Seven Essential Tips for Developing and Implementing Individualized Quality Control Plans

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Today's Goals

- What is IQCP?
- Evolution from QC to EQC to IQCPs
- Overview of the IQCP process
- 7 Tips
- Expected outcomes

Risk Based QC Program

- EQC started as

"Electronic Quality Control"

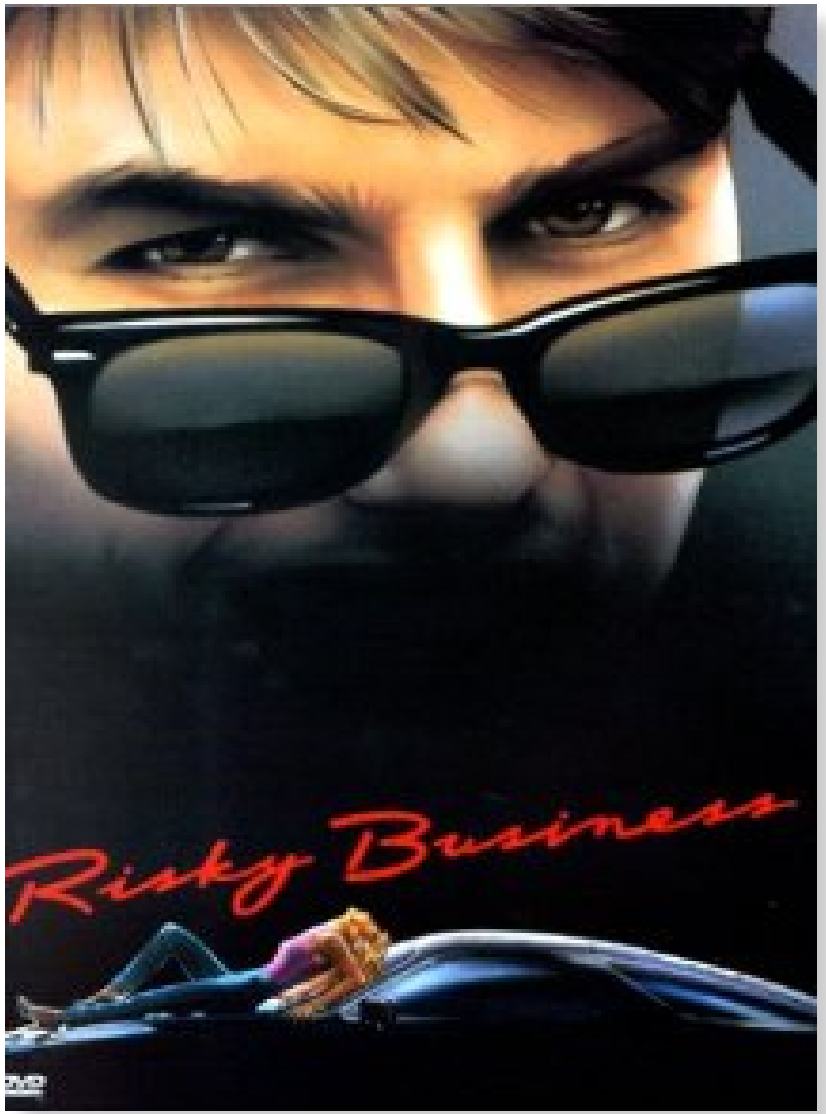
then became…

- **"Equivalent Quality Control"**

expanding to procedural and internal processes monitors…

- and now is:

A QC program based on a comprehensive risk assessment.



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2----21----16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-54-CLIA

DATE: **August 16, 2013**

TO: **State Survey Agency Directors**

FROM: **Director - Survey and Certification Group**

SUBJECT: **Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option**

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

CMS Memorandum Summary

- **IQCP:** The Centers for Medicare & Medicaid Services (CMS) new quality control option for laboratories based on risk management. (CLSI EP-23A)
- **Interpretive Guidelines:** The IQCP Interpretive Guidelines, contain procedures for laboratories and guidance for surveyors.
- **Education and Transition Period:** Began on 01/01/2014, and will conclude on 01/01/2016.
- **Adopted by TJC 3/24/14**

http://www.jointcommission.org/quality_control_option_changing_for_clinical_laboratories/

Individualized Quality Control Plan

CMS is implementing a new 3 part quality control option based on risk management.

