The Individual Quality Control Plan (IQCP)

QMS' New QC Option for Test Sites Inspected for CLIA Compliance

AT7045 REV A

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January 1, 2016 – Effective date for IQCP implementation

January 1, 2016 marks the implementation of the Centers for Medicare and Medicaid Services (CMS) ***new*** QC Option, the Individual Quality Control Plan (IQCP).[1] The IQCP is applicable to test sites using OPTI Analyzers and inspected for compliance with the Clinical Laboratory Improvement Amendments (CLIA). COLA also has adopted the IQCP, so the IQCP is also applicable to sites accredited by COLA.[2]

What does this mean for OPTI Analyzer users?

On January 1, 2016 the *current* Equivalent Quality Control (EQC) option to meet CLIA (and COLA) QC requirements will no longer be valid. After the 2016 implementation date, CMS will not accept EQC for meeting CLIA QC requirement, §493.1256(d).[1,3] The good news is that sites currently using the OPTI Analyzers' built-in quality assessments to meet CLIA's daily QC requirements can continue to do so provided these instrument assessments are included in their IQCP.

What is IQCP?

IQCP is the ***new*** QC option for non-waived test devices such as the OPTI CCA-TS, OPTI CCA-TS2, and OPTI LION. With this new option, CMS expands the role of QC beyond the analytical phase of the testing process. CMS states that an IQCP is specific for a testing device and testing situation.[1] It is a strategy that incorporates the practices, resources, and procedures followed during the *entire testing process* to ensure quality. The intent is to eliminate failures and detect nonconformities *before* reporting incorrect results. CMS mandates that IQCPs be developed by "in-house" personnel using information collected "in-house". While each IQCP is unique due to the "distinctiveness" of every testing situation, test sites can use any available (web-based, user-group, manufacturer, etc.) information and/or tools.

What is the basis for IQCP?

CMS structured IQCP on the risk management concepts presented in the Clinical and Laboratory Standards Institute (CLSI) EP23-A guideline, *Laboratory Quality Control based on Risk Management.* [4] CMS provides all the necessary information to develop an IQCP.[1] The development process is discussed later in this document. Do remember that CLSI is not a regulatory body and the purchase of EP23-A is not necessary to develop an IQCP.

What are risk management concepts?

RISK MANAGEMENT (RM) concepts encompass the systematic identification, analysis, evaluation, control, and monitoring of risks/potential errors throughout the testing process.[1,4] Risks or errors are any factors that can potentially impact the testing process and affect test result quality. The good news is that test sites continually (but often unknowingly) use RM concepts. Developing standard operating procedures (SOPs) is a prime example.

Is an IQCP mandatory?

NO, BUT…although the ***new*** IQCP QC option is *voluntary*, just remember that the current EQC option will no longer be acceptable after January 1, 2016. Until that time, test sites can *continue* to use EQC to meet CLIA's daily QC requirements. At that time (January 1, 2016), OPTI Analyzer test sites **NOT** wanting to develop an IQCP will need to perform CLIA's default QC, which for most analytes is a minimum of 2 levels of QC per day of testing. QC for blood gas analysis differs. The CLIA regulations specify the requirements in § 493.1267, below:[3]

> (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;
> (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing;
> (c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes;
> (d) Document all control procedures performed, as specified in this section.

Does my test site need to develop an IQCP? My site is inspected by College of American Pathologists (CAP), The Joint Commission (TJC), etc.?

CMS developed the IQCP QC option for those laboratories inspected for CLIA compliance. COLA now includes IQCP as a QC option. It is assumed that other accrediting organizations (AOs) WILL incorporate IQCP as a QC option. It is important for testing sites accrediting by an AO to monitor their organization's requirements. Also when AOs embrace IQCP, the specific requirements for IQCP development may differ somewhat from those of CLIA.

Where is the IQCP development information?

The *essential* information needed for IQCP development is in the CMS memo of August 2013.[1] (For COLA accredited laboratories, the information can be found in the latest COLA Laboratory Accreditation Manual.[2]) After the official CMS implementation date (January 1, 2016), CMS will include the development information in the revised CMS Interpretive Guidelines (Appendix C of the State Operations Manual).[5]

What are the steps in IQCP development?

EP23-A provides an overview (**Figure 1**) of the development process.[3] So that the IQCP can be developed on appropriate facts, the process begins with gathering **information** on medical and regulatory requirements, test device/system capabilities, and the testing environment. The **risk assessment** (RA) process identifies risks/errors that potentially can impact test quality in all three phases of the testing process. Once the potential risks are identified, test sites review their current SOPs, policies, practices, and procedures and the OPTI Analyzers' built-in quality assessments and error mitigation features to determine which risks are eliminated and/or detected. For those risks/errors identified in the RA but NOT detected or eliminated, the test site then assesses the significance of each. For those judged to be significant, test sites need to implement additional risk mitigations.

