

CLIA BITS



North Dakota Department of Health
Division of Health Facilities Winter 2007

CLIA Quality Systems Assessment – Part 1 of a continuing series:

What is quality assessment? Quality is defined as the degree to which a set of inherent characteristics fulfills requirements or the degree of excellence. Quality assurance is a component of quality management concentrated on ensuring the satisfaction of quality requirements. Quality assessment focuses on monitoring and evaluating activities and processes that fulfill the quality requirements.

The laboratory testing process encompasses four quality systems:

- General laboratory
- Preanalytic
- Analytic
- Postanalytic

For each quality system, the laboratory:

- Establishes and follows written policies and procedures for an ongoing mechanism to monitor and assess quality activities.
- Identifies any problem.
- Takes corrective action when indicated.
- Reviews the effectiveness of the corrective action taken.
- Revises policies and procedures, as necessary, to prevent recurrence.
- Communicates findings with the appropriate staff.
- Documents all assessment activities.

(Continued on page 2)

Point of Care Testing Seminar

Where: St. Alexius Medical Center
Boniface Auditorium

Date: Thursday, March 1, 2007

Time: Noon-5 p.m. Cost: Free

CEUs: 4-5 hours

Topics will include:

- ◇ CLIA & POCT
- ◇ North Dakota Licensure Updates & Changes
- ◇ POCT Roundtable Discussions
- ◇ POCT Vendors

Watch for your invitation in the mail.

For more information, contact SAMC

POCT Coordinators at 701.530.6782.

ASCLS-ND

American Society of Clinical
Laboratory Science - North Dakota
2007 Annual Spring Meeting

April 25, 2007 8 a.m. – 5 p.m.

Quality Inn and Suites

507 25th Street SW Jamestown, ND

For more information, check the website

www.asclsnd.org

Inside this Issue:

CLIA Quality Systems Assessment	Page 1-3
Point of Care Testing Seminar	Page 1
ASCLS-ND	Page 1
Questions & Answers	Page 3

(Continued from page 1)

General Laboratory Systems – 493.1230-493.1239

General Laboratory Systems is the first of the four quality systems. General Laboratory Systems encompasses the general operational functions of laboratory testing that are not specific to any one specialty or subspecialty.

General Laboratory Systems includes confidentiality of patient information, specimen identification and integrity, complaint investigation, communications, personnel competency assessment policies, and evaluation of proficiency testing performance.

The laboratory must maintain confidentiality of patient information throughout all phases of the total testing process. The laboratory should:

- Limit visitor access to areas where patient information may be easily viewed.
- Put into place safeguards to ensure confidentiality of patient information.
- Prohibit unauthorized users from entering the laboratory information system.
- Secure the record storage system.
- Instruct employees regarding confidentiality of patient information.

The laboratory must ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of specimen through the testing process and the reporting of results. The laboratory should ensure:

- Manufacturer's instructions are being followed to obtain appropriate specimens.
- Specimens are being stored properly.
- Positive identification of patient specimens is maintained throughout all phases of testing.
- Policies are in place to ensure positive patient identification.
- Specimens are labeled properly.
- The process is in place to handle improperly labeled specimens.

The laboratory must have a system in place to document complaints and investigate those complaints when necessary. Complaints may originate from patients, providers or other sources. The laboratory should have a mechanism:

- For individuals to report a complaint to the laboratory.
- To report complaints to its reference laboratories.

The laboratory must have a system in place to identify and document problems that occur as a result of communication breakdown between the laboratory and an authorized person who orders tests or receives test results. The laboratory should:

- Communicate changes and updates to the appropriate persons.
- Provide instructions for patient preparation and specimen handling.
- Ensure the test report is easily understood.

The laboratory must establish and follow written policies to assess employee and, if applicable, consultant competency. The laboratory should:

- Have a policy in place to evaluate employee competency.
- Have a protocol to follow if an employee is deemed incompetent.
- Have an orientation program for new employees.
- Have a policy to evaluate new employees at six months, yearly, and yearly thereafter.
- Train employees when new tests systems or methods are introduced and document the training.
- Evaluate personnel for consistency in slide review.
- Evaluate the consultant's competency.

The laboratory must review and evaluate proficiency testing results. The laboratory should:

- Show evidence results are reviewed and evaluated.
- Perform corrective action for any unacceptable result (less than 100%)

(Continued on page 3)



(Continued from page 2)

- Evaluate any results not graded by the proficiency testing company.
- Verify the accuracy of non-regulated analytes twice annually.
- Document all proficiency testing evaluation and verification activities.

All of these components make up General Laboratory Systems. The laboratory's quality assessment plan could include monitoring of any of these areas.

Quality assessment focuses on monitoring the effectiveness of corrective actions taken for problems identified through quality assurance activities. Watch for part 2—Preanalytic Quality Systems in the next newsletter.

Sources for this article: Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; CLIA Basic and Beyond Training September 2006; National Laboratory Training Network Teleconference January 19, 2006.

QUESTIONS AND ANSWERS (Q & A)

Centers for Medicare & 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 will be 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.

Q. Does CMS plan to do unannounced laboratory surveys like some of the accreditation agencies?

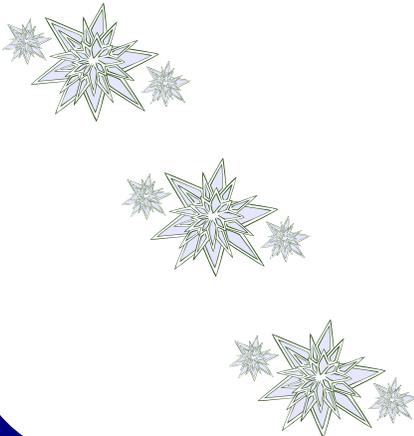
A. There are no immediate plans to move to unannounced surveys, but it may be investigated in the future. Complaint and follow-up surveys are unannounced.

Q. Please clarify the five-lab limit for laboratory directors. Can the director have as many certificates of waiver as wanted?

A. A director may have an unlimited number of waived laboratories. There is a five-lab limit in any combination for certificates of compliance, provider-performed microscopy procedures and accreditation.

Q. For twice annual verification, how does a laboratory do a split sample for a direct wet prep? How does the laboratory compare slide preparations and read?

A. Make two slides when the specimen is collected or have more than one person read the same slide, keeping in mind the specimen is labile. Make sure criteria for acceptability is established and all results are documented. There are other options for twice-annual verification, such as proficiency testing and educational programs.



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