SIEMENS

October 2, 2013- 1:00 PM EST

EP-23 & IQCP

“You Are More Ready Than You Know!”

Answers for life.

Introduction

Key Learning Objectives

- EP-23 overview
- Plan development
- Putting a plan into action
- Case studies of Risk Assessment based Quality Plans using Informatics

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Agenda

EP23

- What is it?
- Why is it?
- How do we use it?
- What's the impact?

What is EP-23?

EP23-A Laboratory Quality Control Based on Risk Management

CLSI Guidance document providing a process to develop an overall Quality Control Plan (QCP) for the laboratory using risk management principles

It is …

- Flexible
  - Can design QCP to meet needs of any clinical laboratory situation
- Adaptable
  - New testing and QC technologies can readily be incorporated
- Meets Regulatory needs
  - Built on well established principles and accepted by CMS
- Leverages current QC practices
  - Incorporates and enhances current protocols

Why is it?

- Value Stream Management
  - Doing the best, right process with minimal resources to achieve the best outcome

- Rate of Change in Healthcare
  - Processes change swiftly and often
  - New Federal requirements American Recovery and Reinvestment Act (ARRA) and Affordable Care Act (ACA) shift the focus

- Technology Change
  - Technologies offer new and changing tools for quality management

How do we use EP-23?

Assess the Risk to Mitigate It

- The Test: Manufacturer's quality control recommendations, storage requirements, potential areas of error, predictive value, how is it documented, how it will be used

- Your Organization's Regulatory Requirements: What are the quality control and assurance requirements

- Who Will Perform Testing: What is their level of experience with laboratory testing, education, and foreign concepts

EP-23 Impact

Oct. 24, 2011 - EP 23-A published

- Risk Management approach to develop a Quality Control Plan

Nov. 4, 2011 - CMS announces commitment to move to IQCP

- EP23 will be approved guidance for developing an individualized QC plan (IQCP).
- EQC will be phased out

Aug. 23, 2013 - CMS announces, "Effective January 1, 2014, laboratories with a Certificate of Compliance (COC) or a Certificate of Provider Performed Microscopy Procedures (PPM) will begin a two year education and transition period to learn about and develop their IQCP, if this is the option they elect to implement. COC and PPM Laboratories can also begin implementation of an Individualized Quality Control Plan (IQCP) as a Quality Control (QC) option prior to January 1st if they so choose."

- Lab may begin IQCP now

Agenda

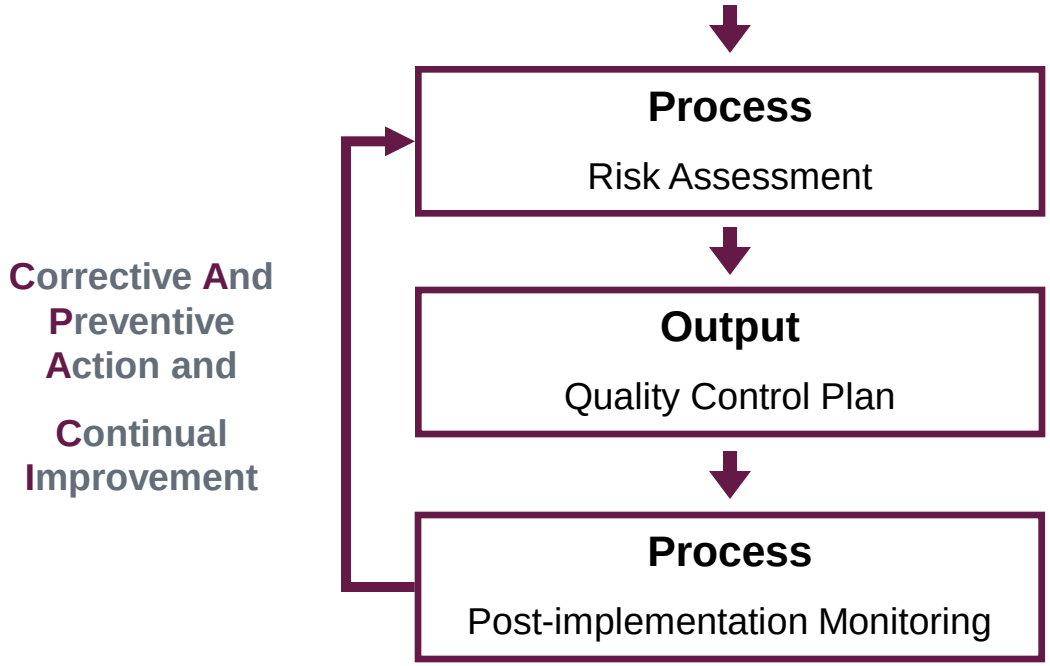
Developing an IQCP

- Where to begin?
- What to catalog?
- How to use the information?
- What does a formal IQCP Risk Assessment look like?

EP-23 Guideline

Measuring System Information

- **Medical Requirements for the Test Results**
- **Regulatory and Accreditation Requirements**
- **Measuring System Information**
  - Provided by the Manufacturer
  - Obtained by the Laboratory
- **Information About Healthcare and Test Site Setting**

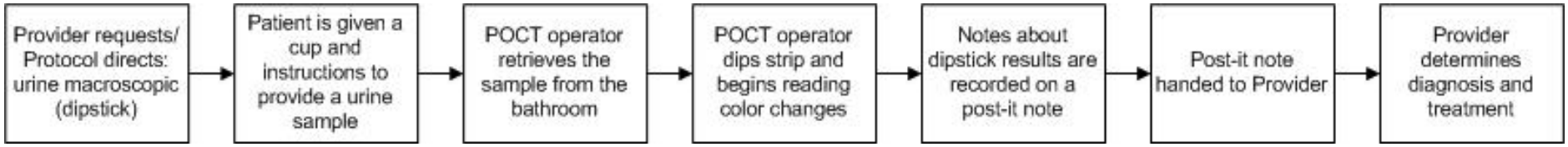


Corrective And Preventive Action and Continual Improvement

Mitigates identified risks

Where to begin?

