INDIVIDUALIZED QUALITY CONTROL PLAN

IQCP for The Laboratories

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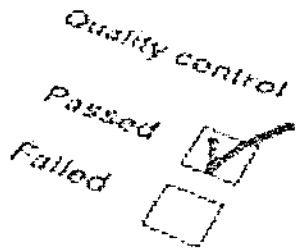
Development of IQCP

- Customized QC plan
- Requires labs to consider QC in a broader context
- IQCP is intended to ensure effective QC for each laboratory and the tests it performs
- IQCP is optional
- IQCP does not apply to waived testing
- IQCP cannot be implemented in a Joint Commission accredited lab until January 1, 2016
- January 1, 2016 – EQC and CLSI Streamlined QC guidelines are no longer Quality Control options
  - No exceptions, no extensions, no grandfathering

Minimum QC Frequency

- There is not a minimum QC frequency for labs performing IQCP
- However…
  - Not performing any QC is unacceptable
  - QC frequency must not be less than the manufacturer's instructions
  - Your Risk Assessment must support your QC frequency



IQCP is not needed if…

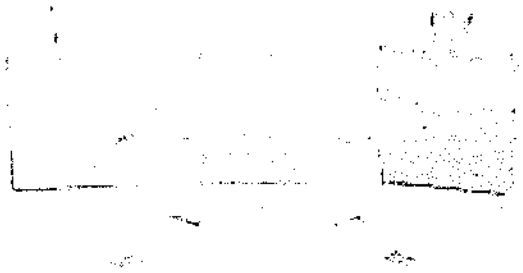
- Your quality control frequency follows the default CLIA quality control procedure and Joint Commission standards

OR

- Due to the identified risks in your lab, you have determined that your quality control must be performed more often than the default CLIA quality control procedure and Joint Commission standards requires

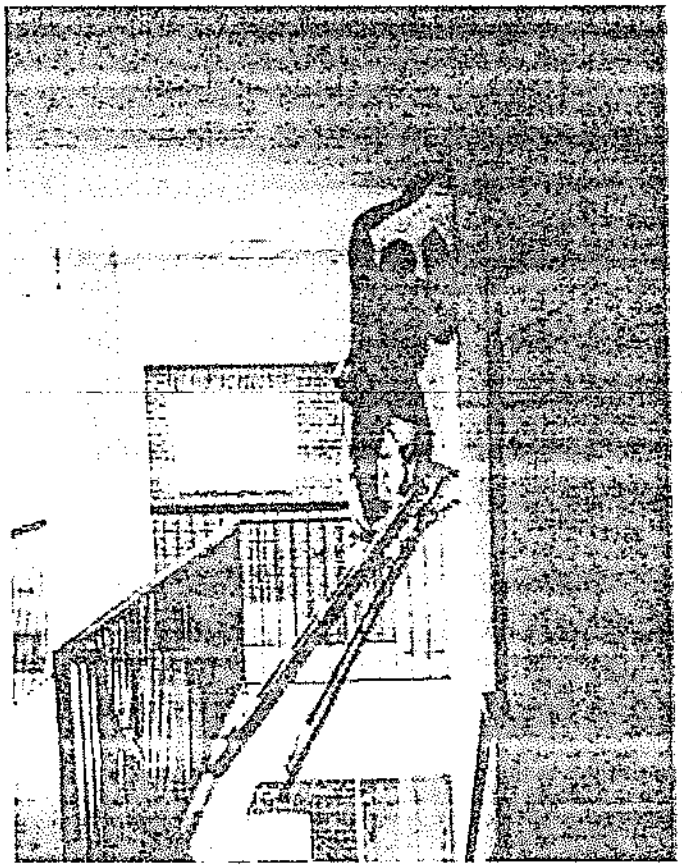
The Three Parts of IQCP

- Risk Assessment (RA)
  - ID & evaluation of potential failures and sources of errors in a testing process
- Quality Control Plan (QCP)
  - Policies/procedures to prevent or reduce the risk
- Quality Assurance (QA)
  - Monitoring