Part 1: a comprehensive risk assessment for the test system

Part 2: the IQCP provides flexibility in Quality Control (QC) policies and procedures

Part 3: Quality Assessment of the plan's effectiveness

Regulatory Background: Phase-out of EQC & move to IQCP

- As IQCP policy is phased in during 2014 and 2015, the current **Equivalent Quality Control (EQC) option will be phased out and no longer permissible under CLIA.**

- IQCP will be voluntary and will only impact non-waived testing.

- Laboratories will have two options for quality control testing:

    1.) Following traditional CLIA QC regulations

    2.) Developing their own IQCPs


IT'S A WAIVED TEST, NOT A WAVE TEST!!
TESTING
© 2006 STEVE SKELTON

IQCP's: Are they really optional?

- Per regulatory, implementing IQCPs is voluntary
- For facilities using EQC, the added costs of reverting to daily QC prohibitive
- Many facilities may have to discontinue affected testing
- Effectively, IQCP may be compulsory for institutions to maintain the current near-patient testing and availability of point-of-care testing devices

Process approach required

- Healthcare facilities that are considering IQCP's will need to develop a strategy for implementation for each test, and potentially, each test location that will be covered by an IQCP

- **Where are we to begin??**

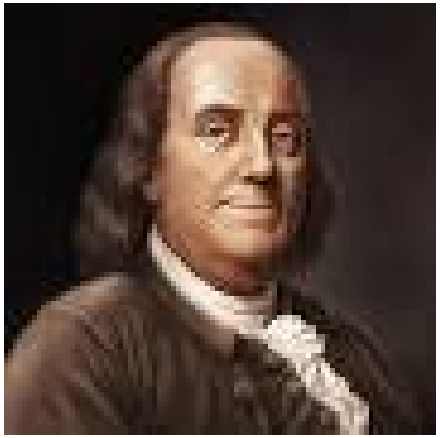
The IQCP development process
7 essential tips:

1. Develop an IQCP Implementation Strategy
2. Organize an IQCP Implementation Committee
3. Create an IQCP Policy
4. Prepare a checklist of resources
5. Establish a data collection and document control system
6. Divide risk assessment into logical sections
7. Design report templates

1. Develop an IQCP Implementation Strategy

“If you fail to plan, you are planning to fail!”

- Benjamin Franklin



Understanding the scope of an IQCP will allow buy-in from key stakeholders in the process and help build consensus.

1. Develop an IQCP Implementation Strategy

- Inventory each risk or source of error
- Make a list of measures taken to mitigate those risks
- Estimate the residual risk after mitigation
- Gather data to support your determined QC frequency
- Document each component of your IQCP
- Evaluate the effectiveness of your IQCP

1. Develop an IQCP Implementation Strategy

In this effort, the focus should be on **'process'**.

In fact for the final IQCP document, one could argue that the **'means'** you use to arrive at your IQCP are more important than the **'ends'**.

2. Organize an IQCP Implementation Committee

- CLIA Laboratory Director is ultimately responsible for the IQCP
- Creating an IQCP will require the participation and approval of a cross functional team
- Different risk categories may call for participation from different staff with appropriate expertise
- Given the clinical, legal and regulatory considerations with developing an IQCP, it would be prudent to share responsibility as appropriate with members of your management team

2. Organize an IQCP Implementation Committee

Potential committee members:

- Laboratory Director
- Regulatory Affairs Coordinator
- Chief Nursing Officer
- Nurse Manager
- Medical Director
- Laboratory Manager
- Point of Care Coordinator
- Infection Control Practitioner
- Department Managers
  Chemistry, Hematology, etc.
- QA Director
- Quality Manager
- Respiratory Therapy Manager
- Nursing Education
- Pharmacy Manager
- Materials Manager
- Phlebotomy Supervisor
- Laboratory Supervisors
- Engineering, Facilities
- Service Line Directors

2. Organize an IQCP Implementation Committee

According to the CMS Interpretive Guidelines[1]:

"Laboratories must involve a representative sample of testing personnel in the process of conducting the risk assessment. It is not necessary for all personnel to be involved."

