



Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2012, through Sept. 30, 2013.

D2016 — Successful Participation in Proficiency Testing. Each laboratory performing non-waived testing must successfully participate in an approved proficiency testing program.

D5439 — Calibration Verification. Calibration verification must be performed at least once every six months. See CLIA regulations at 493.1255(b) for more details.

D2009 — Testing of Proficiency Samples. The individual testing the proficiency samples and the laboratory director must attest the proficiency samples were tested in the same manner as patient specimens.

D2181 — Compatibility Testing. Failure of the laboratory to achieve an overall proficiency testing event score of satisfactory in compatibility proficiency testing for two consecutive testing events or two of three consecutive testing events is unsuccessful performance.

D5401 — Procedure Manual. A written procedure manual for all tests performed by the laboratory must be available to and followed by laboratory personnel.

D5413 — Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies. Reagents, solutions, culture media, control materials and other supplies must not be used when they have exceeded their expiration date, have deteriorated or are of substandard quality.

D6087 — Laboratory Director Responsibilities. The laboratory director must ensure laboratory personnel perform the test methods as required for accurate and reliable results.

D6054/D6128 — Technical Consultant/Technical Supervisor Responsibilities. The technical consultant/technical supervisor is responsible for evaluating and documenting the performance of moderate/high complexity testing personnel at least annually.

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Farewell to EQC

The Centers for Medicare and Medicaid Services (CMS) developed Individualized Quality Control Plan (IQCP) in response to concerns with Equivalent Quality Control (EQC) from industry, laboratories, experts, surveyors and others. EQC will be phased out at the end of the IQCP educational and transitional period on January 1, 2016.

What are the differences between IQCP and EQC? EQC used a standardized format whereas IQCP is flexible, so each laboratory can customize a quality control plan to fit their laboratory. EQC had a narrow regulatory scope with limited specialties eligible whereas IQCP has a broad regulatory scope with all specialties eligible except pathology. EQC focused on the analytic phase of testing whereas IQCP encompasses all phases of testing, including pre-analytic, analytic, and post-analytic. EQC required performance of internal quality control to decrease external quality control whereas IQCP does not require internal quality control, but IQCP may not decrease external quality control. IQCP is touted as the “right” quality control.

Now Is The Time for IQCP

The educational and transitional period for Individualized Quality Control Plan (IQCP) has arrived. This period began January 1, 2014, and ends January 1, 2016. During this timeframe, laboratories will have three options:

- Continue to follow the Equivalent Quality Control (EQC) procedures
- Follow the Clinical Laboratory Improvement Amendments (CLIA) requirement of performing two levels of external controls on each day of testing
- Implement IQCP

Participation in IQCP is voluntary. All non-waived testing systems are eligible for IQCP except pathology.

IQCP Components

The Individualized Quality Control Plan is composed of three elements: risk assessment (RA), quality control plan (QCP) and quality assessment (QA).

Potential failures and sources of testing error should be identified and evaluated during risk assessment.

The laboratory should assess, at least, the following:

- The specimen
- The environment
- The reagent
- The test system
- The testing personnel

The QCP is a written plan that entails the practices, resources and procedures to ensure the quality of a test process. The QCP must, at a minimum, include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control.

Quality Assessment monitoring is a key component in the IQCP to ensure its effectiveness. Areas the laboratory may want to consider monitoring include:

- Quality control records.
- Proficiency testing results.
- Patient results.
- Specimen rejection records.
- Turnaround time reports.
- Records of preventive measures and corrective actions.
- Testing personnel competency assessments.

If testing processes fail, the laboratory must investigate and identify the cause and its impact on patient results. If necessary, the risk assessment must be updated and the IQCP modified in response.



Questions and Answers (Q&A)

The Centers for Medicare and Medicaid Services (CMS) provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.



1. **Where can I find information regarding IQCP (Individualized Quality Control Plan)?**

Information is available at the following:

- CLIA website: www.cms.hhs.gov/clia
- CLIA Brochure #11 on the CLIA website
- Centers for Disease Control and Prevention (CDC) is developing educational material that will be available in the future.

2. **My lab has a PPM certificate. How does IQCP affect my lab?** For laboratories performing Provider Performed Microscopy (PPM) testing, the lab must continue to follow the CLIA regulatory requirements for PPM and moderate complexity testing. While IQCP may not be practical for PPM laboratories due to the nature of PPM testing, IQCP is an option.

3. **My lab has been using EQC (Equivalent Quality Control) for several test methods for many years. Will we be able to continue using EQC for these tests after January 1, 2016?** No, after the education and transition period, the laboratory must either follow the CLIA requirement of performing two levels of external controls on each day of patient testing or implement IQCP.

4. **Does the laboratory need to collect new data to use in the IQCP evaluation process?** No, the laboratory may use historical data, including EQC data.

5. **How do the manufacturer's instructions for quality control affect IQCP?** If the manufacturer's instructions are more stringent, you must follow those instructions.

Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; IQCP National Training Nov. 2013; Centers for Medicare & Medicaid Services S & C; 13-54-CLIA; CLIA Brochure #11; and CMS CLIA website at www.cms.hhs.gov/clia.



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