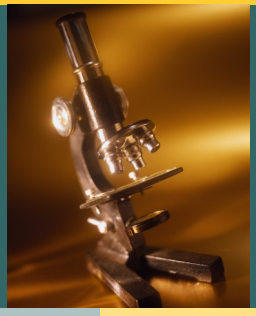
Fall 2013



NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF HEALTH FACILITIES

CLIA BITS

Quality Control for the Future

The Centers for Medicare and Medicaid Services (CMS) will be implementing a new quality control (QC) option to meet the Clinical Laboratory Improvement Amendments (CLIA) QC requirements. The new QC option is called Individualized Quality Control Plan or IQCP. IQCP will offer laboratories the flexibility to customize a QC plan for non-waived testing while maintaining CLIA compliance. Participation in IQCP will be voluntary.

Using an IQCP does not guarantee the reduction of QC frequency, but does allow the customization of a QC protocol. IQCP covers all phases of the testing process by assessing risk factors in the pre-analytic, analytic and post-analytic systems. IQCP takes into consideration the test system, manufacturers' instructions, environment, patient population, personnel competency, staffing, how test results are used, etc. The laboratory director will maintain responsibility for implementing and approving QC procedures. All non-waived testing systems, except pathology, will be eligible for IQCP.

The IQCP education and transition period will begin on January 1, 2014, and conclude on January 1, 2016. During this timeframe, laboratories will have three options:

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

At the conclusion of the education and transition period, EQC will no longer be an acceptable QC option. Test systems using EQC will not be grandfathered. Laboratories must either perform two levels of external controls on each day of testing or implement IQCP.

For more information regarding IQCP, check the CLIA website at www.cms.hhs.gov/clia.

Inside this issue:

If you would like to receive CLIA Bits electronically, please send your e-mail address and company name to Bridget Weidner at bweidner@nd.gov.

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. **Will accredited laboratories have the option to use an Individualized Quality Control Plan (IQCP)?** The accrediting agencies have been informed of IQCP during its development. They have the option of adopting the new QC protocol. Keep in touch with your accrediting agency for further developments regarding IQCP.
2. **Will IQCP apply only to new testing systems?** No, IQCP will apply to all non-waived test systems, including existing test systems.
3. **Do I have to participate in IQCP?** No, laboratory participation in IQCP is voluntary. The laboratory may choose to use the CLIA default quality control option of performing two levels of external control each day of patient testing.
4. **Can a General Supervisor perform testing personnel competency evaluations?** Yes, the laboratory director or technical supervisor can delegate, in writing, this duty to the General Supervisor.
5. **Does a General Supervisor need to provide direct supervision of a newly graduated Medical Laboratory Technician (MLT) with an associate's degree performing high complexity testing?** No, an MLT with an associate's degree can perform high complexity testing without direct supervision. The General Supervisor needs to be available to provide consultation on-site by telephone or by electronic communication when high complexity testing is performed.

Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; CMS S&C: 13-54-CLIA, CLIA Brochure #11; CMS CLIA website at www.cms.hhs.gov/clia.

The Role of the General Supervisor

A General Supervisor is required in laboratories performing high complexity testing. The General Supervisor must be available to provide on-site, telephone or electronic consultation when high complexity testing is performed. The General Supervisor:

- Resolves technical problems per laboratory policy and procedure.
- Provides day-to-day supervision of high complexity testing performed.
- Provides direct supervision of high complexity testing performance by personnel who are high school graduates or equivalent with the training and experience to perform high complexity testing (see CLIA regulations at 493.1489(b)(5) and 493.1463(c)).
- Ensures the maintenance of acceptable performance of patient testing.
- Performs the following duties if delegated by the director or technical supervisor:
  - ◊ Ensures corrective action is taken if test systems are not operating at an acceptable level.
  - ◊ Ensures patient test results are not reported until corrective action is taken and the test system is operating at an acceptable level.
  - ◊ Provides orientation to testing personnel.
  - ◊ Evaluates and documents the annual performance of testing personnel.

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