1: CMS Survey & Certification Letter 13-54, August 16, 2013: Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

3. Create an IQCP Policy

- The first task of your IQCP committee should be to draft an IQCP Policy for your institution.

- The policy provides opportunity to think through your implementation strategy and the roles and responsibilities of your IQCP committee members.

- Your 'IQCP Policy & Procedures' can also satisfy a number of documentation requirements mandated by the IQCP regulations.

3. Create an IQCP Policy

Your policy should cover:

- The purpose and the scope of your IQCP's
- Define roles and responsibilities
- Include regulatory and accreditation agency references

It should also include:

- Establish IQCP development committee
- Titles of committee members (for your facility)
- Define committee and work groups expectations
- Explain the IQCP approval process

3. Create an IQCP Policy

In addition, your IQCP Policy might also address:

- The test systems covered by IQCP's
- The locations covered by the same IQCP vs. those that require separate IQCP's
- Your procedure in the event of a testing process failure (e.g., physician review of all patient test results since the last acceptable QC, etc.)
- How you will monitor and evaluate the effectiveness of your IQCP over time

How many test devices are you planning to cover with IQCP's?

a.) 1 - 3

b.) 4 - 6

c.) 7 - 9

d.) 10 - 12

e.) 13 or greater

How many different locations under your oversight will require IQCP's?

a.) 1 - 3

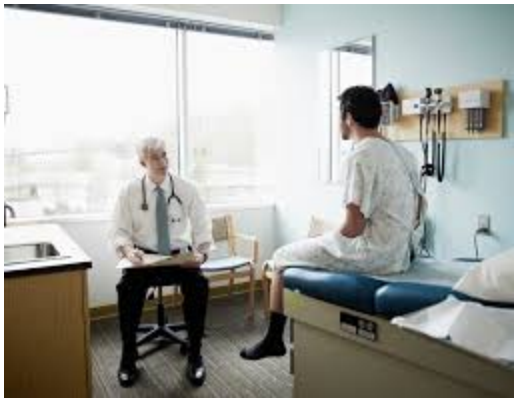
b.) 4 - 6

c.) 7 - 9

d.) 10 - 15

e.) 16 - 20

f.) 21 or greater



3. Create an IQCP Policy

A risk assessment walk-through can help determine possible *location specific* differences for each method.

Consider:

- Number of testing personnel performing testing
- Education and experience of testing personnel
- Environmental instability
- Lower test volumes
- Physician complaints
- Patient population differences

4. Prepare a Checklist of Resources

- Regulatory and/or accreditation agency requirements
- Manufacturer's package inserts
- Manufacturer's operator manuals
- Troubleshooting guides
- Manufacturer's/FDA alerts, bulletins & recalls

4. Prepare a Checklist of Resources

- Verification or establishment of performance specifications
- Personnel qualifications, training & competency records
- QC and Proficiency Testing data
- Quality Assessment information, including corrective action
- Scientific publications

5. Establish a Data Collection and Document Control System

Variables to consider in QC frequency:

- CMS requires your own in-house data
- Variation (SD, CV%) of historical QC results
- Whether you establish your own QC means and ranges, or use the control manufacturer provided ranges
- QC acceptance criteria and Westgard Rules employed
- History of test system performance in your location (e.g., QC issues, patient look backs, etc.)

5. Establish a Data Collection and Document Control System

Your supporting data could take many forms:

- Manufacturer's minimum recommendations for QC
- Total allowable error (Sigma targets, etc.)
- For multi-analyte test systems using multi-analyte controls, which analytes are more likely to cause errors or increased variation

5. Establish a Data Collection and Document Control System

More variables to consider when assessing frequency of external QC include:

- Number of patient samples tested between QC checks
- Number of levels of QC used and rotation of levels
- Analytical measurement range verification
- Medical decision point for the test

5. Establish a Data Collection and Document Control System

More variables to consider when assessing frequency of external QC include:

- The number of unreliable patient test results that can be tolerated between QC checks
- Severity of harm to patients should an error go undetected for a period of time
- Response plan when an out of control determination is made (e.g., patient test result recheck, physician notifications, retesting, etc.)

