CLIA Corner

State Hygienic Laboratory at The University of Iowa

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In This Issue of the CLIA Corner we adress:

- **Quality Assessment Plan in Relation to the Individualized Quality Control Plan (IQCP)**

Quality Assessment is the third and final component that must be addressed in any IQCP plan. As stated in the *2014 – Third and Fourth Quarter CLIA Corners*, after the laboratory has conducted the risk assessment and used the resulting risk assessment to develop the quality control plan, it is now time to establish a Quality Assessment (QA) Plan.

Definitions:

The Centers for Medicare & Medicaid Services (CMS) defines a quality assessment as an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed.

Let's get started!!

Before we begin with the QA, let's do a quick review of the other two components: risk assessment and quality control plan (QCP). Risk assessment must encompass the entire testing process: **pre-analytic, analytic and post-analytic**. When performing risk assessment in regards to IQCP, the risk assessment must include (at a minimum) an evaluation of five risk assessment components: **specimen, environment, reagent, test system and testing personnel**. For more details on Risk Assessment, refer to the *2014 Third Quarter CLIA Corner* located at http://www.shl.uiowa.edu/publications/.

The laboratory's QCP must establish control procedures that reduce the likelihood of providing an inaccurate patient test result. The QCP plan must at least include the number, type, and frequency of testing, and criteria for acceptable result(s) of the quality control(s). For more details on a Quality Control Plan, refer to the *2014 Fourth Quarter CLIA Corner* located at http://www.shl.uiowa.edu/publications/.

As with risk assessment and the quality control plan, there is no right or wrong way to develop a quality assessment plan. The IQCP quality assessment monitoring must be part of the laboratory's overall Quality Assessment plan. The laboratory should include review monitors identified in the risk assessment components of: testing personnel, environment, specimens, reagents and test system. Documents to consider for QA review may include, but are not limited to:

- Quality control records,
- Proficiency testing records (scores, testing failures, trends),
- Patient results review,
- Specimen rejection log,
- Turnaround time reports,
- Records of preventative measures,
- Corrective actions and follow-up, and
- Personnel competency records.

You are not limited to the number of monitors used to verify the continued performance of a testing process. Good monitors ensure that you continue to identify and minimize problems and that accurate test results are being reported.

When the laboratory discovers a testing process failure, the laboratory must perform an investigation to identify the cause of the failure and its impact on patient care. 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 the corrective actions(s) necessary to resolve the failure and reduce the risk of recurrence of the failure in the future. If

necessary, the laboratory may also need to update the risk assessment based upon the new information and modify the QCP, as needed.

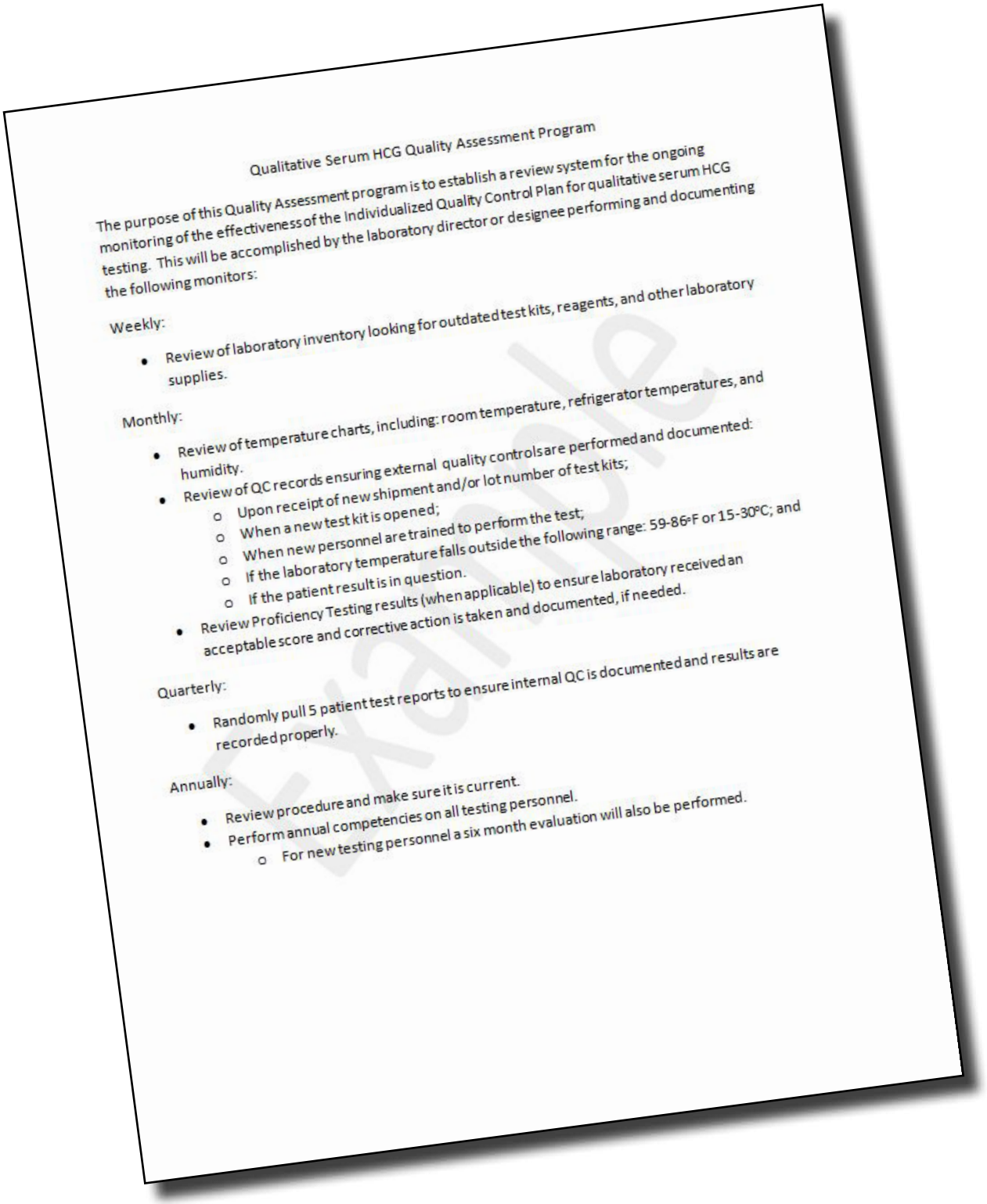
In summary, quality assessment is nothing new to the laboratory. However, in order for a laboratory to implement IQCP for one or more of its non-waived test systems, the laboratory will be required to incorporate quality assessment processes as part of its IQCP.

