Laboratory Risk Assessment: IQCP and Beyond

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Objectives

- Explain the importance of risk assessment in the laboratory environment
- Identify requirements related to risk assessment
- Outline tips that should keep your organization in compliance with the risk assessment requirements
- Provide an overview of The Joint Commission's approach to risk management



The Big Push











Risk – Definition

The chance of suffering or encountering harm or loss (Webster's Dictionary and Thesaurus, Ashiand, OH; Landall, Inc.; 1993)

The probability or threat of quantifiable damage, injury, liability, loss, or any other negative occurrence that is caused by external or internal vulnerabilities, and that may be avoided through preemptive action (Wikipedia®; as modified on 20 March 2014)

Combination of probability of occurrence of harm and the severity of that harm (ISO/IEC 51)



Risk Assessment – Definition

The identification and evaluations of potential failures and sources of errors in a testing process. (S&C-13-54-CLIA, Attachment 1, Risk Assessment Section)

Overall process comprising a risk analysis and a risk evaluation (ISO/IEC Guide 51)



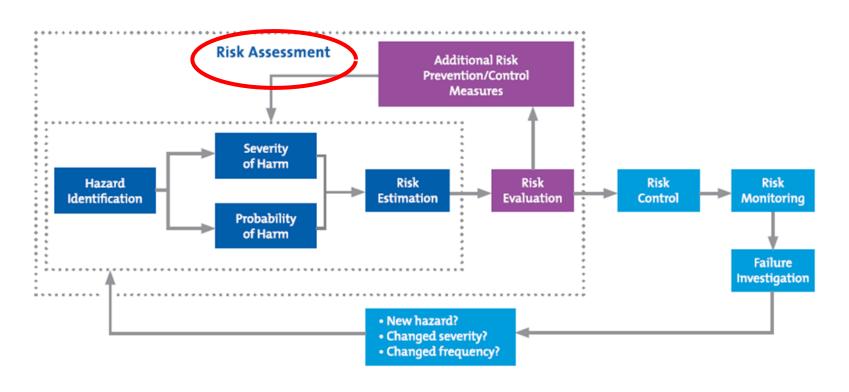
Risk Assessment – where in the process?





Risk Management – Approach

Life Cycle Risk Management Process



Source: CLSI EP23 – Laboratory Quality Control Based on Risk Management; 2011

Risk Management in Practice











Focusing on Risk Assessment

CLIA IG states...

To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality



Focusing on Risk Assessment

CLIA IG states...

A risk assessment is the process of identifying and evaluating the potential failures and errors that could occur during the preanalytical (before testing), analytical (testing), and postanalytical (after testing) phases of testing.



Focusing on Risk Assessment

IQCP requires...

At a minimum, evaluate the following <u>five</u> <u>components</u> of the testing process for potential failures and errors:

- -Reagent
- Environment
- Specimen
- Test system
- -\Testing personnel



Joint Commission Standards

Standard QSA.02.04.01; **Element of Performances** states that...

Laboratories that develop and implement an individualized quality control plan (IQCP) include the following....



Joint Commission Standards

- 2. A risk assessment that is established by the laboratory in its own environment by its own testing personnel.
- A risk assessment that contains an evaluation of the following five components: Specimen Environment Reagent Test system Testing personnel

Joint Commission

Laboratory

Joint Commission Standards

- A risk assessment that encompasses the following three phases of the entire testing process: - Preanalytic -Analytic - Postanalytic
- A risk assessment that includes the manufacturer's instructions or other information needed to assess risk in all three phases of the testing process.



IQCP Risk Assessment

In summary....