Risk

Risk - the chance of suffering or encountering harm or loss (*Webster's Dictionary and Thesaurus. Ashland, OH: Landall, Inc.; 1993)*



Risk Assessment

Risk Assessment - the identification and evaluation of potential failures and sources of errors in a testing process. *(S&C-13-54-CLIA, Risk Assessment Section)*

IQCP Risk Assessment

- Must be established in its own environment by its own testing personnel
- 5 Required Components:
  - Specimen
  - Environment
  - Reagent
  - Test system
  - Testing personnel

- Include the entire testing process:
  - Pre analytic
  - Analytic
  - Post analytic
- Must evaluate the frequency and impact of the identified failures and sources of error
- Must include the manufacturer's instructions or other information needed to assess risk

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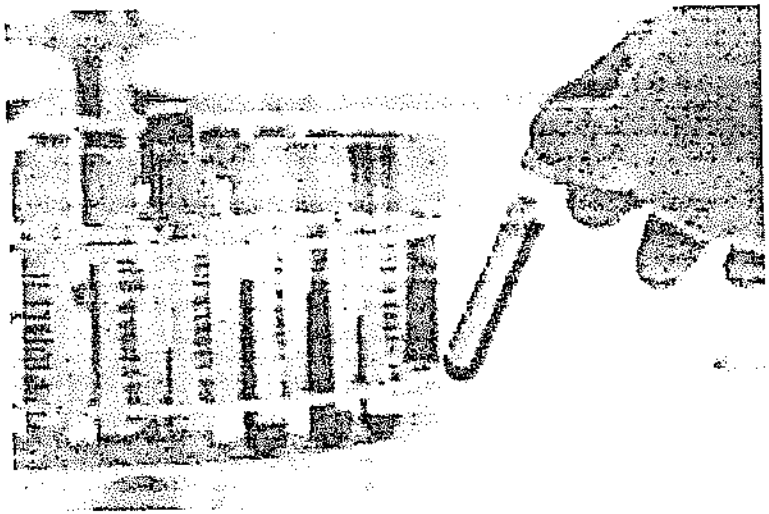
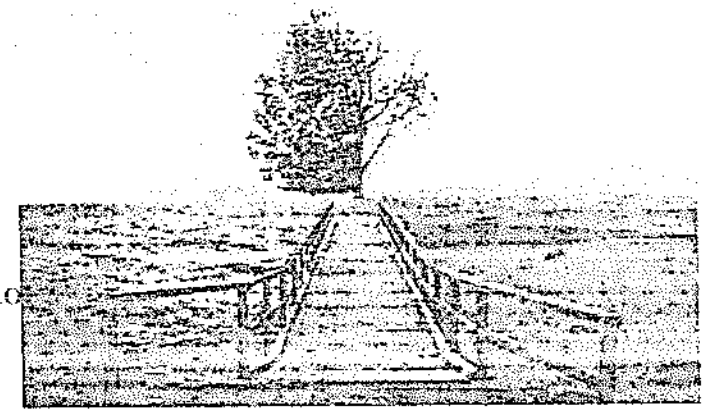
RA: Specimen



- Patient preparation
- Specimen collection
- Specimen labeling
- Specimen storage, preservation, and stability
- Specimen transportation
- Specimen processing
- Specimen acceptability and rejection
- Specimen referral