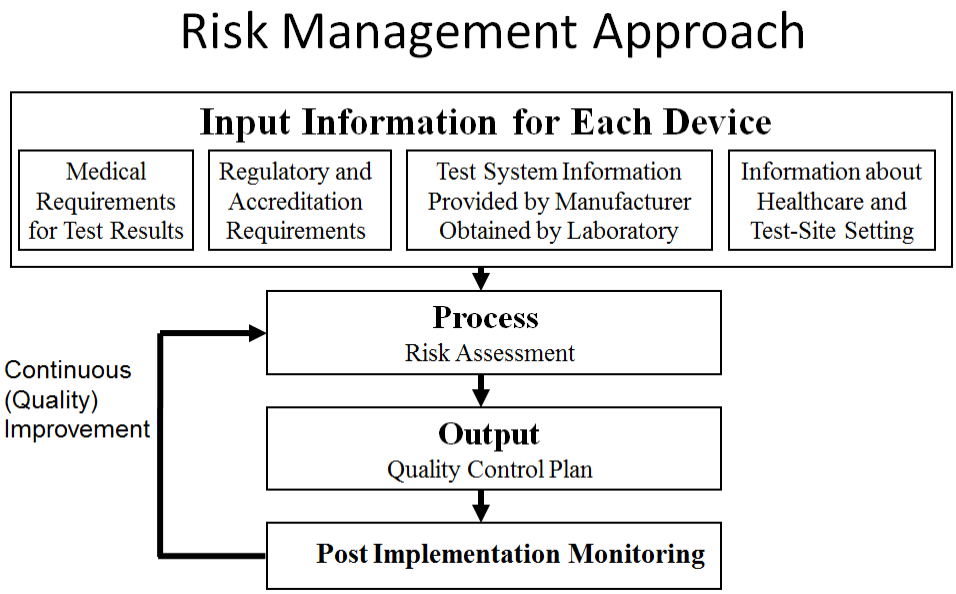

Figure 1: Overview of the IQCP Development Process[4]

A **Quality Control Plan** (QCP) is the next step that details the test site's specific approach to ensure analytical quality. CMS states that the QCP must ensure accuracy and reliability of test results and test result quality as appropriate for patient care; provide for immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance; and monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance. The QCP component of the IQCP must at least include the number, type, frequency of testing and criteria for acceptable results(s) of the quality control(s).

The last component of the IQCP is **quality assessment**. This step is no different then what CMS requires for test sites to evaluate the effectiveness of all their practices. **Figure 2** shows the typical Plan-Do-Check-Act cycle employed by most test sites for quality assessment and quality improvement.

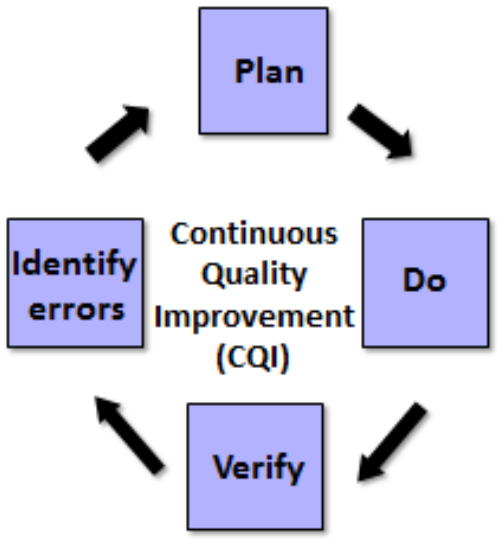

Figure 2: Quality Assessment Cycle for Continuous Quality Improvement

How are the IQCP process and findings documented?

The last step of the development process is to put everything together. The IQCP summarizes the development process and findings and demonstrates compliance with the CMS requirements. The details of the specific changes resulting from the RA are detailed in the site's policies, procedures and practices. Test sites have flexibility in presenting the information in their IQCP, since CMS provides no specified or official format. The IQCP and accompanying documentation are essential for surveyor "buy-in." The IQCP documentation needs to be saved for the "life" of the instrument and then two additional years.

CMS/CLIA IQCP Development Process

Figure 3 shows an overview of the IQCP development process.[1,4] It begins with collecting facts so that "correct" information is used in making the final decisions for the IQCP. The information is specific to each analyte, testing device, and testing situation. It centers on clinical, regulatory, and organizational requirements along with the OPTI Analyzer's capabilities in terms of analytical quality checks and error mitigation/detection. The final IQCP must meet needs (accuracy, precision, reportable range, timeliness of reporting, etc.) of the clinicians ordering the testing. All appropriate CLIA regulatory requirements including personnel training and competency assessments; specific regulatory mandates associated with the pre-analytical, analytical, and post-analytical phases of testing; and organizational/environmental requirements (safety, confidentiality, patient identification, environmental conditions, analysts, etc.) must be met. Realize that OPTI Analyzer's approach to assessing quality and mitigating / detecting errors is an essential component of the development process features.