Document the process



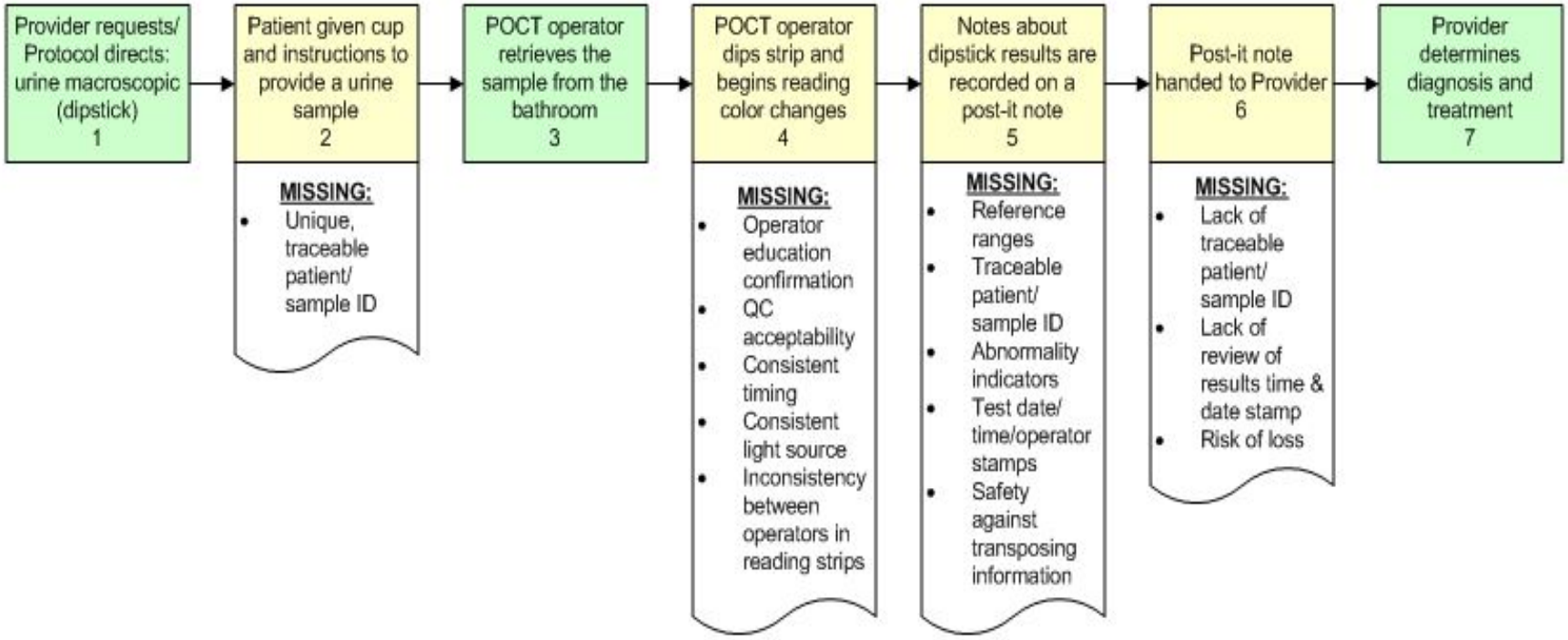
Continue documenting the process

Define and Grade the Risk, Color code the steps with errors or risks

Risk & Frequency	1 No patient harm	2 rare potential of patient harm	3 Low risk of patient harm	4 Moderate risk of patient harm	5 High risk of patient harm
A = Never	1A	2A	3A	4A	5A
B = Rare	1B	2B	3B	4B	5B
C = Occasional	1C	2C	3C	4C	5C
D = Frequent	1D	2D	3D	4D	5D
E= Regular	1E	2E	3E	4E	5E

Continue documenting the process

Define and Grade the Risk, Color code the steps with errors or risks



Examine the test

POC devices were principle drivers in starting the project

- Manufacturer's quality control recommendations
- Storage requirements
- Potential areas of error
- Predictive value
- How is it documented
- How it will be used
- Who will be performing it

Key concept:

- By understanding the test, its uses and operators, risk for errors can be identified

What to Catalog?

Table 1. Sources for Collecting Information for Risk Analysis

Information	Source
Regulatory and accreditation requirements • Mandated QC procedures • Required quality assurance activities • Regulatory agency recall and device failure notifications	Regulatory authorities; accreditation agencies
Measuring system information • Intended use (including limitations, warnings, and precautions) • Environmental requirements • Instructions for calibration, maintenance, use, and reagent storage • Calibrator traceability information • QC features • Risk mitigation recommendations	*In vitro* diagnostic (IVD) manufacturer
Laboratory information • Environmental conditions, including facilities and utilities, and existing controls • Installation/operational qualification reports • Operator training and competency • Internal performance evaluation/verification data • External performance data (eg, proficiency test results) • Process map covering the steps analyzed	Laboratory
Publications and reports from laboratory peers • Published performance evaluations • Published clinical studies • Other users (eg, user groups, listservs, forums)	Laboratory
Clinical information • Clinical applications for use of a test result • Biological reference intervals and clinical decision levels • Foreseeable medical errors that could result from incorrect, delayed, or no results • The severity of patient harm that would result from the hazardous situations	Laboratory, in consultation with medical users of the test results

How to Use that Information

From EP23: ***"Each QC tool has strengths and weaknesses. There is no perfect QC tool that consistently prevents or detects all failures. Understanding their strengths and weaknesses allows use of the tools to effectively reduce risk."***

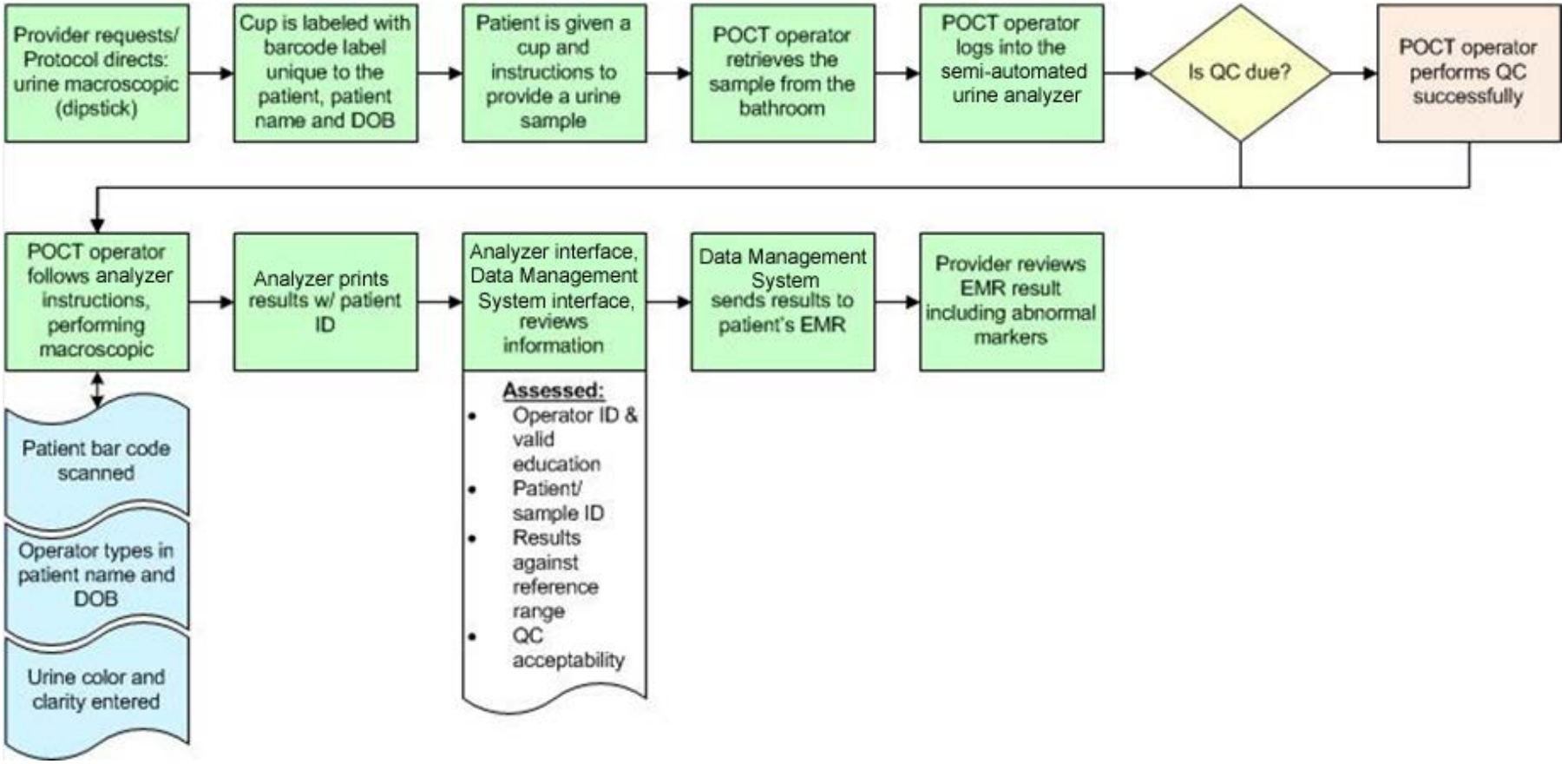
- Determine the best QC schedule to identify failures before they effect a patient
- Determine the best QC process to identify failure
- Determine the best tools and supplies to facilitate a QC process

What does a formal EP-23 Risk Assessment look like?