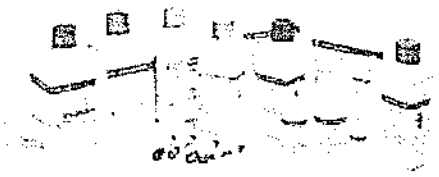
RA: Environment

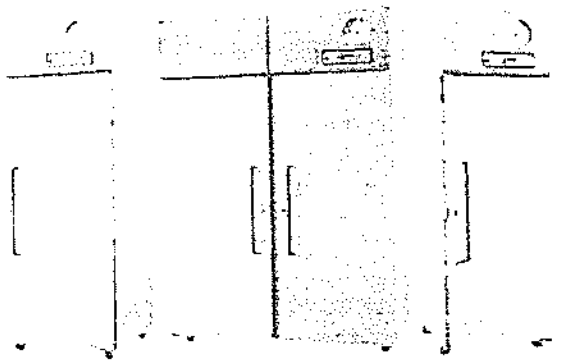
- Temperature
- Airflow/ventilation
- Lighting/intensity
- Noise and vibration
- Humidity
- Adequate space
- Altitude
- Dust
- Water
- Static Discharges
- Utilities (Electrical failure/current variations or surges)



RA: Reagent

- Shipping/receiving conditions
- Storage conditions
- Expiration Date (may differ based on storage requirements)
- Preparation instructions/requirements

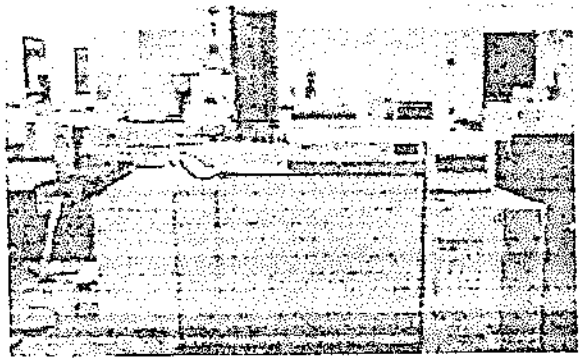




RA: Test Systems

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
- Calibration associated issues

- Failure of system controls and function checks
  - Built-in procedural and electronic controls (internal controls)
  - External or internal liquid quality control (assayed vs. unassayed)
  - Temperature monitors and controllers



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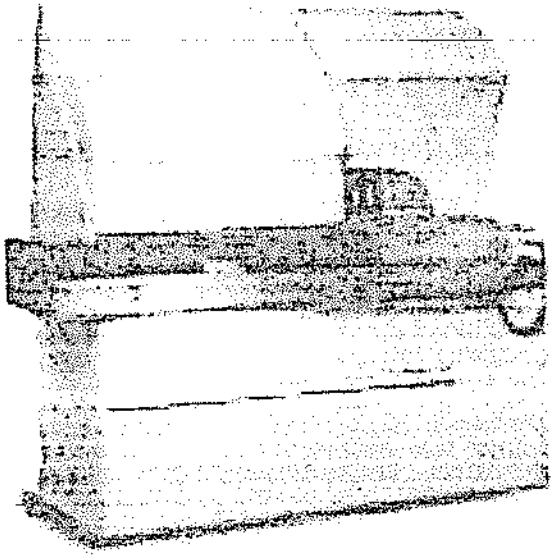
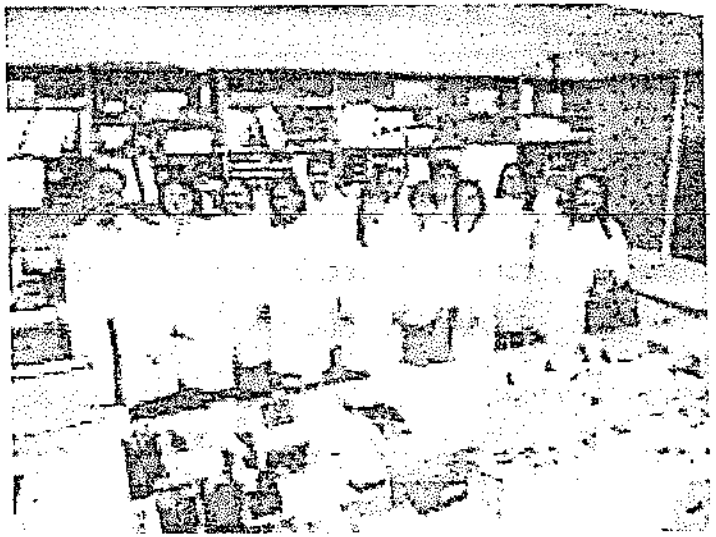
RA: Test Systems