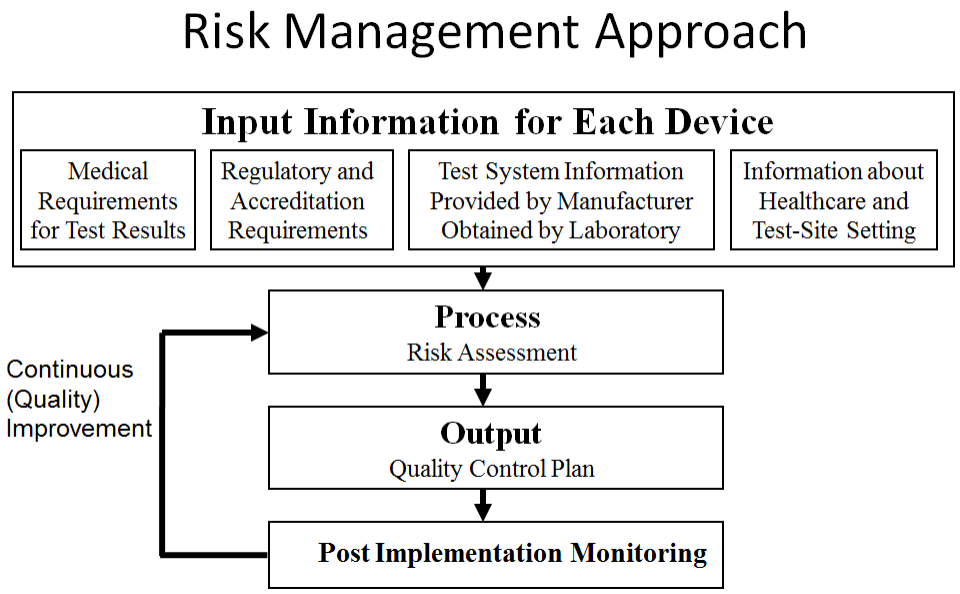

Figure 3: Overview of the IQCP Development Process[4]

CMS surveyors will scrutinize closely the development process and final IQCP as part of their CLIA compliance inspection of the test site. Therefore it is essential that the process and information collected are documented, understandable and available for surveyor review. Start with a folder labeled for IQCP of your OPTI Analyzer. This folder can be a 3-ringed binder, an expandable folder, or a file on the computer. The key to successfully passing inspection is that the information collected throughout the process is complete, organized, defensible and readily available for inspector review. For completeness, it should contain minutes from all meetings associated with IQCP development. It may be useful to include the appropriate CLIA regulations (reference # 3) and the CMS IQCP memo (reference #1) that identifies requirements.

CMS suggests some possible sources of information/facts necessary for the development process.[1]

- Regulatory requirements - identify CLIA requirements that impact blood gas testing;
- Manufacturer's package inserts - determine intended use, limitations of test methodologies, environmental requirements, mandated/suggested QC frequency, specimen requirements, reagent storage, instrument maintenance and calibration, substances that interfere with the test methodologies, and any other testing limitations/concerns;
- Manufacturer's operator manual, troubleshooting guide, alerts and bulletins - identify additional input (remember that all manufacturer requirements must be met);
- Clinical usefulness and method performance information – use data collected from verification or establishment of performance specifications, quality control and proficiency testing, and information from quality assessment findings and corrective actions;
- Literature reviews - input for the decision making process;
- Testing personnel qualifications, training, and competency records - input for making decisions for training and the testing environment.

Do realize that clinical and organizational requirements can vary from one test site and organization to another. When testing situations (environment, personnel, etc.) vary even in the same organization, more than one IQCP may be necessary for the same testing device and analyte(s). The collected information is taken into account for the next steps of the development process and should be included in the IQCP documentation file.

Risk Assessment

CMS takes a much broader view of QC with IQCPs because, for example, quality and value of the test result is dependent not only on the "quality" of the analytical process, but on the quality of the sample and the timeliness of the result. Therefore, CMS requires test sites to conduct a risk assessment to identify *potential* errors (risks) that ultimately can impact quality in each phase of the testing process. Many sources suggest that the best identification of these risks is by "phase-expert" teams that are very familiar with one or all of the 3 phases of the testing process. [6, 7] One commonly suggested approach is to have these "expert" teams map the entire testing process to better identify where and what *potential* errors can enter each phase and ultimately impact test result quality.

At a minimum for RA, CMS mandates each test site to consider the specimen, operator, environment, reagents, and test system. [1] For the RA process of identifying *potential* (possible) errors, the "experts" need to keep the clinical, regulatory, and institutional and environmental requirements in mind, since these must be met through the site's practices. In identifying *potential* risks, the "experts" should be in the "brainstorming" mode so not to be constrained. As for most CLIA requirements, CMS provides "clues" through a series of "probes" for surveyors to consider in determining a test site's IQCP compliance.[1]
Figure 4 shows the CMS "surveyor" probes for the 5 mandated RA components. Since surveyors will specifically use these probes during inspections to determine compliance, it is essential that test sites address these probes as part of their *potential* error identification.

Figure 4: CMS "Surveyor" Probes for the 5 CMS mandated RA Components[1]

Specimen

Has the labortory identified and evaluated the potential failures and sources of error in the preanalytical phase as applicable, for:

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

Figure 4 cont'd

Environment

Has the labortory evaluated environmental conditions which may affect test system performance, including but not limited to:

- Temperature
- Airflow/ventilation
- Light intensity
- Noise and vibration
- Humidity
- Altitude
- Dust
- Water
- Utilities (electrical failure/power supply variance or surge)
- Adequate space

Reagent

Factors to consider in the RA for reagents, QC materials, calibrators, and similar materials may include, but are not limit to:

- Shipping/receiving
- Storage conditions requirements
- Expiration date (may differ based on storage requirements)
- Preparation
- Has the laboratory addressed assessed test system failures which may result from reagent, QC material, and clibrator contamination or deterioration and reagent lot variation?