An Illustrative Example of a Urine Macroscopic (Dipstick) Measuring System						
Step #	Targeted Failure Mode (Hazard)	Measuring System Feature or Recommendation Action	Known Limitation of Feature or Recommended Action	Control Process Effective?	The QCP Actions Required to Address Known Limitation	Residual Risk Acceptable ? (Yes/N0)
4	Consistent interpretation of dipstick pad among operators	Use semi-automated urine analyzer to perform urine macroscopic (dipstick) testing	Use of a semi-automated urine dipstick reader ensures consistent interpretation of individual pad reading.	Complete	Site implemented control process: Implement Semi-automated use for all urine dipstick testing. Monitor staff compliance by individual.	YES

What does a formal IQCP Risk Assessment look like?

Post Risk Mitigation Process flow Map



What does a formal IQCP look like?

Urine Macroscopic Exam Quality Plan

Definition: General Hospital uses the Siemens Clinitek Status+ Connect in tandem with the PEP and RAPIDComm products to produce a more discretely managed quality plan. This replaced the manual urine dipstick reading and communication process.

Effective Date: January 1, 2013

Description: Based on the information provided in Sections F through I, General Hospital has determined the processes defined in Sections A-E to provide the best Quality Control Plan for its operation.

Section A: Maintenance

1. Follow the Siemens Operation Manual maintenance schedule with defined points to check lamp output, clean barcode readers, and clean dipstick travel pathway.
2. Monitor room and refrigerator temperature daily via the continuous monitoring system employed by General Hospital.
3. Monitor room and refrigerator humidity daily via the continuous monitoring system employed by General Hospital.

Section B: Operator Training

1. Provide PEP module assignment to all users to be completed within 60 days of initial orientation and annually thereafter to ensure technical competency.
2. Provide one-on-one demonstration of testing process to all users to be completed within 60 days of initial orientation and annually thereafter.

Section C: Electronic Control

1. The Clinitek Status+ Connect will perform self testing with each test to ensure proper function of all components contained within its system prior to initiating patient testing.

Section D: QC Samples

1. Two levels of commercially prepared QC material will be performed each day of patient testing, prior to patient testing.
2. Two levels of commercially prepared QC material will be performed upon opening a new container of reagent test strips (dipsticks), prior to patient testing.

Urine Macroscopic Exam Quality Plan 2013

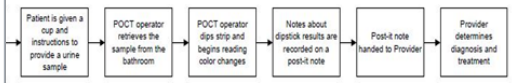
1

linitek Status + Connect will assess all QC results and determine acceptability and
ment the results in the RAPIDComm system.
linitek Status+ Connect will disable additional testing if two consecutive QC tests are
eptable and corrective action(s) has been taken and documented.
perator or POCC can document corrective actions in the RAPIDComm system QC chart.
ral Hospital may choose to use blind samples created from retained patient samples of
n values, to assess quality concerns as defined in the General Hospital Laboratory Quality
gement policy # 12123.

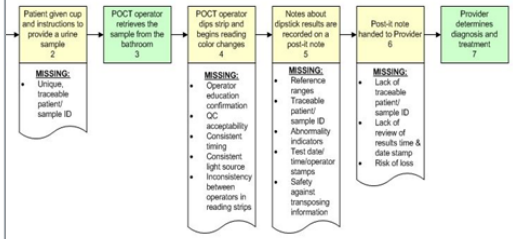
ernal Quality Assessment

ral Hospital employs and external quality assessment program, or Proficiency Testing to
s the performance of the Clinitek Status+ Connect, its reagent strips and operators on a
annual basis from both a known value assignment and peer group perspective.

ial Process Flow



k Assigned Process Flow

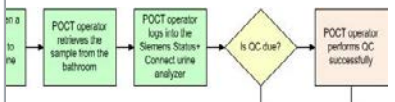


k Assessment

nt A.

opic Exam Quality Plan 2013

2



3

Agenda

Putting the IQCP into Action

- Modify the process or practice
- Train operators
- Placing new tools in use
- Monitor the effectiveness of the Plan

Putting the IQCP Quality Plan into Action

- Modify the process or practice
  - Switch from a manual to automated process
  - Add management software to add safety features like QC lock-out
- Train operators
  - Use an operator management software, such as PEP, to train, track, and certify operators
  - Use vendor created training videos to enhance computer based education
- Placing new tools in use
  - Implement PEP* training
  - Implement automated devices with safety features activated
  - Queue regular operations pointers, factoids, tidbits or alert emails to enhance performance

*PEP – Personalized Education Plan or PEP is a free Siemens Healthcare service to assist in managing operator education and certification.

Putting the IQCP into Action

Evaluate Effectiveness

- Review method performance data to verify QCP detected issues
- Survey clinical customers with regards to clinical correlation of results
- Investigate all clinical complaints
- Track and trend issues and complaints looking for patterns

Investigate Unacceptable Performance – Take Corrective Action

Review and revise the QCP as needed

Appendix E. Example of Failure Investigation and Corrective Action for Glucose Measurement on an Automated Measuring System

Scenario: A 10-member health care provider group practice with an automated glucose measuring system in an office laboratory. Clinical medical assistants perform glucose testing. This health care provider's office is using a quality control plan (QCP) as developed in Appendix B and shown in Appendix D.

A 45-year-old diabetic woman visits the clinic, complaining of nausea, night sweats, thirst, and increased frequency of urination. A glucose test performed in the office laboratory has a result of 220 mg/dL (12.2 mmol/L). On the way to her car, the woman collapses in the garage; her partner summons an ambulance, and she is brought to the emergency room. Her admission glucose measured in the hospital's clinical