- Mechanical/electronic failure of test system optics
  - Pipettes or pipettors
  - barcode readers



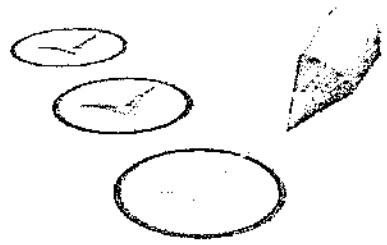
RA: Testing Personnel

- Appropriate education and experience qualifications
- Training
- Competency
- Adequate staffing
- Evaluations



Performing the Risk Assessment

- You can have 1 risk assessment per test system as long as it includes the risks from all testing locations
- The lab must:
  - Use their own testing personnel and their own data
  - Evaluate the 5 components across 3 phases of testing
  - Identify sources of potential failure/errors for a testing process
  - Uses manufacturer's information or other available data
  - Evaluate frequency/impact of those failures (Does not have to be documented as part of the risk assessment)
  - Includes function and maintenance checks
  - Document the risk assessment



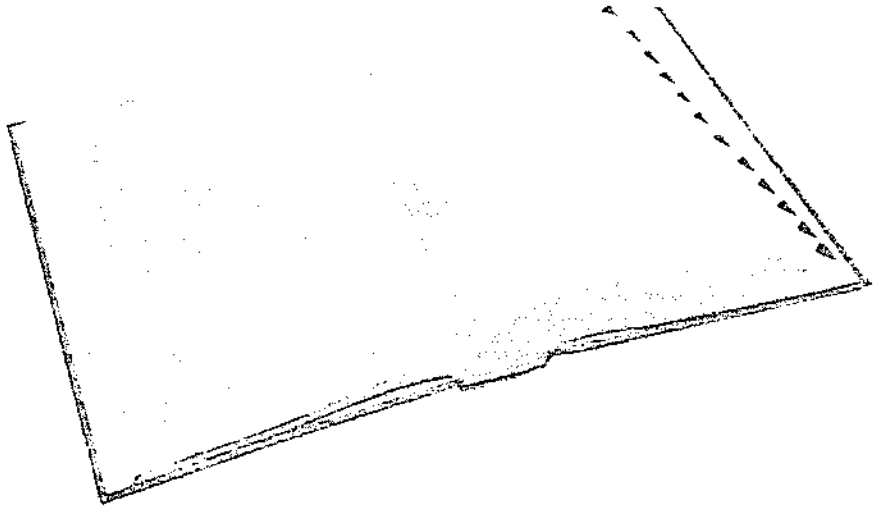
The risk assessment for any given test system may look very different in different laboratories

From RA to QCP

After the lab has identified/evaluated the sources of potential failures and errors for a testing process and evaluated the frequency and impact of those failures and errors, the resulting RA is used to develop the Quality Control Plan (QCP). *(S&C-13-54-CLIA, Risk Assessment Section)*

Quality Control Plan (QCP)

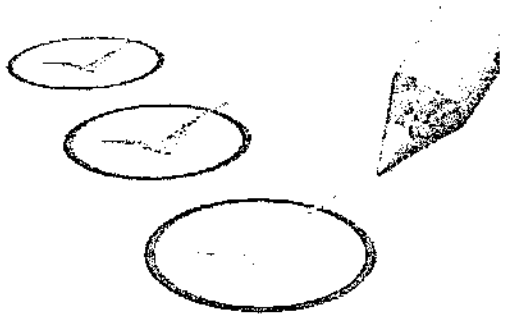
A laboratory's standard operating procedure that describes the practice, resources, and procedures to control the quality of a particular test.