Figure 4 cont'd

Test System

The RA must include function checks and maintenance checks as required by, and not less than, maufacturer instructions. In addition, the RA should take into consideration the laboratory's test volume and intended use of the test results (i.e., screening or diagnostic).

Additional factors to consider in the RA for analyte and test systems may include, but are not limited to:

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
- Calibration associated issues
- Mechanical/electronic failur of test system
  - Optics
  - Barcode readers
- Failure of system controls and function checks
  - Built-in procedural and electronic controls (internal controls)
  - External or internal liquid QC (assayed vs. unassayed)
  - Temperature monitors and controllers
- Software/hardware
- Transmission of data to LIS
- Result reporting

Testing Personnel

Laboratories must involve a representative sample of testing personnel in the process of conducting the RA. It is not necessary for all personnel to be involved. Has the laboratory assessed the risks associated with testing personnel by evaluating the following?:

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

Once the "experts" list the *potential* errors for the 3 phases of the testing process, the next step is to determine whether or not these errors are being mitigated/eliminated/detected by current policies, procedures and practices included by the OPTI Analyzer.

Table 1 (Appendix) identifies OPTI Analyzer's targeted failure modes and error mitigation/detection features for each of the 5 CMS mandated RA components. Sites typically will find that most of the *potential* errors identified by the expert teams are accounted for in their current protocols and testing device. (In reality, the RA process is another check and opportunity to make improvements, where necessary, on current practices.) Remember CMS (CLIA) surveyors will review the RA process and information used for IQCP development. Documentation/proof is essential! Make sure to include everything in the IQCP file.

Table 2 (Appendix) shows an example template for documenting the RA process – *potential* error identification and mitigation. For each *potential* error identified, complete the first 4 columns in the Table. If "yes" is stated in column #4, then the test site needs to indicate where the information can be found, e.g., where training protocols are located, policies and where procedures for sample collection are located, etc. For the *potential* errors listed in column #1 and having a "no" response in column #4 (meaning NOT mitigated with current activities), another step is needed. This step is to determine the significance or impact of each potential error. Realize that not all *potential* risks identified may be significant in terms of devising a mitigation/detection protocol.

There are many approaches to judge the significance of the residual (leftover-not mitigated/detected), *potential* errors. **Table 3** (Appendix) shows one approach, a risk assessment table, based on the probability of occurrence of the error and the severity of harm to the patient due to the presence of that error. The probability of occurrence, ranging from frequent to inconceivable, is described on the Y-axis and defined on the lower left. The X-axis describes the severity of harm and ranges from negligible to catastrophic. Common definitions for harm are shown on the lower right. To use **Table 3**, test sites need to make their best judgment as to the occurrence or frequency of each unmitigated risk along with the probability of harm resulting from not detecting or eliminating that error/risk.
The significance for each is determined by where the "occurrence and harm" judgments intersect. If these two factors intersect on an "OK (acceptable) box", no further action for mitigation is needed. If the two intersect on a "not OK" box, then the error or risk must be addressed, requiring test sites to decide on how to detect and/or eliminate the error.
The specific mitigation/detection should be documented in column #5 of the RA table and detailed in the appropriate policies, procedures, and practices. Test sites also need to modify training and competency assessment activities accordingly, based on the changes.
The approach to determine significance (**Table 3**) and the template for documenting the RA process (**Table 2**) should be included in the IQCP file.

The Quality Control Plan (QCP)

With the RA process completed, test sites have identified all the *significant* errors and mechanisms to detect/eliminate these errors in the entire testing process to ensure that quality test results are reported. All the information is detailed in the IQCP file and all changes in practices, including training and competency assessment are made.

The next step is the development of the QCP component of the IQCP for the OPTI Analyzer. Test sites should keep in mind that an IQCP, while addressing all 3 phases of testing, is a CLIA QC option included in section §493.1256(d), "control procedures" for analytical systems. The thought is that by maximizing "quality" in the pre- and post-analytical processes, test sites can make appropriate decisions for what is necessary to ensure quality in the analytical process. In developing the QCP, it is important for test sites to remember that they can always do more than what the manufacturer specifies, but they cannot establish QC procedures that are less stringent than those specified by the manufacturer. For the QCP component, test sites must be very familiar with the OPTI Analyzer's capabilities.

CMS describes a QCP as: [1]

> …the practices, resources, and procedures to control quality of a particular test process. The QCP must ensure accuracy and reliability of test results and that the test result quality is appropriate for patient care. The QCP must provide for immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance; and it must monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance.
>
> The QCP must at least include the number, type, frequency of testing and criteria for acceptable results(s) of the quality control(s).
>
> If indicated by the evaluation of the RA, the QCP may also include: electronic controls, procedural controls, training and competency assessment, and other specified QC activities.

The CMS surveyor probes for the QCP section of the IQCP again provide important clues. Specifically for §493.1256(d) the probes are: [1]

> Does the laboratory have a written QCP for each test system, as applicable?
>
> - Does the QCP specify the number, type, and frequency of testing of the QC materials…provide for immediate detection of errors…contain criteria to determine acceptable QC results?
> - Does the QCP require the laboratory [to] perform QC as specified by manufacturer?
> - Is there documented evidence of laboratory director approval… before IQCP is implemented?