5. Establish a Data Collection and Document Control System

Information that you may include from your Quality Assessment Review:

- Quality control review
- Specimen rejection logs
- Personnel competency records
- Proficiency testing records
- Patient test result review
- Turnaround time reports
- Records of preventive measures, corrective actions & follow-up

6. Divide Risk Assessment into Logical Sections

- Manufacturers identify sources of errors and take steps to mitigate those risks by design, good manufacturing practice (GMP), and quality assurance of the test system

- Whatever risk the manufacturer cannot mitigate completely becomes the 'residual risk' that is passed on to the end user of the test device

- Basically you pick up the risk mitigation process where the manufacturer left off

6. Divide Risk Assessment into Logical Sections

risk assessment risk as•sess•ment [risk *uh*-**ses**-m*uh*nt]:
noun
1. the identification and evaluation of potential failures and sources of errors in a testing process.

At a minimum risk assessment must include:

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

6. Divide Risk Assessment into Logical Sections

The scope of risk assessments must encompass the entire testing process:

- Preanalytic phase
- Analytic phase
- Postanalytic phase

The Laboratory Director has the responsibility for ensuring that the risk assessment considers the CLIA requirements for accurate and reliable results and that test result quality is appropriate for patient care.

6. Divide Risk Assessment into Logical Sections

- Breakdown task into manageable sections
- Focus attention on specific areas of interest
- Utilize committee members relative to organizational roles and responsibilities

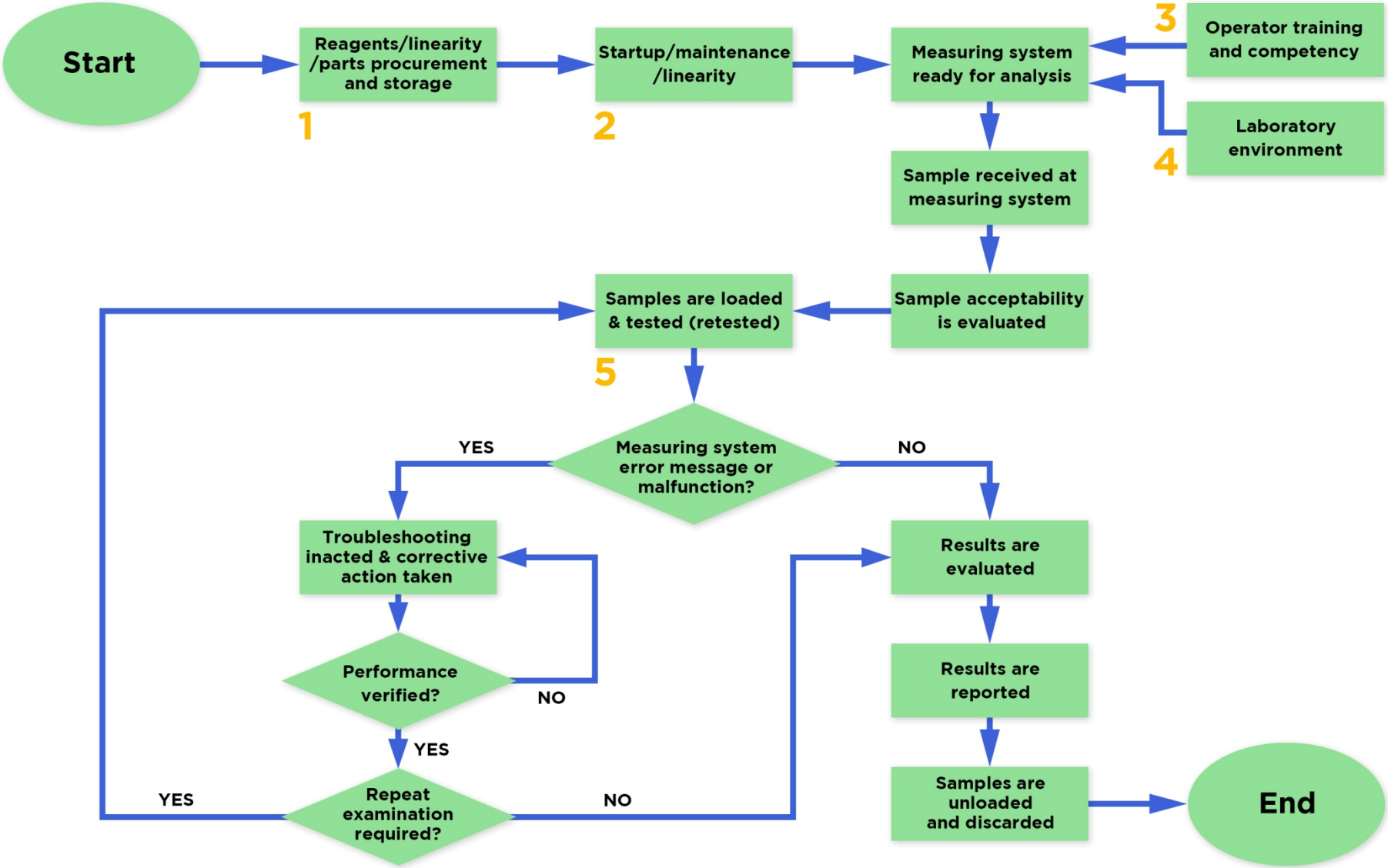
6. Divide Risk Assessment into Logical Sections