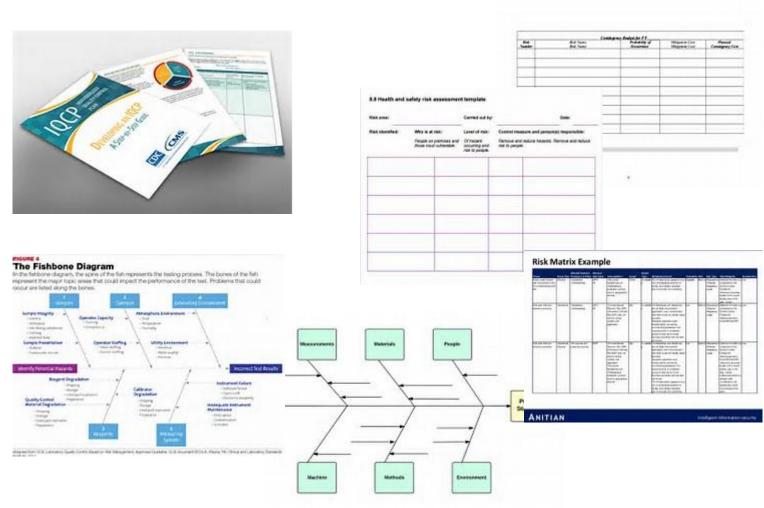
- Three phases of testing
- Five components

In addition, CLIA asks...

- if current practices are sufficient to detect the sources of error/failure in your test system.
- whether identified risks need to be monitored/ controlled

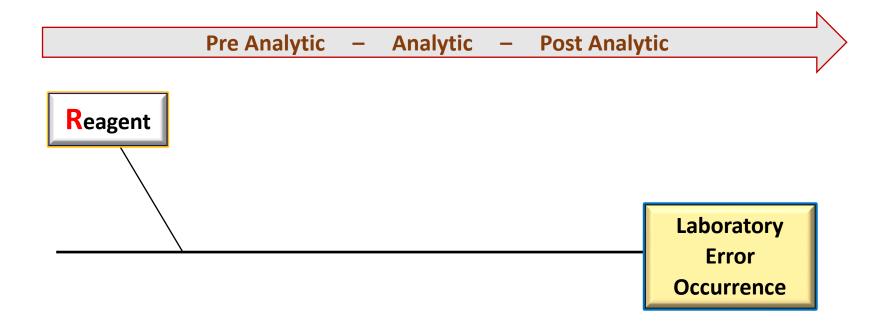


Common Tools





Sample Risk Assessment





Risk Assessment: Reagent

- Transportation
- Storage and Stability
- Expiration dates
- Manufacturer recommendations
- Lot to lot reagent logs
- Preparation requirements



Risk Assessment: Reagent

CLIA IG asks...

- Assessment of potential failures/error, which may result contamination or deterioration and reagent lot variation?
- Assessment of potential failures/error due inadvertently mixing reagents from different kits or lot numbers?



Risk Assessment: Reagent

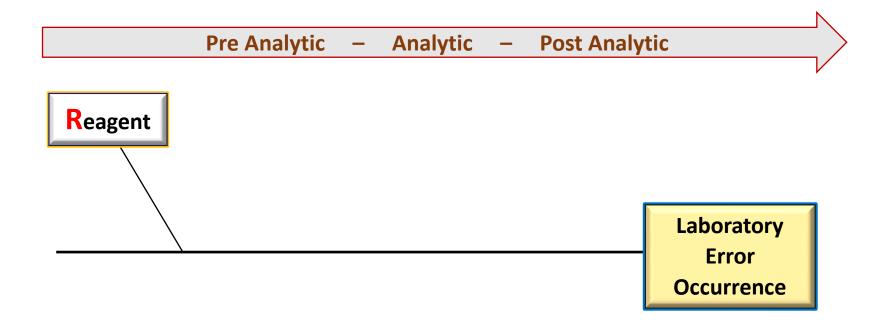
TJC Findings...

"The freezer used to store chemistry reagents and calibrators did not maintain the temperature required by the manufacturer."

"The expiration dates of IStat cartridges stored at room temperature were not adjusted for storage conditions as required by the manufacturer."