Keeping the above CMS "probes" in mind, a test site's QCP must at least include the number, type, and frequency of testing controls, and the criteria for acceptable results(s) for each of the QC(s) used. Make sure to state that the QC identified in the QCP at least meets what is specified by the manufacturer. Test sites need to clearly identify what QC is performed on a daily, weekly and monthly basis as well as what response for each is acceptable. Remember, the QCP only needs to summarize the information. The details are in the site's analytical policies and procedures. Do make sure that changes to practices are reflected in operator training.

CMS is emphatic that the laboratory (test site) director takes responsibility for the proper development and implementation of the IQCP, which includes the QCP. The director can delegate this responsibility in writing, but there must be documented evidence that the director approves of the process and final plan. Typically this mandate is met with the director's signature and the date of the signature at the bottom of the IQCP document. One suggestion to further highlight the director's approval, is to include a statement such as, "I [the director name] approve and authorize the use of this IQCP for the [OPTI CCA-TS Blood Gas System]" above the signature.

The Quality Assessment (QA) for post implementation monitoring

The last component of the IQCP is the quality assessment component. Test sites are accustomed to continually evaluating their testing activities and making changes when necessary. The same evaluation applies to the IQCP. Specific QA monitoring must be part of the IQCP and included in the test site's overall QA plan. **Figure 5** shows the typical Plan-Do-Check cycle employed by most test sites for QA and continuous quality improvement activities. Test sites first develop and then implement the IQCP (the PLAN). Once the PLAN is followed, it is monitored to verify effectiveness. When problems are identified, the PLAN should be improved and implemented, which starts the "cycle" again.

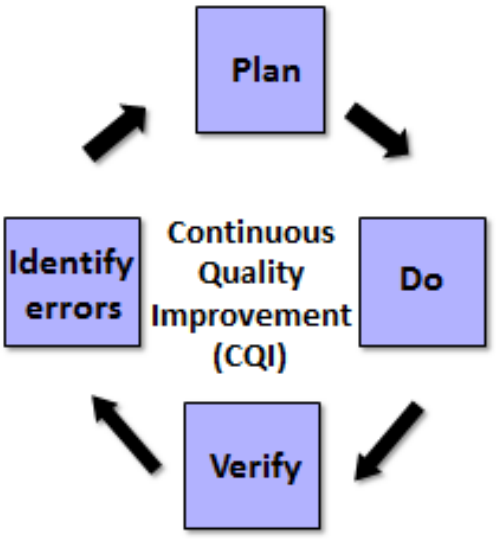

Figure 5: Quality Assessment Cycle for Continuous Quality Improvement

CMS states that the test site must establish a review system for the ongoing monitoring of IQCP effectiveness and this system must at least include the monitoring of the 5 components included in the RA – testing personnel, test environment, specimens, reagents, and test system. [1]

CMS suggests some documents to consider as part of the QA process: QC review; proficiency testing records (scores, testing failures, trends); review of patient results; specimen rejection logs; turnaround time reports; records of preventive measures; corrective actions and the follow-up to these actions; and personnel competency records.

When a testing process failure occurs, test sites need to investigate, determine the cause and impact on patient care, and make process modifications, as appropriate. CMS also states that the investigation must include documentation of all corrections, corresponding corrective actions for all patients affected by the testing process failure, and evaluation of the effectiveness of these action(s). When the corrections(s) and corresponding action(s) do not resolve the problem(s), then the test site must update the RA and modify the QCP, as needed. The specific CMS surveyor probes for QA ask, "…has the laboratory established a review system for the ongoing monitoring of the QCP and evaluation of its effectiveness? In the event of a testing process failure, has the laboratory evaluated all patient test results since the last acceptable quality control?"

Putting the Pieces of the IQCP Together

CMS has not specified an "official" format for putting the IQCP pieces together. Consequently, test sites have flexibility in presenting the information. The IQCP can be an "executive" summary, or a short document to highlight the findings. It should contain pertinent test site and testing information and an overview of the development process. It concisely identifies the RA findings for each of the 3 phases of testing, refers the reader to where the detailed information (policies, procedures, practices, etc.) can be found, includes all of the CMS required QCP information, details the QA approach and clearly shows the site director's approval. This short (1 – 2 page) summary is to the point, demonstrates compliance with the CLIA IQCP requirements and is essential for surveyor "buy-in." **Figure 6** shows a possible outline for the IQCP.