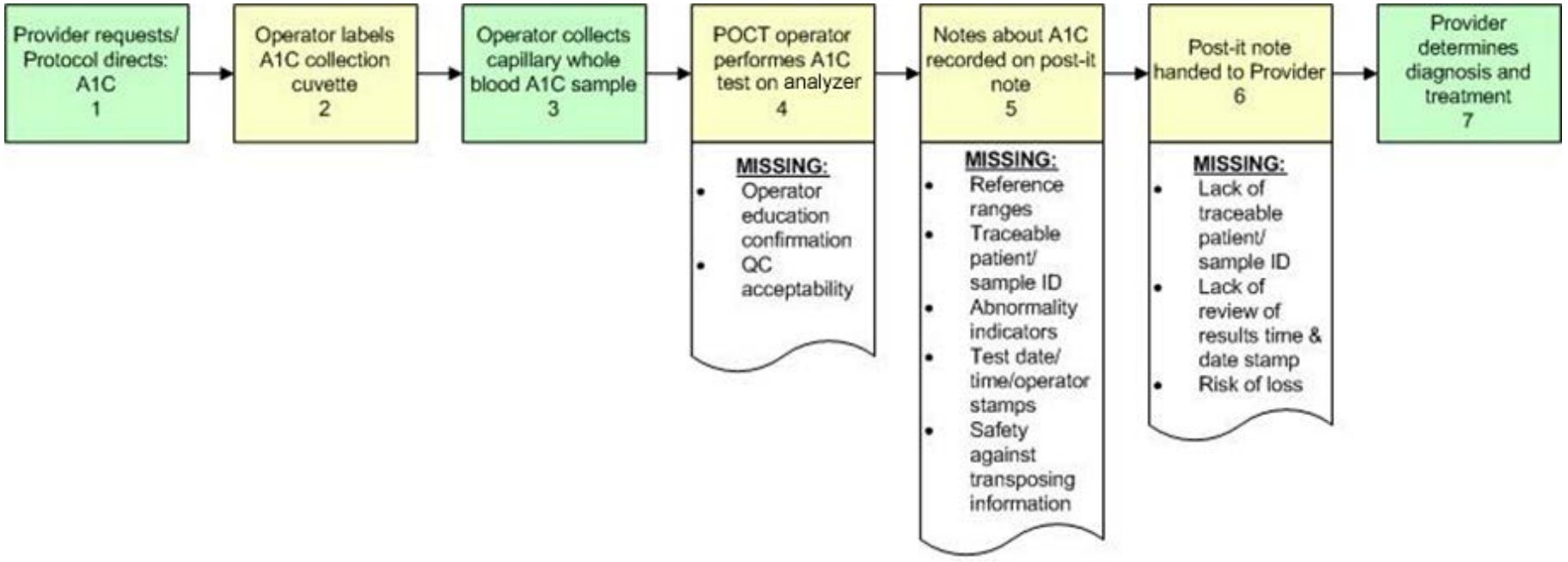
Agenda

Case Studies using Informatics

- Diabetes management with A1c and Urine Microalbumin
- Blood Gases

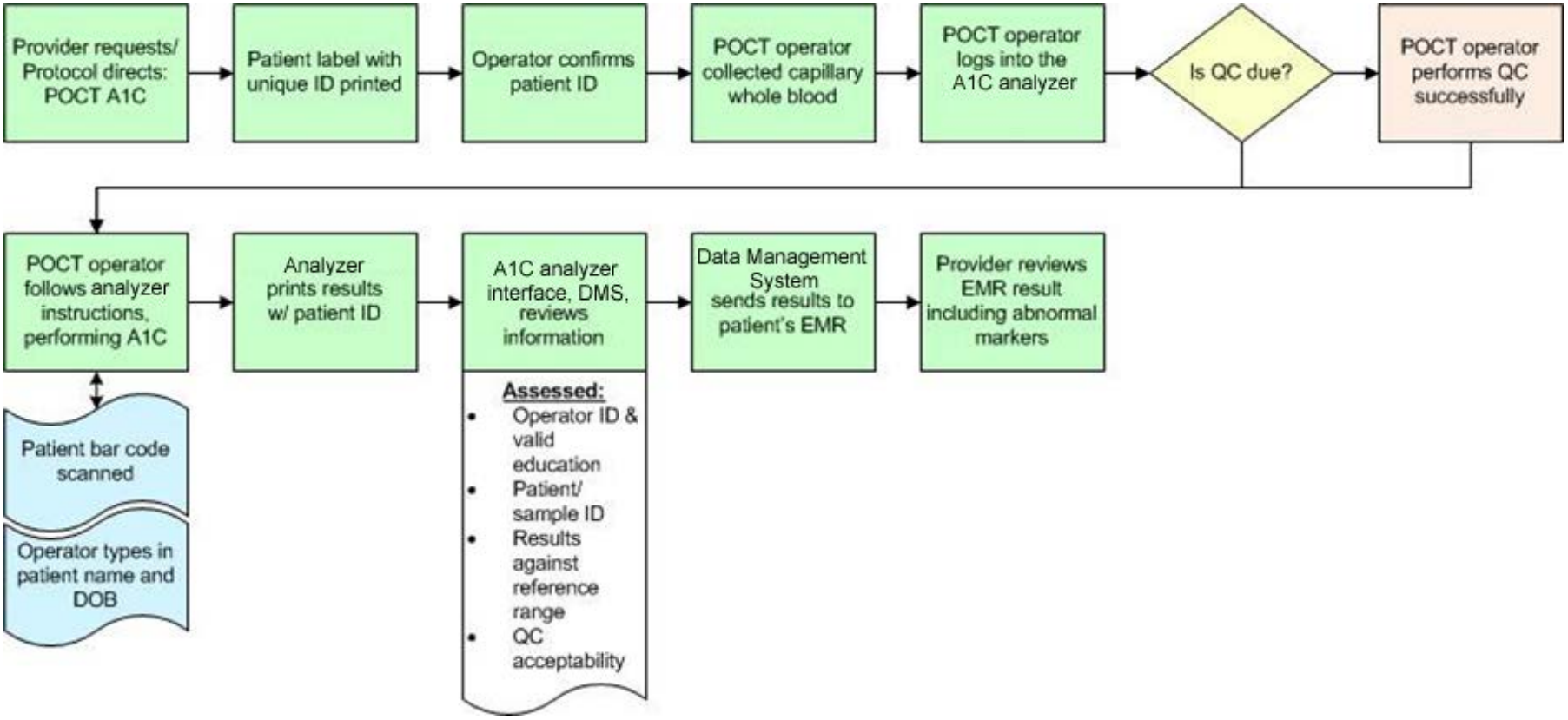
Diabetes Management Use Case

Document the process

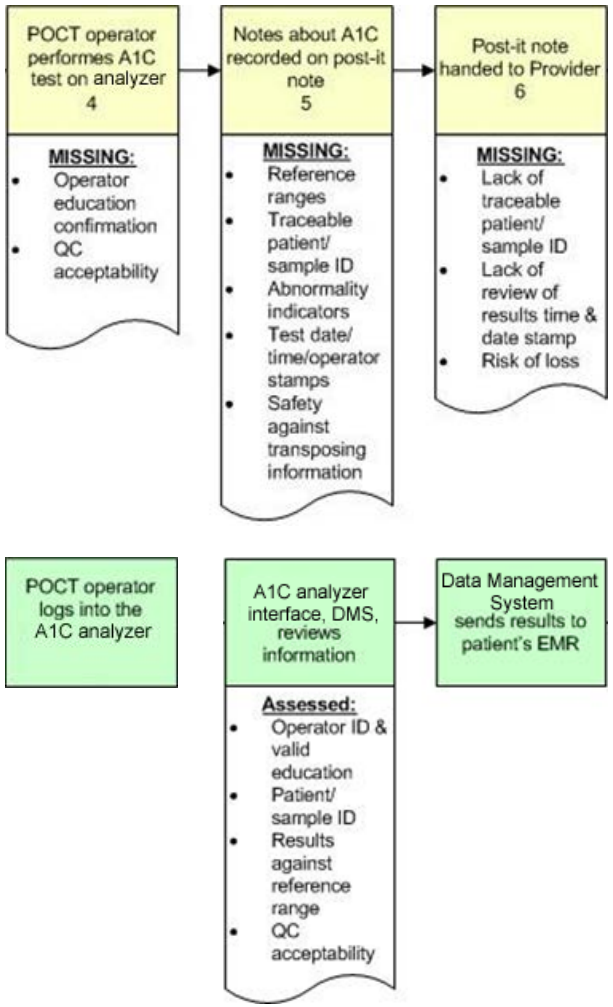


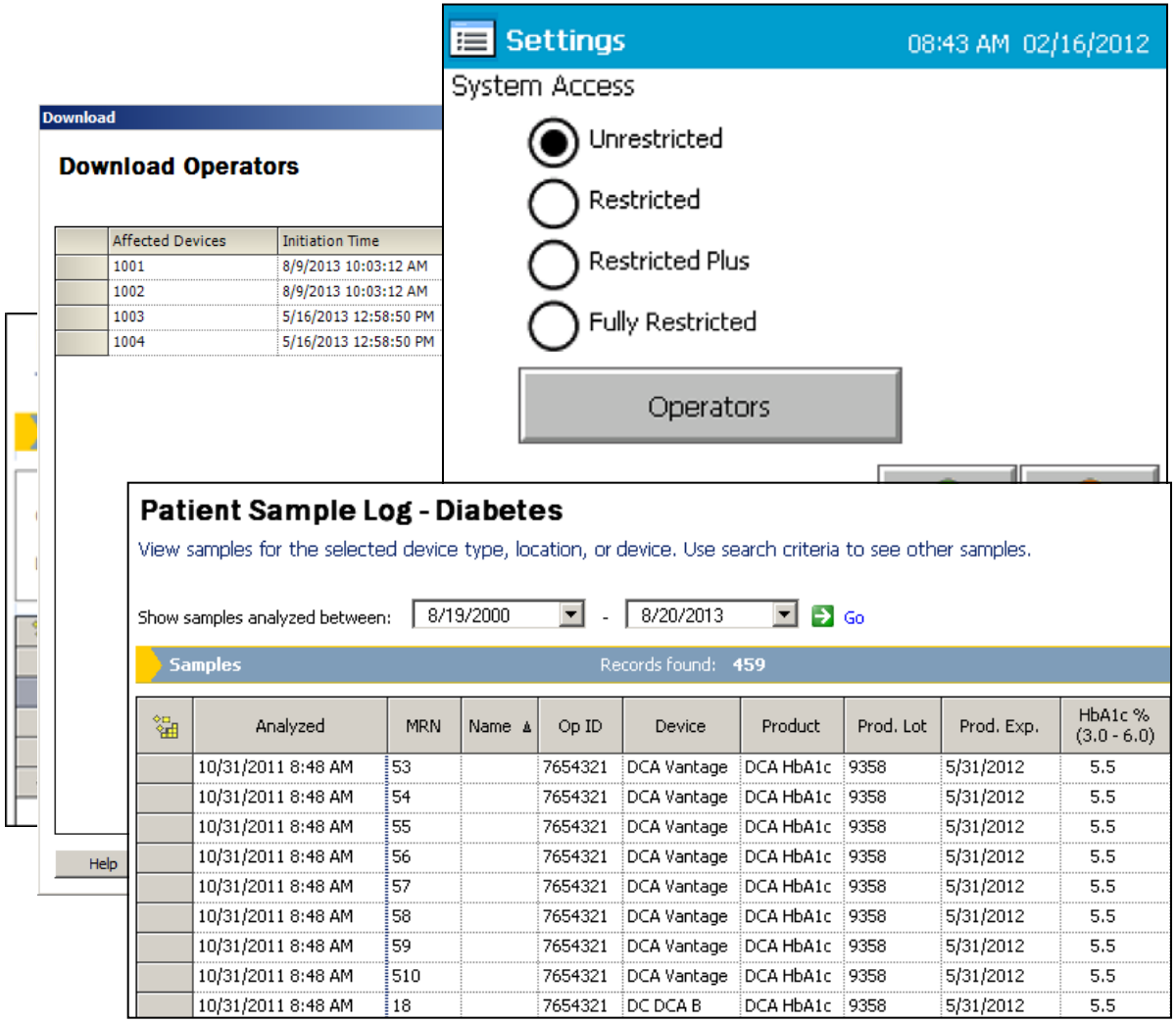
Diabetes Management Use Case

Post Risk Mitigation Process flow Map



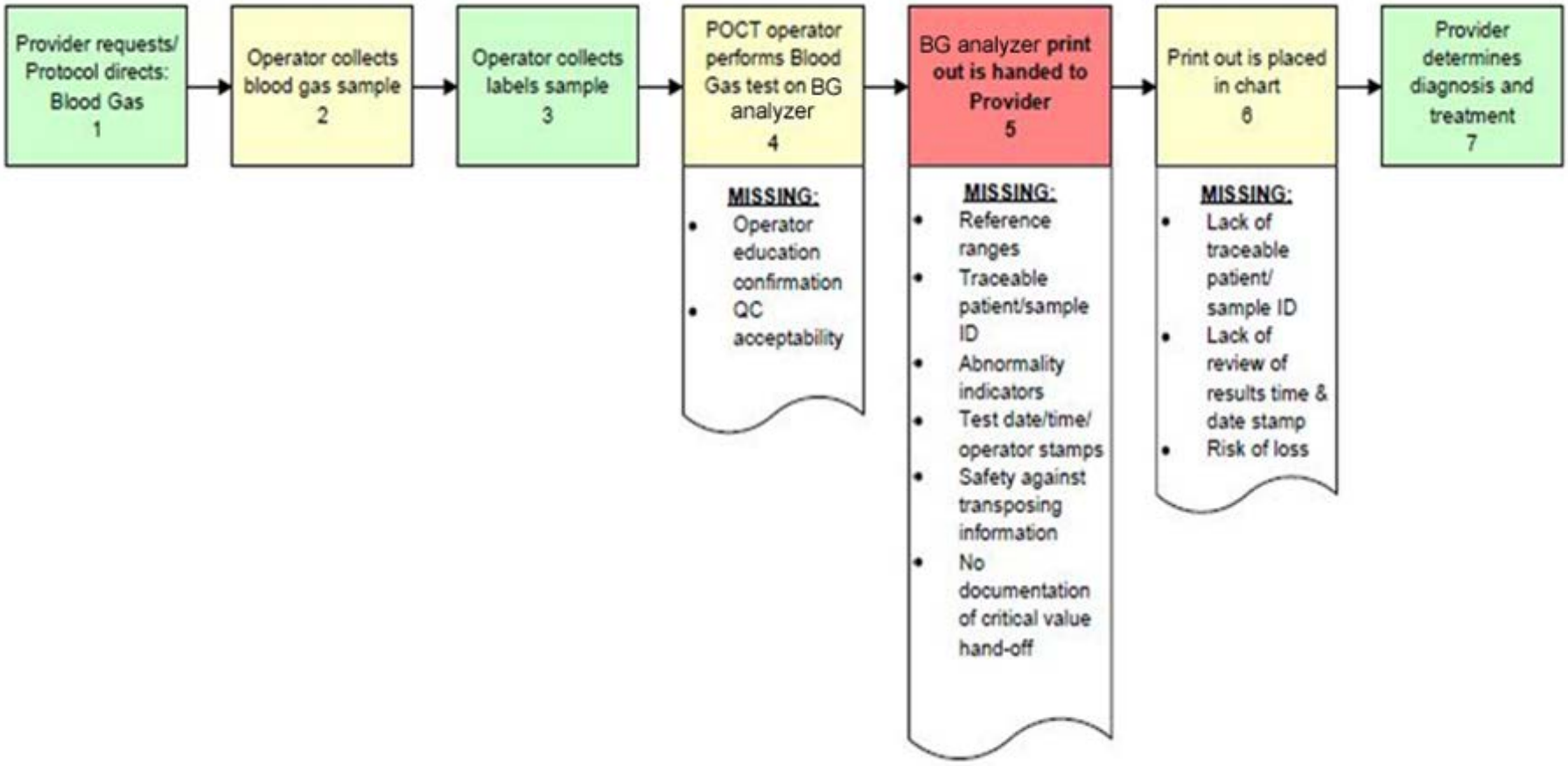
Diabetes Management Use Case





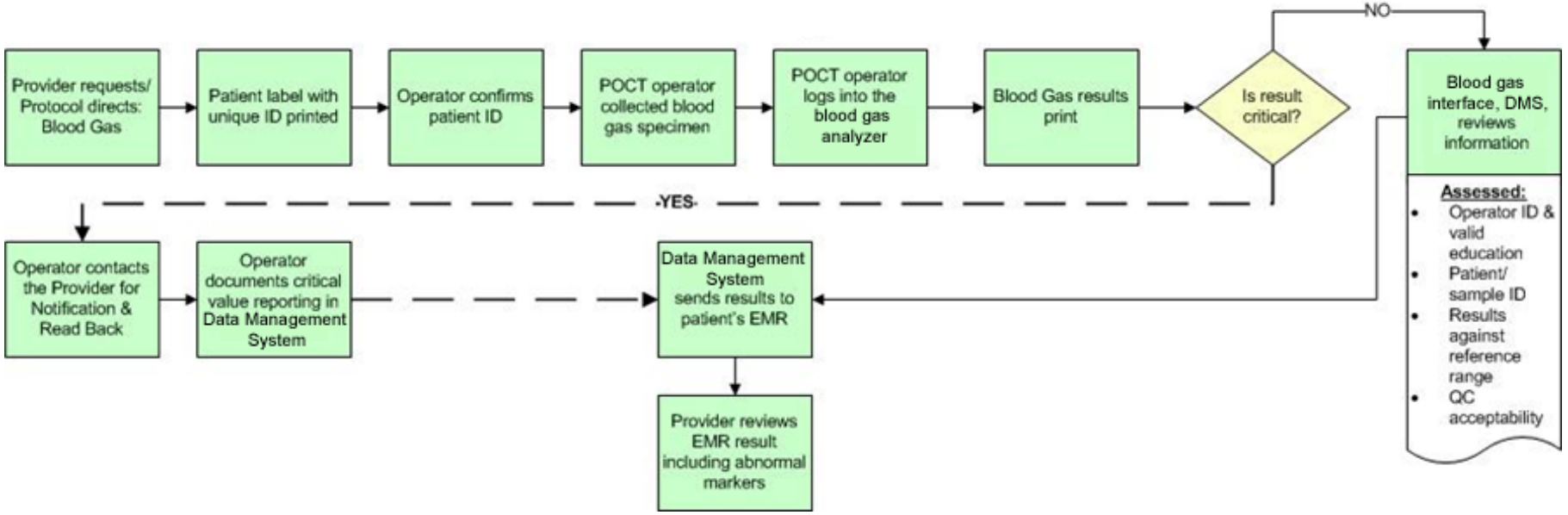