Suggested list of the risk categories:

- Patient ID
- Sample Collection
- Sample Presentation
- Test Result Review
- Testing Personnel
- Instrument Operation & Failure
- Hospital Acquired Infections
- External Quality Control
- Device Configuration
- Reagent Degradation
- Environmental Variables
- Proficiency Testing
- Other Risks

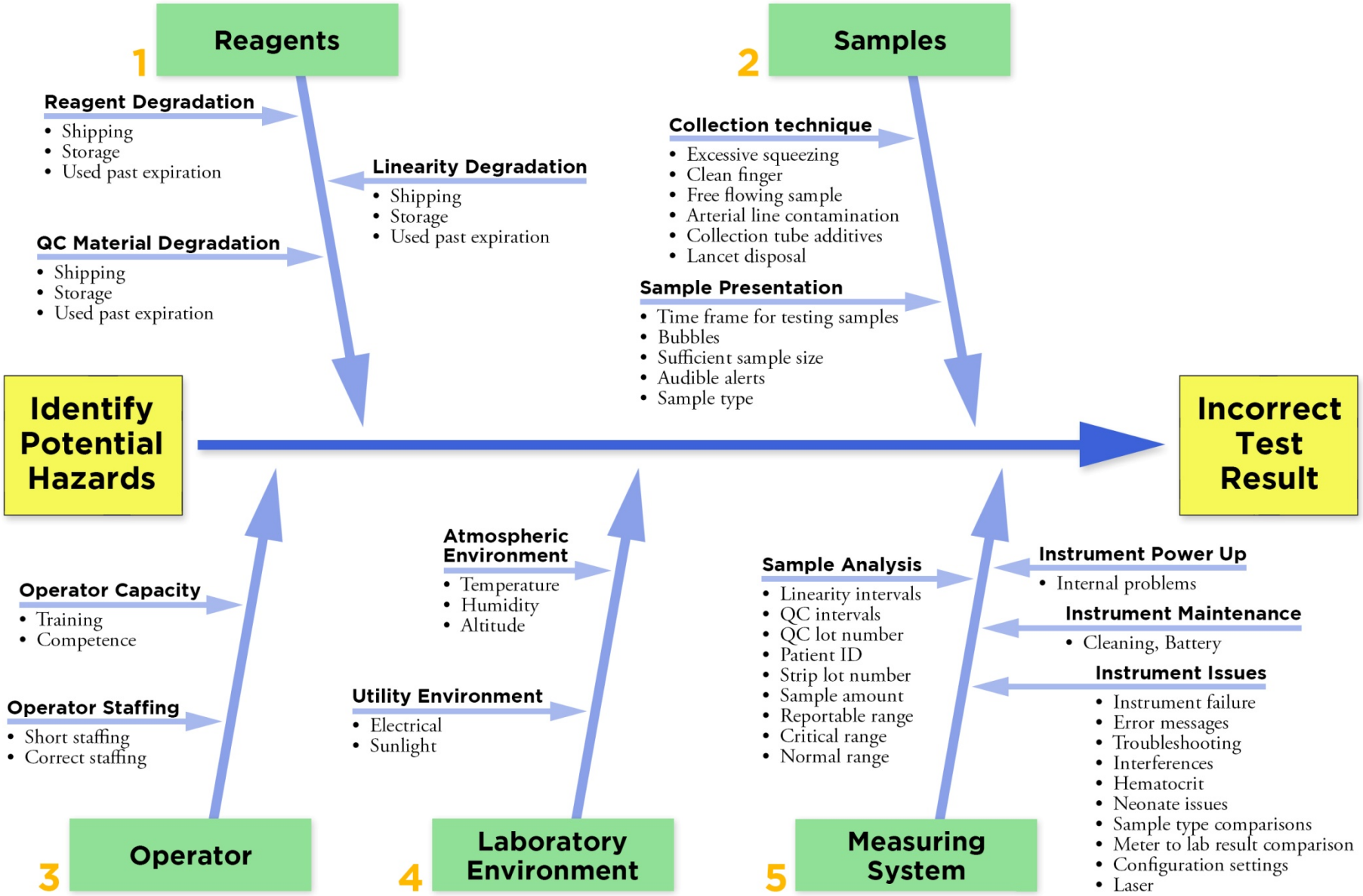
Nova Biomedical StatStrip Glucose Meter

Process Map: High-Level Measurement Procedure



Nova Biomedical StatStrip Glucose Meter

Fishbone Diagram: Identification of Potential Failure Modes



7. Design Report Templates

a.) Risk Mitigation Report

b.) Residual Risk Report

c.) Suggestion Report

d.) Action Plan

e.) Individualized Quality Control Plan

7 a.) Risk Mitigation Report

Itemizes actions that the laboratory is taking to prevent errors in the test system.

- This information will be essential **when defending IQCP's during inspections.**

- The Risk Mitigation Report should be reviewed and verified on a regular basis.

7 b.) Residual Risk Report

Documents remaining potential for error after measures have been taken to mitigate risk within a process.

- **Residual Risk =**
  frequency x severity x detectability

- Identifying residual risk by sections will focus attention on problem areas, where additional mitigating actions could have the most impact.

7 c.) Suggestion Report

A list of actions that the laboratory is not currently performing, but could consider employing to further reduce the residual risk of the test system.

7 d.) Action Plan