Figure 6: Sample Outline for Assembling an IQCP

I. **The specifics**
   a. Testing device/analytes
   b. Test site's name and address
   c. Effective date
   d. CLIA number
   e. Site director
   f. Other relevant information

II. **RA process summary**
   a. Steps
   b. Staff that conducted RA
   c. Information collected
   d. Other relevant information

III. **Changes in practice(s) as a result of RA**
   a. Pre-analytical
   b. Analytical
   c. Post-analytical

IV. **Name and location of supporting details/documentation for changes in practices**

V. **QCP**
   a. Number, type, frequency of testing QC
   b. Criteria for acceptable results(s) of the quality control(s).
   c. May want to include - Manufacturer's QC requirements – daily, weekly, monthly

VI. **QA approach**
   a. Monitors
   b. Frequency of monitoring
   c. Follow-up to failures
   d. Inclusion into lab's QA plan

VII. **Director's approval**
   a. Signature
   b. Date of signature

References

1. *Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option* Available at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

2. 2014 COLA Laboratory Accreditation Manual. (www.cola.org)

3. US Centers for Medicare & Medicaid Services (CMS). Medicare, Medicaid, and CLIA Programs: *Laboratory Requirements Relating to quality Systems and Certain Personnel Qualifications*. Final Rule. Current CLIA Regulations (including all changes through 01/24/2003) Available at: http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml

4. CLSI EP23A. *Laboratory Quality Control based on Risk Management*. Clinical and Laboratory Standards Institute, Wayne, PA, 2011. (www.clsi.org)

5. CMS State Operations Manual Appendix C, *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services* **(**Subpart K, Part 1**).** Available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html

6. JO Westgard. *Six Sigma Risk Analysis* (2011). Westgard QC, Inc. Madison, WI

7. The Joint Commission Resources. *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction (3rd ed.).* TJC Resources. Oakbrook, IL.

Additional Resources

CMS/CLIA Website: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

CMS CLIA Central Office: 410-786-3531

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

CMS IQCP Questions: Forward specific questions to: IQCP@cms.hhs.gov

Appendix

Table 1: OPTI Analyzer Targeted Failure Modes, Error Mitigation and Detection Features for each of the 5 CMS mandated RA Components

1. Specimen		
1.1 Specimen Integrity		
Targeted Failure Mode	**Detection Feature or Recommended Action**	**Notes**
Clots in the sensor cassette may cause incomplete sample aspiration and consequently erroneous results	The OPTI verifies complete aspiration of the sample. Cassette design prevents clots. Sample clotting will be flagged and the sample will be rejected.	
Lipemia (>3000mg/dl triglycerides) may cause biased results	The OPTI will flag out-of-range patient results, but does not directly detect lipemia. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error. *Potential Solutions to Mitigate Risks/Errors:* When lipemia is suspected a sample aliquot can be centrifuges and plasma examined for lipemia.
Hemolysis (>10%) may cause biased patient results	OPTI will flag out- of-range patient results, but does not directly detect hemolysis. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample. Ideally, specimen should be collected to avoid hemolysis.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error. *Potential Solutions to Mitigate Risks/Errors:* When potassium is >6.0 mmol/L, sample aliquot can be centrifuged and plasma examined for hemolysis OR All samples with potassium >6.0 mmol/L can be confirmed by routine chemistry analyzer with spectroscopic detection of interferences

Use of **improper anti-coagulants** biases patient results Citrate, oxalate, and EDTA anti-coagulants demonstrate significant interference in the OPTI pH, sodium, and potassium sensors	OPTI will flag out- of-range patient results, but does not directly detect incorrect anti-coagulant usage. Use only heparin based anti-coagulants for specimen collection. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error.
Interfering substances in the sample may cause measurement biases (ex. dyes, fluorescein)	OPTI will flag out- of-range patient results or produce an 'unstable sensor' message. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error.
Air introduced into the specimen biases patient results	OPTI will flag out- of-range patient results. OPTI detects bubbles but does not detect air contamination other than changes to blood gas parameters. Specimen should be collected to avoid introduction of air. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error.
Dilution of sample from **intravenous fluids**	OPTI will flag out- of-range patient results, but does not directly detect dilution from intravenous fluids. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error. *Potential Solutions to Mitigate Risks/Errors:* Recollection of a new specimen can be initiated if appropriate triggers to flag a specimen integrity investigation are seen. These triggers include: ionized calcium < 0.7 mmol/L or > 1.7 mmol/L, tHB < 6 mg/dL, bicarbonate > 60 mmol/L, potassium <2.5 or >7.4 mmol/L, sodium <120 or >160 mmol/L, and chloride <65 or > 135 mmol/L

1.2 Specimen Presentation

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Bubbles may be present in the sample container and get aspirated into the cassette.	The OPTI checks for bubbles and flags/rejects the sample if bubbles are detected. The OPTI sample sensors may not catch all bubbles. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error. *Potential Solutions to Mitigate Risks/Errors:* At the end of the measurement, upon removal of cassette, the user can check for bubbles over the sensors as the sample is left in the measuring chamber.
Inadequate sample volume may cause incompletely filled sensors and biased results.	The OPTI checks and automatically rejects short samples.	
Improperly mixed sample may cause a tHb measurement bias	The OPTI checks for the homogeneity of the sample during each measurement and suppresses tHb/ SO2 in case the check fails. The OPTI may not catch all improper mixing. User may get a high rate of suppressed tHb or biased tHb due to improper sample mixing. **Training** at regular intervals on pre-analytical precautions is critical for getting a good sample.	See Operator's Manual - Sample Preparation and Interferences. Include your site's **current protocols**, including **training**, to address this potential pre-analytical error. *Potential Solutions to Mitigate Risks/Errors:* Repeat testing (including remixing) for any tHb <7g/dL. If rerun is discrepant draw a new sample OR Confirm abnormal tHb with a hematology cell counter OR Monitor difference between split patient samples run on OPTI compared to a cell counter.
Sample cannot be aspirated (sample not attached or sample container clogged)	The OPTI checks for the presence of a sample. If sample is not detected, OPTI flags it and asks the user to re-attach the sample	

2 Operator

2.1 Unauthorized use

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Unauthorized use	The OPTI can be setup to require ausername/ password to use the anlyzer. TS2 only – user passwords can be linked with an expiration date.	See Operator's Manual – Setting up Security. Include your site's **current protocols**, including **training**, to address this potential operator error. Set Passwords to prevent unauthorized use.

