysis of risk for device failure;
- the operational variables that are monitored through integrated function checks; and,
- the capabilities of function checks for detection of conditions (e.g., environmental, operator variance, nonconformance of device performance to manufactured specifications) that should invalidate the use of the test device.
Clinical Laboratory Standards of Practice

Quality Control Sustaining Standard of Practice 2 (QC SS2): Single-Use Test Devices

If the design details and capabilities of function checks are not available from the manufacturer, the laboratory must follow manufacturer recommendations for use of function checks and apply minimum requirements for quality control as defined under Process QC SS2 (typically, the assay of external control materials each day of use).

Function checks integrated within single-use test devices may serve as a surrogate to the analysis of quality control materials where requirements under QC SS2 are met (adequate manufacturer description of the capabilities of integrated/procedural controls) and the laboratory establishes that function checks are adequate to detect, wholly or partially, device failure or test errors, and:
Clinical Laboratory Standards of Practice


Appropriate quality control materials are analyzed at least weekly where function checks are determined by the laboratory to provide insufficient monitors for all aspects of device performance or conditions of use; or,
Clinical Laboratory Standards of Practice


Appropriate quality control materials are analyzed at least **monthly** where function checks are determined by the laboratory to be wholly adequate as **monitors for all aspects** of device performance or conditions of use; **and**, 
Clinical Laboratory Standards of Practice


Appropriate quality control materials are analyzed with each:

- change of reagent lot number;
- new shipment;
- change in storage conditions;
- replacement of a critical part; or
- following any major preventative maintenance
Clinical Laboratory Standards of Practice

Where function checks in routine patient specimen analysis fail, the laboratory must follow requirements specified in Process Review SS4, Non-Conformance and Reporting SS4, Error Correction. Requirements under HR SS9, Competency Assessment apply to all users of single-use test devices.

Records of all analyses associated with the use of single-use test devices must be retained as required under Retention SS3 Test Request and Process Documents.
Single-Use Device Package Inserts

- Are QC recommendations adequately described?

- Are the design capabilities of function checks (integrated/procedural controls) adequately described to allow the laboratory director to identify risks for device failure and their mitigation?
Quality Control

“Good laboratory practice recommends the periodic use of control materials to ensure proper kit performance. The internal control validates adequate capillary flow across the membrane. Positive and negative controls should be run periodically in place of serum according to Test Procedure.”
Directigen™ EZ Flu A+B
For the Differentiated, Direct Detection of Influenza A and B Viral Antigens

Each Directigen EZ Flu A+B device contains both positive and negative internal/procedural controls:

- The appearance of a reddish purple control line in the Flu A and/or Flu B read windows at the Control "C" position provides an internal positive control that validates the proper reagent function and assures that the correct test procedure was followed.

- The membrane area surrounding the Flu A and/or Flu B test and control lines is the internal negative control for the device. A background area that is white to light pink indicates that the test is performing correctly.

Each Directigen EZ Flu A+B kit contains liquid Control A+/B- and Control B+/A- kit controls:

These controls are tested in the same manner as patient specimens and provide a means of external quality control. At a minimum, these liquid controls should be run as a quality control procedure for each new kit lot or shipment received. If desired, appropriate reagent performance and proper testing technique may also be determined by

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Quality Control Built-In Control Features

“The OraQuick ADVANTAGE Rapid HIV-1/2 Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the Control ("C") area of the Result window indicates that a specimen was added and that the fluid migrated appropriately through the Test Device.”
Quality Control-External Quality Control

Run the Kit Controls under the following circumstances:
- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°- 27°C (35°- 80°F),
- If the temperature of the testing area falls outside of 15°- 37°C (59°- 99°F), and
- At periodic intervals as dictated by the user facility.
Desirable Attributes of a Manufacturer’s Provided Risk Analysis Table

Key:

- **Gray shading** Level of device control
  - No device mitigation; mitigate through training.
  - Device mitigation possible depending on severity of the problem; mitigate with device and training.
  - Device mitigates the error.