A list of initiatives that the laboratory intends to implement over time to further mitigate risk. This plan might also assign a responsible person and a target date for completion.

7 e.) Individualized Quality Control Plan

Defines each component of your 'QC Toolbox' that you utilize to ensure the quality of patient test results.

This could include:

- Liquid quality control
- Electronic quality control
- Proficiency testing
- Linearity testing
- Maintenance
- Personnel training/competency
- Quality assessment review

In Review the 7 Tips:

1. Develop an IQCP Implementation Strategy
2. Organize an IQCP Implementation Committee
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4. Prepare a checklist of resources
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7. Design report templates

SUMMARY

- The process of creating an IQCP for the first time can be daunting and challenging!
- There are few samples, templates, and precedents available for reference.
- Hospitals and laboratories developing IQCP's will need to blaze new trails within their institutions.
- Implementing risk mitigation processes and generating IQCP's will demand dedicated time and resources.

SUMMARY

Investing time in Individual Quality Control Plans can yield many dividends including:

- Improved efficiency and effectiveness of QA measures
- Standardization of QC protocols
- Optimization of QC frequency
- Potential cost savings
- and, most of all:

Positive impact on patient outcomes!

Thank You, Questions??

Resources:

- White paper:

"Seven Essential Tips for Developing and Implementing IQCP's"

www.ezqcp.com/whitepaper01

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