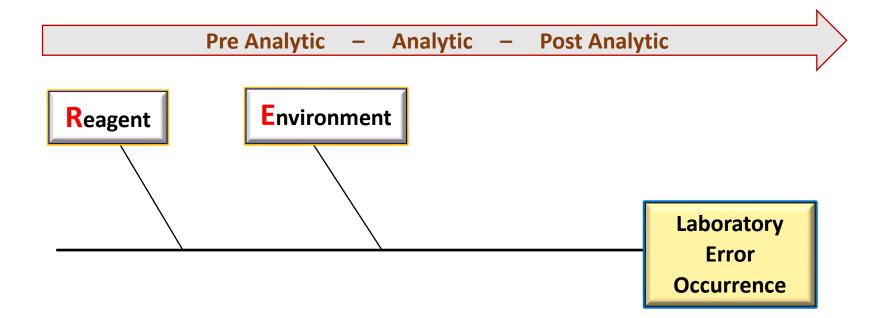


IQCP Risk Assessment





IQCP Risk Assessment





Risk Assessment: Environment

Space

Docking stations VS bedside locations

Physical location

space, altitude, vibration

Room conditions

humidity, ventilation, dust

Utilities

- electrical, water quality



Risk Assessment: Environment

CLIA IG asks...

- risk assessment for each location where testing is performed?
- risk assessment with respect to:
 - Multiple laboratory/testing locations within a single CLIA number
 - Point-of -care devices throughout health care/laboratory systems
 - Error due to transport of instruments/reagents to various location (i.e. mobile laboratory)



Risk Assessment: Environment

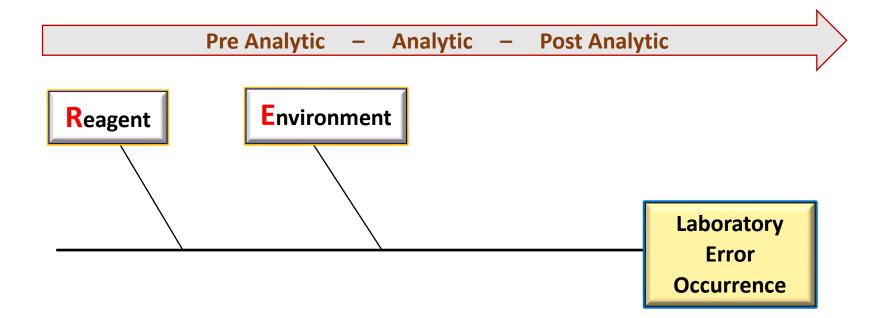
TJC findings:

"The laboratory's air conditioning failed creating an environment too warm for proper functioning of the chemistry analyzer; the analyzer's primary circuitry failed."

"On weekends and holidays, there were no temperatures recorded in areas where POCT devices were stored at room temperature."

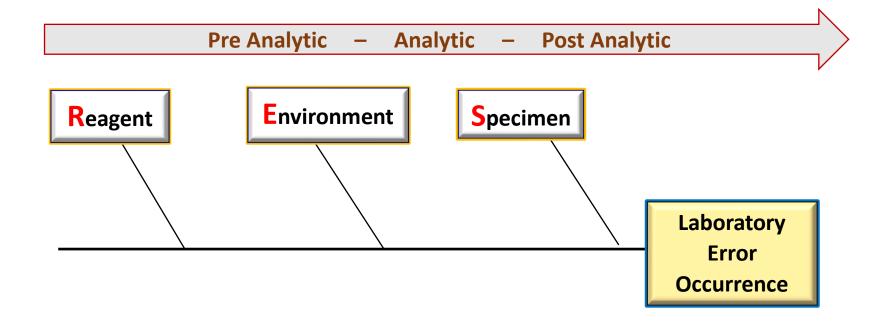


IQCP Risk Assessment





IQCP Risk Assessment





Risk Assessment: Specimen

- Collection, transport, receipt
- Labeling, processing, preparation
- Acceptability and rejection
- Storage and stability
- Referral



Risk Assessment: Specimen

CLIA IG asks....

Assessment of potential failures/error due to:

- inadequate sampling
- -re-collection
- Testing time frame/stability
- Specimen labeling throughout the testing process



Risk Assessment: Specimen

TJC findings:

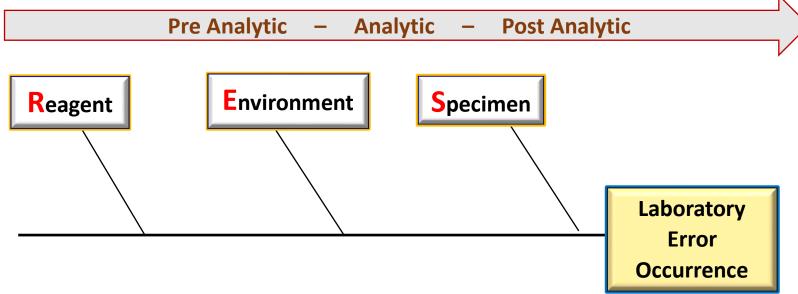
"Containers with patient specimens submitted by offsite clinics did not include two patient identifiers on the container label."