### Pre-analytical and Analytical Risks and Mitigation

<table>
<thead>
<tr>
<th>Risk</th>
<th>Problem</th>
<th>Resolution</th>
<th>Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper specimen collection</td>
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<tr>
<td>Improper sample transport and storage</td>
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<tr>
<td>Improper storage of cassettes</td>
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<td>Incorrect cassette incubation time</td>
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<td>Incorrect sample volume added to cassette</td>
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<td>Improper use of Cal Code and cassette lot</td>
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<td>Reagent instability</td>
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<tr>
<td>Using un-pouched cassettes</td>
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<td>Jarring the analyzer during testing</td>
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<td>Poor sample flow</td>
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</table>
Reliance on device function checks (integrated/procedural controls) is an option, however the capabilities of function checks cannot be presumed, and the director is responsible for informed decision-making on the design of an effective QC program.
Case #4-Burden of Proof: The Power of Document Control
Case #4-Burden of Proof: The Power of Document Control

Background

A patient was notified by his primary care physician that his recent test results showed he was positive for antibody to HCV. He was referred to a specialist, who had the test repeated at another laboratory. The antibody result performed at the second laboratory came back negative, as did the HCV PCR, and it was confirmed that the patient did not have HCV. The patient contacted CLEP and asked that the first laboratory be investigated.
Case #4-Burden of Proof: The Power of Document Control

Investigation

Both laboratories were investigated and asked to recreate the entire test process, from point of receipt of the specimen to final report, as outlined in the Document Control checklist (Exhibit 2). Documents were collected from each laboratory and submitted to the Department for review.
Case #4-Burden of Proof: The Power of Document Control

Documents Collected

Laboratory A

- Requisition
- QC results for the date of the patient’s run
- Summary QC data for the month including the patient’s run
- Copy of the patient’s report (which included the notation “result verified by repeat analysis”, although this could not be substantiated)

Laboratory B

- Requisition
- Packing list for courier run documenting delivery of specimen to laboratory
- Accession records documenting condition of specimen received
- Instrument rack worklist showing actual patient results and QC for the patient’s run
- Summary QC data
- Copy of the patient’s report
Case #4-Burden of Proof: The Power of Document Control

Investigation Narrative-Laboratory A

I visited this laboratory to conduct an investigation in response to a patient complaint about a hepatitis C positive test result. The laboratory tried to obtain all the documents needed to substantiate the positive result but were only able to produce the requisition, QC records, and a copy of the report. They were not able to produce copies of instrument worklists for both assay runs (original and the repeat run the laboratory claimed to have conducted). According to laboratory staff, the analyzer (Advia Centaur) does not hold more than three months of records and the laboratory does not retain a copy or electronically archive the runs.

Documentation from Laboratory B was found acceptable and no further action was required.
Laboratory A was cited against for not providing instrument printouts to substantiate its results:

Section 58-1.11(c)(6)

Worksheets containing instrument readings and/or personal observations upon which the outcome is based shall be retained for one year.

The laboratory failed to maintain and was not able to produce copies of assay runs performed on the Advia Centaur (both original and repeat run) for hepatitis C testing conducted on January 3, 2007.

The laboratory submitted a plan of correction:

The regulation specifies “worksheets containing instrument readings and/or personal observations”. For this test, instrument results are not entered on to a worksheet because they are transmitted directly to the LIS. Therefore this regulation does not apply.
Case #4-Burden of Proof: The Power of Document Control

**The Department’s response:**

This is in reference to your Plan of Correction for the recent deficiency cited under Section 58-1.11(c)(6). Your laboratory was cited for failure to maintain or to reproduce copies of assay runs performed on the Advia Centaur for hepatitis C testing. In your response you questioned the applicability of this citation because information from your analyzer is transmitted directly to your LIS and no worksheets are generated. You are correct in that you do not need to keep paper copies of worksheets if they are not routinely generated. However, if you use an electronic worksheet you must be able to reproduce this to recreate the entire test process so specimens can be traced from receipt through testing and reporting. This is implied in the regulation. Please note that in the our revised laboratory standards, this requirement is clearly defined.
Case #4-Burden of Proof: The Power of Document Control

The Revised Standard:


The laboratory shall be in substantial compliance with Process Review, Reporting, Records and Specimen Retention, and Confidentiality Sustaining Standards of Practice provided in this section as required to ensure: pre-examination and examination procedures have been verified as compliant with specifications prior to release of test findings; test reports are complete, accurate and factual; document control allows the recreation of the test process as necessary to substantiate the report of test findings; specimens have been properly stored and available for re-examination; and, confidentiality of patient identified information is maintained.
Case #4-Burden of Proof: The Power of Document Control

The Revised Standard:

Records Retention Sustaining Standard of Practice 3 (Retention SS3): Test Request and Process Documents
The laboratory shall retain the following records for at least the period specified, except that where other New York State or Federal regulations or statutes require retention for different periods of time.