Example Quality Assessment

Attached is an example of a risk assessment for a serum pregnancy test kit. *The example is for teaching purposes only and is not to be interpreted as a "CLIA-approved" quality assessment for any specific laboratory or test system. As with the other two IQCP components, quality assessments must be customized for each laboratory.* This quality assessment example is based upon the previously given Risk Assessment and QCP examples from the 2014 Third and Fourth Quarter CLIA Corners. This example is a test kit and not an actual analyzer, therefore we did not include information about calibration, calibration verification and instrument maintenance. Finally, there is no supporting data with the example, as it is a fictional example, and we don't have supporting data.

References:

- Centers for Medicare/Medicaid Services (CMS), Center for Clinical Standards and Quality/Survey & Certification Group, Survey & Cert Letter 13-54, Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option, Ref: S&C:13-54-CLIA; Published 08/16/2013.
- CMS CLIA Brochure #11, Individualized Quality Control Plan Introduction
- CMS CLIA Brochure #12, CLIA IQCP, Considerations When Deciding to Develop an IQCP
- CMS CLIA Brochure #13, CLIA IQCP, What is an IQCP?
- Food & Drug Administration, Home Medical Devices Device Advice: Comprehensive Regulatory Assistance Guidance Documents (Medical Devices), Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices [Issued 01/30/2008; OMB control number: 0910-0598; Expiration Date: 07/31/2016].



Qualitative Serum HCG Quality Assessment Program

The purpose of this Quality Assessment program is to establish a review system for the ongoing monitoring of the effectiveness of the Individualized Quality Control Plan for qualitative serum HCG testing. This will be accomplished by the laboratory director or designee performing and documenting the following monitors:

Weekly:

- Review of laboratory inventory looking for outdated test kits, reagents, and other laboratory supplies.

Monthly:

- Review of temperature charts, including: room temperature, refrigerator temperatures, and humidity.
- Review of QC records ensuring external quality controls are performed and documented:
  - Upon receipt of new shipment and/or lot number of test kits;
  - When a new test kit is opened;
  - When new personnel are trained to perform the test;
  - If the laboratory temperature falls outside the following range: 59-86°F or 15-30°C; and
  - If the patient result is in question.
- Review Proficiency Testing results (when applicable) to ensure laboratory received an acceptable score and corrective action is taken and documented, if needed.

Quarterly:

- Randomly pull 5 patient test reports to ensure internal QC is documented and results are recorded properly.

Annually:

- Review procedure and make sure it is current.
- Perform annual competencies on all testing personnel.
  - For new testing personnel a six month evaluation will also be performed.