"The laboratory did not follow its procedures for specimen submission and accepted specimens that exceeded the established time limit and that did not include full labeling as required by its policies."



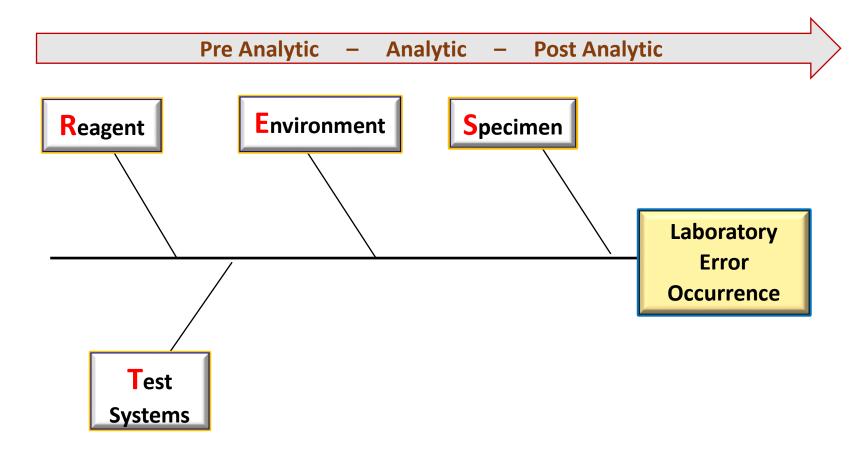
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IQCP Risk Assessment





IQCP Risk Assessment





Risk Assessment: Test Systems

- Calibration verification
 - Frequency
- Sampling capabilities and accuracies
 - Internal and External QC
 - inadequate sampling
- Functionality
 - Interfering substance detection
 - Optics, barcode readers, temperature monitors
 - LIS connection
- Proficiency testing results



Risk Assessment: Test Systems

CLIA IG asks...

- Does the laboratory's RA support its procedures for testing quality control samples, including the frequency of testing?
- Are there any potential risk of producing incorrect test results due to:
 - Not following manufacturer's instructions?
 - Built-in monitors non existent?
 - Non-automated patient ID (barcode system)?



Risk Assessment: Test Systems

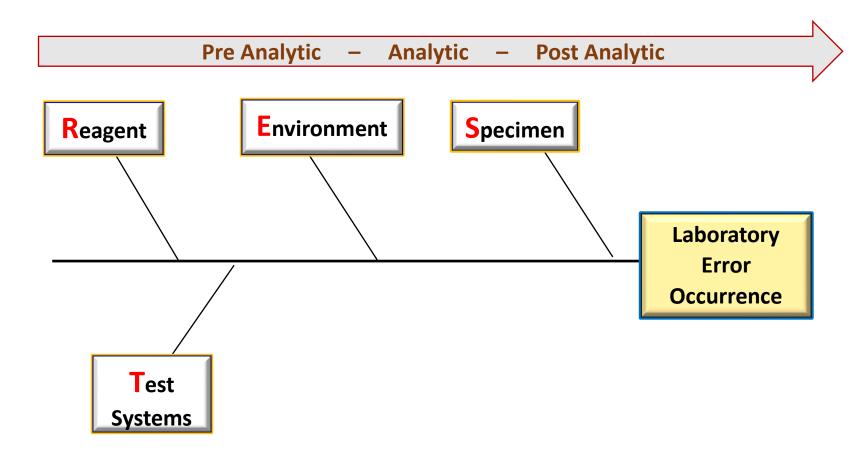
TJC findings:

"Calibration verification of a loaner blood gas analyzer was not performed prior to reporting patient tests.