Quality Control Plan

Your own data must support the rationale used

- Must include:
  - Number
  - Type
  - Frequency of testing
  - Acceptability criteria of the quality control used
- May incorporate:
  - Electronic controls
  - Equipment maintenance
  - Internal controls
  - Personnel training and competency assessment
  - Equipment calibration
  - Other specified quality control activities



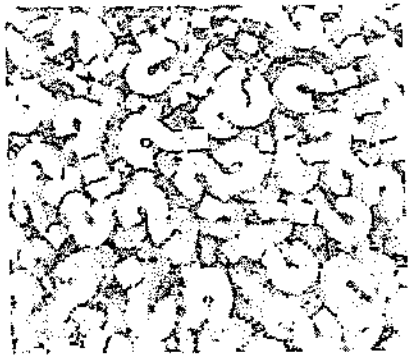
Examples of Data

- External controls
- Electronic controls
- Internal controls
- Procedural controls
- Verification Data or establishment of performance specification Data
- Maintenance records
- Calibrations
- Temperature records
- Proficiency Testing results
- Training and competency assessments
- Corrective Actions taken

Quality Control Plan

- Must provide for the immediate detection of errors
- Must monitor overtime the accuracy and precision of the test performance
- Must not be less stringent than the manufacturer's guidelines
- You choose which risks you want to mitigate – not every identified risk is required to have a quality control activity
- Required for each device location if RA identifies unique risks per location that require a quality control activity
- If all quality control activities are identical, 1 QCP can list all device locations
- Must be signed by the Laboratory Director named on the CLIA certificate before implementation

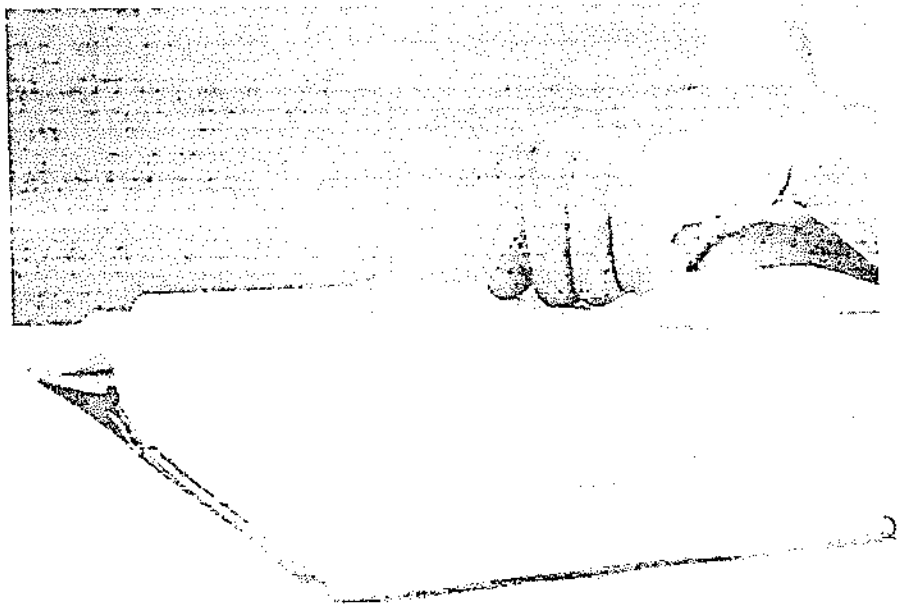
Quality Control Plan



- Ask yourself, does the QCP…
  - **Provide** for immediate detection of errors for each phase of the testing process?
  - **Specify** the number, type and frequency of testing QC material?
  - **Contain** criteria to determine acceptable QC results?
  - **Require** the lab perform QC as specified by the manufacturer instructions?
  - **Indicate** that your Laboratory Director has reviewed, signed, and dated the QCP document before implementation?