2.2 Operator Error

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Opening SMC cover during patient measurement may affect patient results	The OPTI detects the cover open/ closed position and will abort the measurement and flag the error	
Introducing wrong level of liquid controls	The OPTI detects the wrong level and flags the error	
Air contamination of liquid controls	The OPTI Check will fail ranges for PO2 if vial is open for too long.	See Operator's Manual – Calibration and Quality Control. Include your site's **current protocols**, including **training**, to address this potential operator error.
Injecting the sample may cause blood to damage internal tubing and electronics	The OPTI cannot detect blood spillage on the electronics which may cause various intermittent errors. **Training** at regular intervals on proper device usage is critical for prevent potential operator error.	See Operator's Manual – Running a Patient Sample. Include your site's **current protocols**, including **training**, to address this potential operator error.

3 Reagents/Cassettes

3.1 Sensor Cassette Degradation

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Shipping temperatures may affect the sensor cassette and cause biased results	User **must run liquid Quality Control after receipt of each cassette shipment.** Quality Control will fail if cassettes were exposed to extreme shipping temperatures. Cassette shipments are accompanied by a freeze sensor and/ or a high temperature sensor to flag out-of-range shipping temperatures.	See Operator's Manual – Calibration and Quality Control. Include your site's **current protocols**, including **training**, to address this potential reagent/cassette error. **QC Lockout** can be enabled so controls must be run with every new lot of cassettes before patient measurements are allowed.
Improper storage may cause consumable degradation and consequently biased results	Run liquid controls once per month. Quality Control will fail if cassettes were exposed to extreme storage temperatures.	All cassette types have the temperature range printed on the cassette pouch and the cassette box. **QC Lockout** can be enabled so controls must be run at regular intervals before patient measurements are allowed.
Cassette exceeding expiration date may cause a measurement bias.	The OPTI rejects expired cassettes automatically	All cassette types have the expiration date printed on the cassette pouch and the cassette box.
Cassette pouch punctured or seal compromised	The system detects a compromised pouch during calibration and rejects the cassette automatically	
Leaving the cassette out of the pouch too long may cause measurement biases.	The OPTI will detect a compromised cassette and automatically reject it	See Operator's Manual – Sample Handling and Patient Testing.
Running a used cassette	The system detects and rejects a used cassette	

3.2 Liquid Quality Control (OPTI Check) Degradation

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Extreme shipping temperatures may cause degradation of liquid controls	Controls will be flagged with out-of-range results if they were exposed to extreme shipping	

	temperatures.	
Improper storage may cause degradation of liquid controls	Controls will be flagged with out-of-range results if they were exposed to extreme storage temperatures.	Recommened storage conditions are printed on control solution boxes. Include your site's **current protocols**, including **training**, to address this potential reagent/cassette error.
Expired control material is used	Compromised control material will fail the acceptance range. OPTI-CCA and TS - The user must check the controls report to verify that the control material is not expired OPTI-CCA TS2 only – expired control material is automatically rejected	Expiration dates are printed on control solution boxes. Include your site's **current protocols**, including **training**, to address this potential reagent/cassette error.
3.3 Electronic QC (SRC) Degradation		
Targeted Failure Mode	**Detection Feature or Recommended Action**	**Notes**
Extreme shipping temperatures may cause degradation of SRC	Compromised SRCs will be flagged with out-of-range results	SRC can be shipped from -20˚C to + 50 ˚C
Improper storage may cause degradation SRC	Compromised SRCs will be flagged with out-of-range results	SRC can be stored from -20˚C to + 50 ˚C
An **expired** SRC is used	Compromised SRCs will fail the acceptance range and be flagged automatically. OPTI-CCA and TS - The user must check the SRC report to verify that the control material is not expired. OPTI-CCA TS2 only – an expired SRC is automatically rejected	The expiration date is printed on each SRC measurement report. Include your site's **current protocols**, including **training**, to address this potential reagent/cassette error.
3.4 Gas Bottle Degradation		
Targeted Failure Mode	**Detection Feature or Recommended Action**	**Notes**
Extreme shipping temperatures may affect the gas concentrations	The OPTI detects contaminated gas during checks with each cassette calibration.	Gas bottle can withstand short term extreme shipping temperatures.

Improper storage may affect the gas concentrations	System detects contaminated gas during checks with each cassette calibration.	Long-term storage of gas should be from 4˚C to 30 ˚C.
An **expired** gas bottle may affect the gas calibration in the OPTI	The OPTI automatically rejects expired gas bottles.	
Gas bottle thread damaged or gas bottle not present	The system detects the absence of gas pressure, stops operation and alerts the user.	