Blood Gases Use Case

Document the process

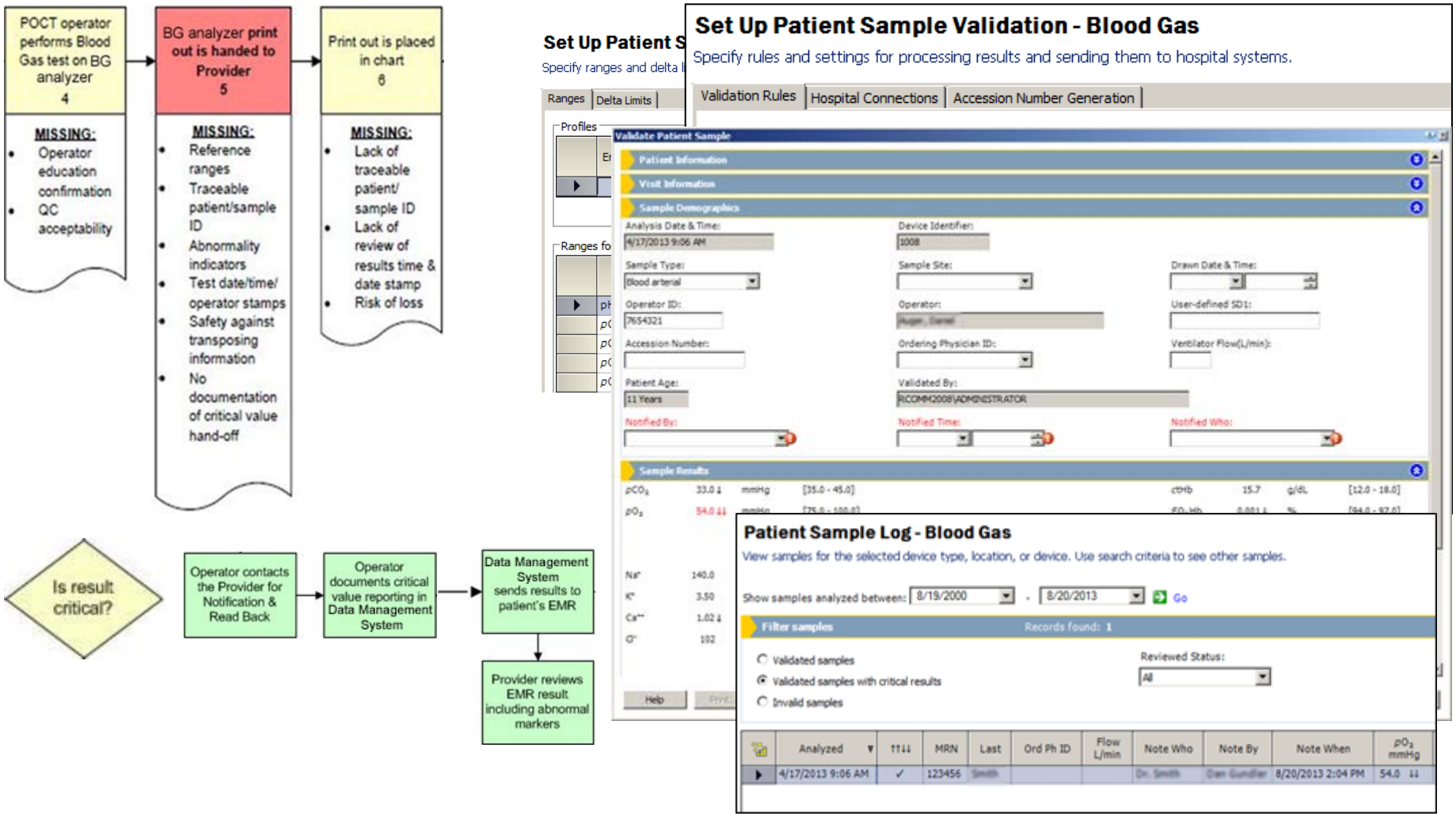


Blood Gases Use Case

Post Risk Mitigation Process flow Map



Blood Gases Use Case



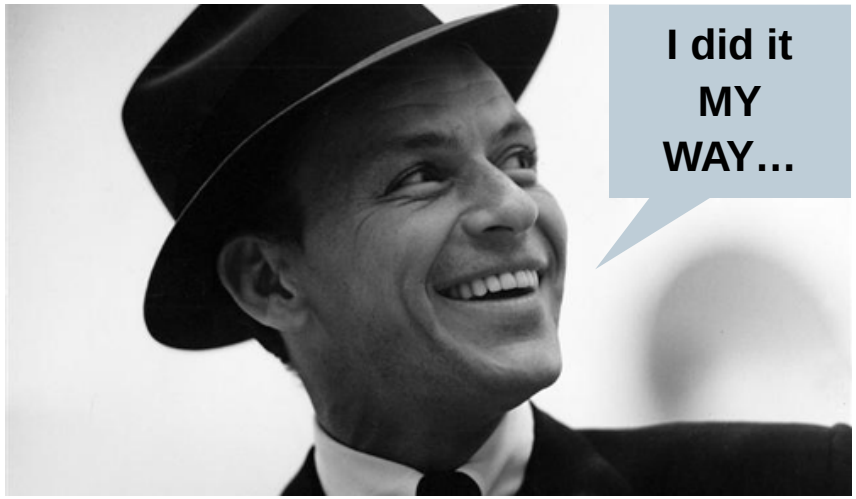
Agenda

Where to find help

CLSI Companion Products for EP23

- Workbook
- Checklist
- CLSI Workshops/Seminars
- For information go to www.CLSI.org

Summary



You Can Do QC YOUR WAY!

BUT you have PROVE what you are doing actually works.

- EP 23 and Individualized QC Plans represent a maturing of CMS's expectations of testing sites