Analytic system records, including worksheets containing instrument readings and/or personal observations upon which the outcome is based, the identity of personnel who performed the tests, quality control and patient results shall be retained for at least two years.

Guidance will be added to specify that laboratories using systems that transmit results directly to a LIS must archive analytic system records such as batch lists and rack lists. (Note that the retention period has been increased to two years to conform with CLIA requirements)
Case #4-Burden of Proof: The Power of Document Control

The Message

It is in the laboratory’s best interest (and good laboratory practice) to ensure that all aspects of the test process can be substantiated through document control.

- Records are subject to FOIL requests and can be used in litigation.
- Records may be needed for troubleshooting or identification and resolution of non-conformances or incidents such as reagent recalls.
Case 5-Proficiency Testing: Referral, Interlaboratory Communication, or Routine Testing?
Case 5-Proficiency Testing Referral

CMS (CLIA) Definition of PT Referral at 42 CFR, Subpart H, Section 492.801(b):

(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing samples until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.
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CMS (CLIA) Sanctions against laboratory for PT referral at 42 CFR, Subpart R, Section 492.1830:

(b) Adverse action based on improper referrals in proficiency testing. If CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

CMS has takes the position that interlaboratory communication is equivalent to referral, and this has been upheld in enforcement proceedings.
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CMS (CLIA) Sanctions for PT referral at 42 CFR, Subpart R, Section 492.1840:

(a) Adverse action based on actions of the laboratory's owner, operator or employees. CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator (*including the director*) or one of its employees has

8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

This means that both the director and the owner are precluded from owning/directing a laboratory for two years……
Example 1: Referral of Gram Stains

**Lab A**
- Hospital Stat Lab
- Gram Stain Only

**Lab B**
- Affiliated Hospital
- Full Service Bacteriology Lab

Gram stains performed at Lab A by MD staff on off shifts only, routine gram stains are referred to Lab B

Is this proficiency testing referral?
Example 2: Network Laboratory Influences

Complaint received from an employee of a laboratory network, stating he was asked to attest to PT results that were not generated by him:

- Network Lab A questioned its PT results for a toxic level of an analyte.
- Network Lab B was asked to analyze the questioned PT specimen, and obtained result discrepant from Lab A’s result.
- Network Lab A adjusted its calibration and reprocessed the PT specimen.
- The result was in agreement with that produced by Network Lab B, and was reported to DOH.

Is this PT referral? Interlaboratory communication?
Example 3: Rogue Employee

- On routine survey of Lab A, surveyor found PT worksheets that included references to a test system the laboratory does not use.
- The technologist who processed the PT specimens for Lab A also works at Lab B, where that test system is used.
- Technologist transferred results from Lab B to Lab A’s PT report form; director and technologist signed attestation.

Is this PT referral? Interlaboratory communication?
Example 4: Reference Laboratory

- DOH alerted by CAP to an investigation of CAP PT referral at a hospital
- Joint investigation (CAP/JCAHO/DOH) initiated, CMS notified
- Specialized testing laboratory within hospital referred PT specimens to a reference laboratory for confirmation (as it does patients)
- Hospital submits PT results to CAP acknowledging referral to the reference laboratory.

Is this PT referral?
Case 5-Proficiency Testing Referral

CMS has advised NYS DOH that it must apply equivalent sanctions to those imposed by CMS for PT referral and interlaboratory communication, as a condition of CLIA exemption.

- Laboratory can lose permit for one year (and not just in affected category)
- Director cannot serve as director for two years (must surrender CQ)
- Owner cannot own or operate a laboratory for two years
- Additional penalties (fines) may be imposed