4 Laboratory Environment

4.1 Atmospheric Environment

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Dusty environment may cause system failure	The SRC and/or cassette calibration checks will fail if pollution affects the system	The OPTI is rated for pollution Degree 2, normal indoor laboratory environment: air contains only non-conductive pollutants with occasional condensation.
High ambient temperature may affect patient results	The system monitors temperature and stops operation if temperature of measuring chamber or ambient conditions are out of range	
High or low **humidity** may affect the system	The SRC and/or cassette calibration checks will fail if humidity affected the system	The OPTI's humidity rating is 5% to 95% non-condensing.
The local **barometric pressure** may be outside of the OPTI's operating range	OPTI CCA-TS2 – The OPTI will stop operation and flag a Baro Error if the barometric pressure is outside of the operating range OPTI CCA/TS - Liquid control measurement will fail if the OPTI is operated outside the barometric pressure operating range. Verify altitude during installation or run at least 3 levels of liquid controls during installation. Check barometric pressure on print out.	The OPTI is specified for operation up to 10,000 feet

4.2 Utility Environment

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Improper **electrical** connection may affect the OPTI's operation	The OPTI will not operate if the power connection is inadequate	The OPTI works on a wide range of power: 100V to 240V 50-Hz/ 60Hz.

5 Measuring System

5.1 Software and Hardware

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
The **software** may encounter a corrupt data base or other critical errors	The System will not operate. The OPTI generates an Exception report in case of a software error, and a System error in case of data-base issues.	
Optics module failure, such as drift, bad LED etc. may bias patient results	**Run at least 2 levels of SRC measurements daily.** During each patient measurement, the OPTI checks for Optics drift and rejects the cassette/flags the results.	The SRC checks for optics drift, optics intensities etc. Any problem will result in a failing SRC measurement.
Main controller board failure on the OPTI may affect system performance	The OPTI performs checks during power up and operation. If any action cannot be performed correctly, it will stop operation and produce an error message	
Pump motor failure may cause inconsistent system performance	The system verifies proper pump performance by monitoring sample flow. A bad pump will cause calibration, aspiration, and misseat 2 errors which prevent testing.	
Cassette valve drive failure may affect calibration or sample aspiration	The OPTI verifies the valve positions and detects failures in the valve drive mechanism including a stalling motor	
Gas module failure may affect gas flow subsequently affecting calibration	The OPTI verifies adequate gas flow during calibration. If outside the range it flags a bad calibration	
Pressure transducer failure may cause an empty gas bottle not to be detected which may affect the gas calibration	The system compares the CO_2 concentration of the calibration gas to the cassette buffer. If outside the range it flags a bad calibration	
Electromagnetic fields or static electricity may affect results	The system was tested for immunity against electromagnetic fields as well as electrostatic discharge by UL to EN61326 and CISPR.	The system is immune to static electricity and electromagnetic fields if properly installed. See Operator's Manual – Setup

6 Maintenance

6.1 OPTI Analyzer Maintenance

Targeted Failure Mode	Detection Feature or Recommended Action	Notes
Dirty optics glass may cause measurement bias	If contaminants that might affect operation are detected, it is flagged by the system. **The measurement chamber should be cleaned weekly.**	The system is largely not affected by contaminants on the optics glass. See Operator's Manual – Maintenance. Include your site's **current protocols**, including **mainence logs**, to address this potential maintenance error.
Annual pump replacement not performed may cause inconsistent system performance due to pump wear.	The system checks the pump and flags an error when the pump does not perform. **The pump should be replaced annually.** OPTI CCA-TS2 – The system includes a pump replacement maintenance reminder.	See Operator's Manual – Maintenance. Include your site's **current protocols**, including **mainence logs**, to address this potential maintenance error.
Quarterly tHb calibration not performed may affect tHb results.	**The system requires a tHb calibration every 3 months.** The system automatically reminds the user when a tHb calibration is due and adds a note to printouts. **Test SRCs daily to catch drift in tHb calibration.**	See Operator's Manual – Maintenance. Include your site's **current protocols**, including **mainence logs**, to address this potential maintenance error.

Table 2: Template for Documenting RA Process

Potential Error/Risk	Potential Failure	Phase of Test Process	Error addressed with Current Practices (yes/no)	Solutions to Mitigate Significant Risks/Errors
Pre-analytical				
Analytical				
Post-analytical				

Table 3: Sample Risk Assessment Table to determine Significance of Potential Risks[4,6,7]

Severity of Harm

Occurrence	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	**Not OK**	**Not OK**	**Not OK**	**Not OK**	**Not OK**
Probable	OK	**Not OK**	**Not OK**	**Not OK**	**Not OK**
Occasional	OK	OK	OK	**Not OK**	**Not OK**
Remote	OK	OK	OK	OK	**Not OK**
Inconceivable	OK	OK	OK	OK	OK

Frequent = once/week
Probable = once/month
Occasional = once/year
Remote = once every few years
Inconceivable = once in the life of the measuring system

Negligible = inconvenience or temporary discomfort
Minor = temporary injury or impairment not requiring professional medical intervention
Serious = injury or impairment requiring professional medical intervention
Critical = permanent impairment or life-threatening injury
Catastrophic = results in patient death