- Instead of mandating "one size fits all" QC that really doesn't work well for anyone, now there is a CLIA approved way to do QC that allows each testing site to decide what works best
- You have to document it does the job

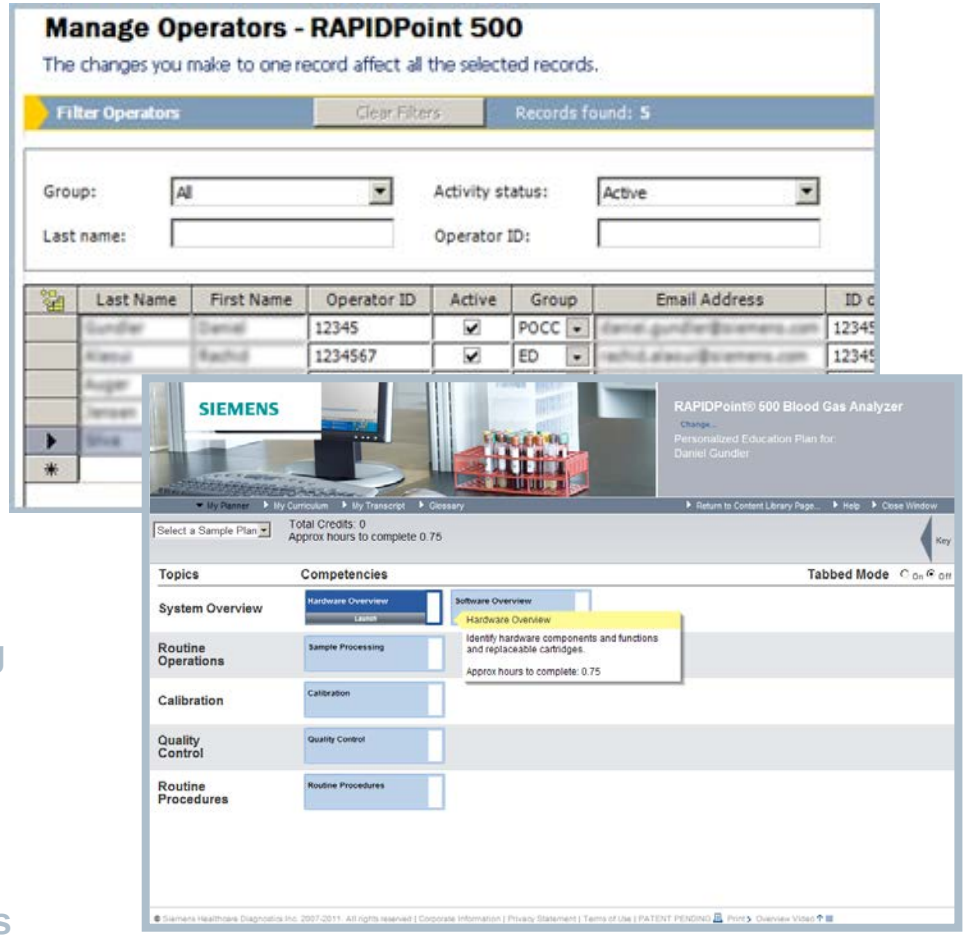
You are more ready than you know!

Daniel C. Gundler
Business Manager
Informatics - Point of Care
Siemens Healthcare Diagnostics

Siemens POC Ecosystem™ Solutions

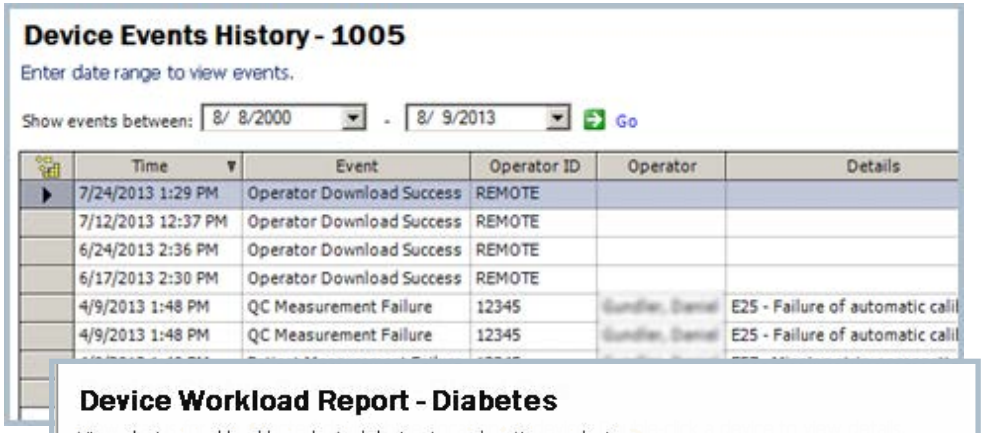
RAPIDComm® and the POC Ecosystem™ Solutions

- Automated Operator Download
- Operator Lockout
- Training Date
- Trainer Recording
- Automatic Recertification
- Certification History
- Assessment Date
- Assessor Recording
- Custom User Views
- Role Based Privilege Assignment
- Interface to PEPa, Siemens Web-based LMS
- Competency Based Training
- Create & Assign e-Quizzes
- Auto-updates of Training & Recertification
- Recertification Information
- Proficiency Testing
- Personalized Learning Plans