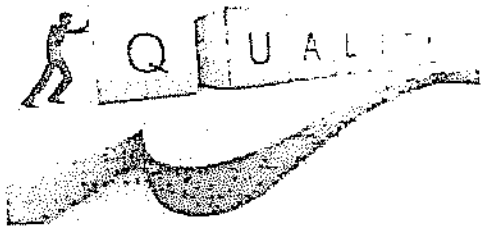
Quality Assessment

An ongoing review process that encompasses all facets of the laboratory's technical and nontechnical functions and all locations/sites where testing is performed.



Quality Assessment

- Required regardless of QC option the laboratory chooses to implement
- Do not have to have a separate QA just for the QCP and IQCP



Quality Assessment helps you

- Make sure that your QCP is working as expected
- Monitor errors and QC failures
- Identify errors and failures so you can take the appropriate corrective action
- Investigate the cause of the error and reassess your risk assessment if needed
- Evaluate whether any changes need to be made in the QCP

QC vs. QA

Quality Control	Quality Assessment
Recording the refrigerator temperature	Reviewing the temperature records
Documenting control results	Reviewing control results
Documenting personnel training	Reviewing personnel training records
Documenting maintenance	Reviewing maintenance records
Documenting personnel competency	Reviewing personnel competency documentation

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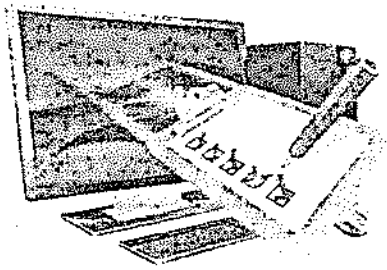
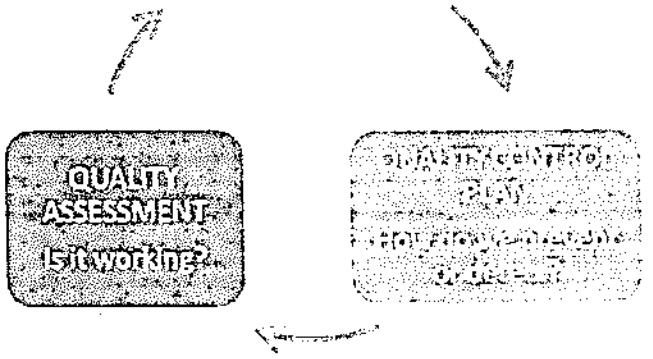
Examples of Documents to Review



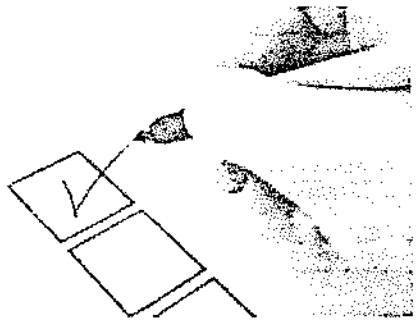
- QC results
- PT performance review (scores, failures, and trends)
- Temperature logs
- Specimen rejection/QNS log
- TAT reports
- Complaint reports
- Specimen recollection logs
- Communication logs
- Review of preventive measures, corrective actions, and follow-up
- Maintenance log
- Patient results review
- Training and competency documents
- FDA alerts
- Delta check logs
- Panic value/critical results log

Quality Assessment

- Closes the loop to your RA and QCP
- Activities you are already doing
- Should have a QA activity for each QC activity
- 1 QA may be sufficient for all testing locations
- All devices and locations must be monitored
- QA is used to determine if the quality activities you have put in place are working



Quality Assessment



- Ask yourself, does your QA do the following…
  - **Outline** the QA practices for your laboratory?
  - **Monitor** continuously for effectiveness?
  - **Revise** policies and procedures necessary to prevent recurrence of the problem?
  - **Discuss** QA reviews with appropriate staff?
  - **Document** all QA activities?