"There was no documentation to show that preventive maintenance was performed on the chemistry or hematology analyzers."

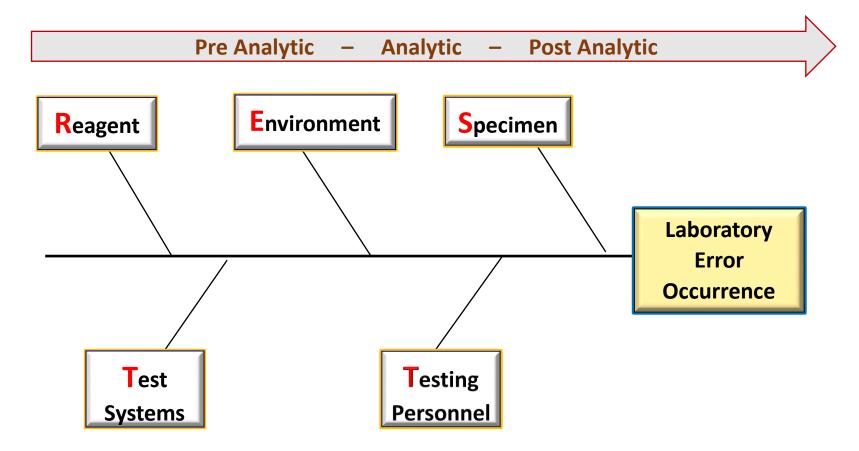


IQCP Risk Assessment





IQCP Risk Assessment





Risk Assessment: Testing Personnel

- Training and competency
- Education and experience qualifications
- Adequate staffing



Risk Assessment: Testing Personnel

CLIA IG asks...

Do you see a potential risk of an error in test results due to:

- There is no documentation of CLIA-required competency assessment for all laboratory personnel
- The laboratory does not have adequate personnel to perform patient testing in a safe and timely manner?



Risk Assessment: Testing Personnel

TJC findings...

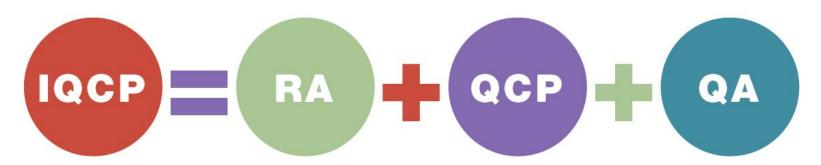
"Staff competency for transfusion services was completed by an individual that did not quality as a technical supervisor."

"The lack of communication between lab staff and leadership did not allow reporting of damage to handheld instrumentation."



Risk Assessment: How Critical?

The IQCP Equation



Step 1 Step 2

Step 3



Risk Assessment: How Critical?





Invalid Risk Assessment = Invalid IQCP



"IQCP had not been used to justify accepting manufacturer's QC for microbiology media. Since January 1 2016, The laboratory had not performed in-house QC on receipt of all lots of media used."

"The chemistry and hematology laboratories did not use in-house data to assess risk. All sources of error were from the manufacturer."



The Joint Commission Risk Assessment

"Proactive" Risk Assessment

An assessment that examines a process in detail including sequencing of events; actual and potential risks; and failure or points of vulnerability; and that, through a logical process, prioritizes areas for improvement based on the actual or potential impact (that is, criticality) of care, treatment, or services provided.



"Proactive" Risk Assessment

Pre-analytical Analytical Post-analytical Reagent
Environment
Specimen
Test Systems
Testing Personnel

An assessment that examines a process in detail including sequencing of events actual and potential risks; and failure or points of vulnerability; and that, through a logical process, prioritizes areas for improvement based on the actual or potential impact (that is, criticality) of care, treatment, or services provided.