RAPIDComm® and the POC Ecosystem™ Solutions

- Robust Connectivity
- Maintenance Scheduling & Recording
- Configurable Priorities for Device Events
- Software Firmware Version Tracking
- Remote Configuration of Devices
- Linearity Testing for Blood Gas
- Consumable Monitoring
- Consumable Alerts
- Material Usage Reports
- Device Workload Reports

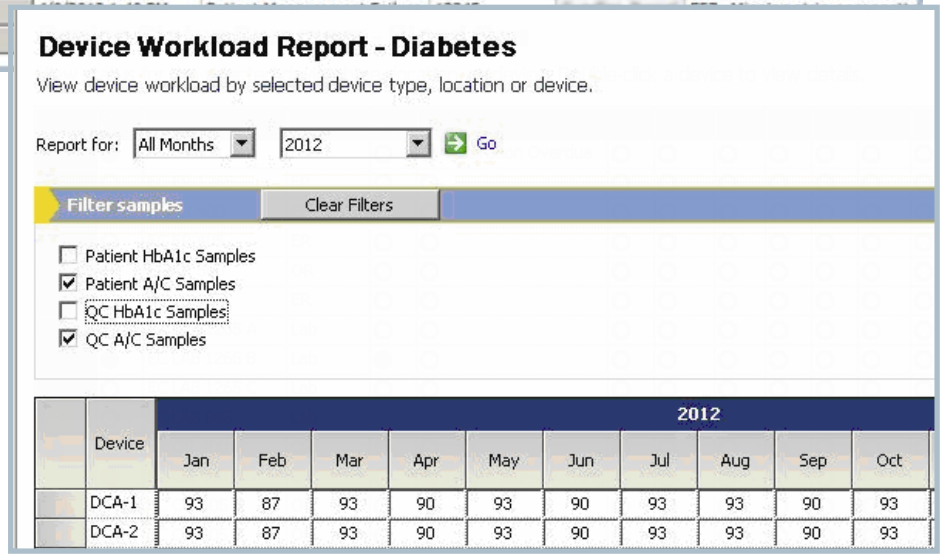


Device Events History - 1005

Enter date range to view events.

Show events between: 8/ 8/2000 - 8/ 9/2013 Go

Time	Event	Operator ID	Operator	Details
7/24/2013 1:29 PM	Operator Download Success	REMOTE		
7/12/2013 12:37 PM	Operator Download Success	REMOTE		
6/24/2013 2:36 PM	Operator Download Success	REMOTE		
6/17/2013 2:30 PM	Operator Download Success	REMOTE		
4/9/2013 1:48 PM	QC Measurement Failure	12345	[redacted]	E25 - Failure of automatic calil
4/9/2013 1:48 PM	QC Measurement Failure	12345	[redacted]	E25 - Failure of automatic calil



Device Workload Report - Diabetes

View device workload by selected device type, location or device.

Report for: All Months 2012 Go

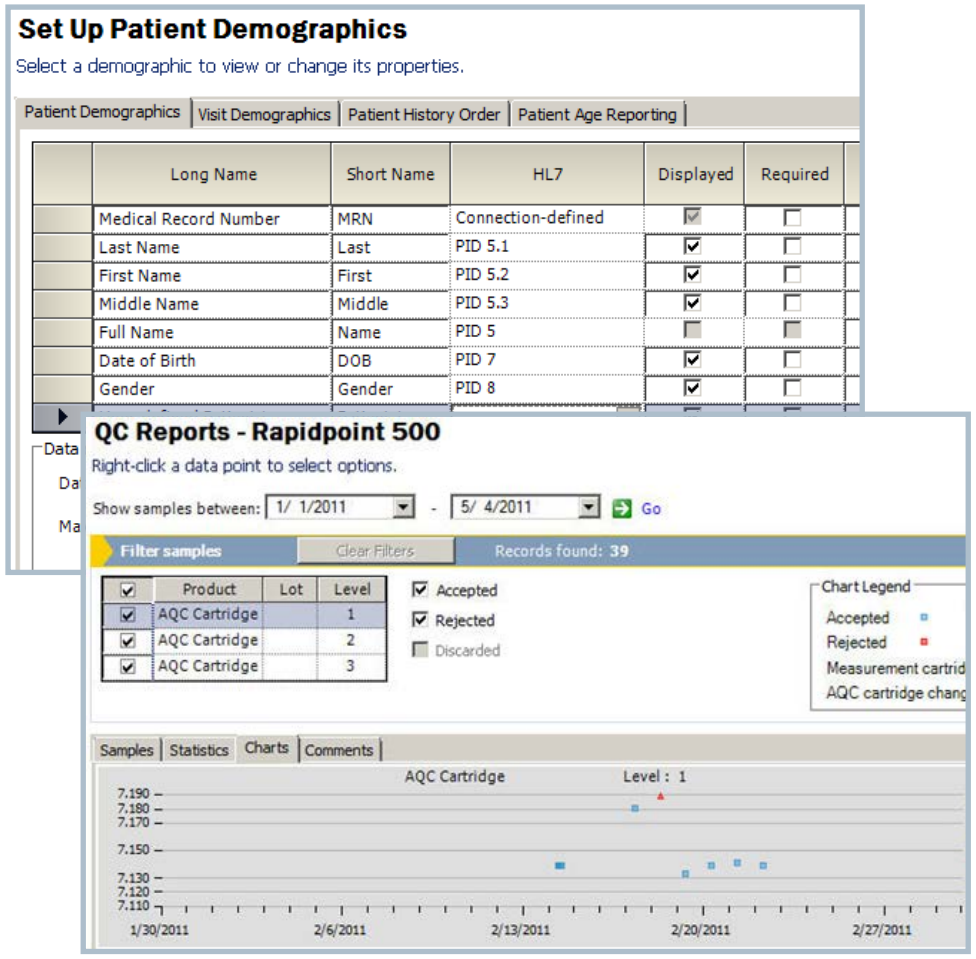
Filter samples | Clear Filters

- ☐ Patient HbA1c Samples
- ☑ Patient A/C Samples
- ☐ QC HbA1c Samples
- ☑ QC A/C Samples

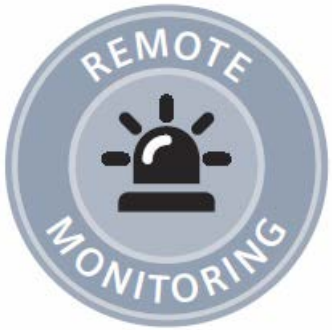
Device	2012									
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
DCA-1	93	87	93	90	93	90	93	93	90	93
DCA-2	93	87	93	90	93	90	93	93	90	93

RAPIDComm® and the POC Ecosystem™ Solutions

- Custom Report Designer
- Calibration Reports
- Maintenance Reports
- Proficiency Reporting
- Audit Trail
- Customized Screens & Add Required Fields
- Advanced Rules Wizard
- Advanced Sample Management
- Mask Sensitive Data
- QC Data Management
- Configurable Compliance Criteria
- Advanced Rule Result Processing
- QC Charts, Statistics
- QC Exporting for Peer Comparison Programs
- Electronic Recorded Reviews



RAPIDComm® and the POC Ecosystem™ Solutions



- Wireless Connectivity
- Web Application
- Hand-held Device Support
- Web Browser Access
- Hand-held Remote View & Control
- Configurable Dashboard
- Audible Alerts
- Remote View
- Remote Control
- Remote Commands

More information about RAPIDComm?

www.usa.siemens.com/RAPIDComm