Priority and Criticality of each identified risk

Current and Future Effect



The Joint Commission Risk Assessment Approach

SAFER Matrix

The Joint Commission has developed the Survey Analysis for Evaluating Risk (SAFER)™ matrix

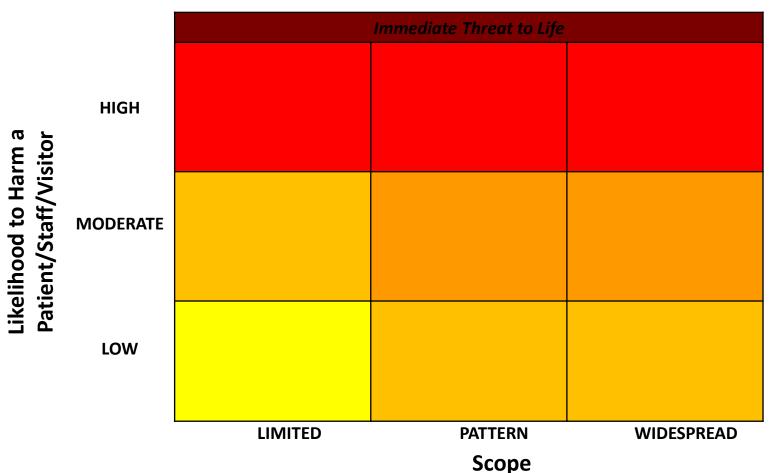


What is SAFER™?

- transformative approach for identifying risk levels associated with deficiencies
 - helps organizations prioritize corrective actions
- visual representation of findings
 - Findings plotted according to the likelihood to cause harm and how widespread the problem is
- replaces the current scoring methodology based on pre-determined categorizations
 - allow surveyors to perform real-time, on-site evaluations of deficiencies.

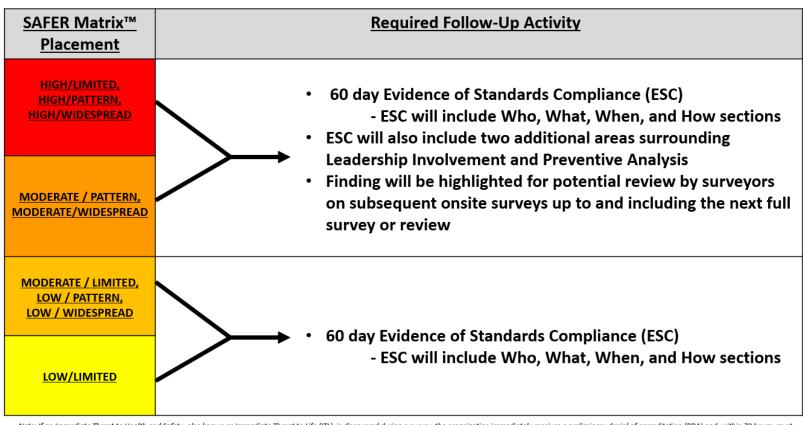


The Joint Commission's Survey Analysis for Evaluating Risk (SAFER) Matrix™





The Joint Commission's Survey Analysis for Evaluating Risk (SAFER) Matrix™



Note: If an Immediate Threat to Health and Sofety, also known as Immediate Threat to Life (ITL), is discovered during a survey, the organization immediately receives a preliminary denial of accreditation (PDA) and, within 72 hours, must either entirely eliminate the ITL). Please see the Accreditation Process Chapter within the Comprehensive Accreditation Manual for more information.



The Key to Continuous Compliance is...

performing you own Mock Tracers!





The Purpose of Mock Tracers

- Evaluate the effectiveness of policies and procedures
- Engage staff in looking for opportunities to improve processes
- To be certain compliance issues have been addressed
- ▶ Benefit: Heightens the awareness of the regulatory requirements



Tracer Methodology

- Patients are the framework
- Follows the experience of care



- Includes preanalytics and postanalytics
- Involves multiple staff, the patient, and even family
- All specialties and subspecialties for a 2 year period
 - 13 24 months
 - 6 12 months
 - Within the last 6 months







Documents Reviewed

- Examples of documents reviewed
 - Instrument maintenance records, quality control, proficiency testing
 - Testing logs
 - Policies and procedures
 - Employee competency, training, education, and qualifications
 - Process improvement
 - Patient medical records
 - Manufacturer instructions





Final Advice

- Question "Risks" associated at every process
- 2. Think of the "Domino Effect"
- Consider Risk Assessment "Beyond" IQCP
- 4. Seek "Leadership Involvement"



Questions/Suggestions

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