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LABORATORY REMINDERS

The following are common deficient practices we’ve encountered recently while surveying; we wanted to share them as reminders for all laboratories.

Proficiency testing
- Failure to rotate proficiency testing to include ALL personnel who perform the test(s).
- Failure to retain all proficiency testing records and reports for a minimum of two years, including attestation statements signed by the laboratory director and testing personnel.
- Failure to evaluate proficiency testing results that the PT program has not graded for some reason (e.g. lack of consensus, too few participants, etc.).
- Failure to take and document corrective action to prevent a reoccurrence after the laboratory has reviewed the results and identified the cause of an unacceptable or unsatisfactory proficiency performance.
- Failure to verify the accuracy of non-regulated tests twice annually. Non-regulated tests are those tests for which the laboratory does not have to enroll in an approved proficiency testing program (e.g. potassium hydroxide, wet mount testing, etc).

Validation of new test systems or methods
Most laboratories fulfill the requirements of verifying the accuracy, precision, reportable range and reference ranges. However, many forget to include in the validation process:
- Laboratory director approval of the new procedure or procedure manual, and
- Document training of testing personnel.

Equivalent quality control (EQC)
EQC is still alive and well as part of the CLIA regulations for control procedures. The CLIA regulations require that the laboratory perform two levels of external controls each day of testing. Following the manufacturer’s instructions is not sufficient if the CLIA regulations are more stringent (e.g. manufacturer requires testing of
external controls only with a new test kit). CLIA surveyors currently do not cite this as a formal deficiency—but send a letter discussing the deficient practice.

If the test system is eligible, the laboratory may select one of the EQC options to reduce the frequency of quality control testing. For more information about EQC and the process, go to www.cms.hhs.gov/clia, click on link for CLIA Brochures, go to downloads and click on Brochure #4-Equivalent Quality Control Procedures.

Completion of Form CMS-116, Application for Certification Section V. Multiple Sites

With each recertification survey, we obtain an updated CMS-116 form. This provides us with the most current demographics for the laboratory as well as the signature of the laboratory director. The CMS data system now allows us to enter the demographics and tests performed for multiple testing sites (e.g. main laboratory, respiratory therapy, nursing services, emergency room, etc). However, the laboratory must meet one of the exceptions for multiple sites under one CLIA certificate (see below). When completing the CMS-116 form, please include any of the ancillary testing sites that may fall under the laboratory’s CLIA certificate.

The laboratory completes section V. if it meets one of the regulatory exceptions for multiple testing sites under one CLIA certificate:

1. A laboratory that has temporary testing sites (e.g. home health agencies, hospice).
2. A not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites.
3. A hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations.

CMS MEMORANDUM ON ELECTRONIC EXCHANGE OF LABORATORY INFORMATION

On March 1, 2010, the Centers for Medicare and Medicaid Services (CMS) issued a memorandum for the CLIA State Survey Agency Directors. The subject was the issuance of revised survey procedures and interpretive guidelines for laboratories and laboratory services in Appendix C of the State Operations Manual to facilitate the electronic exchange of laboratory information.

Memorandum Summary

- **Goal:** to support the commitment of the Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS) to create an environment in which most Americans will have access to health information exchange and Electronic Health Records (EHR) by 2014.
- **CLIA Role:** Laboratory information is an integral part of an EHR. CLIA requires accurate and reliable laboratory results be released to the authorized individual who ordered the test, the individuals responsible for using the test results, and the laboratory that initially requested the tests.
- **Revised Guidance (Authorized individuals and others):** D5305, D5811, and D5813 are revised and offer guidance for the exchange of laboratory information by allowing laboratory results to be sent to the authorized individual and others designated by the authorized person to receive the information.
- **Revised Guidance (Electronic exchange of laboratory information):** D3041, D5207, D5301, D5659, D5801, D5809 and D5821 are revised to offer additional guidance when surveying laboratories using Health Information Technology (HIT) for the electronic exchange of laboratory information.
The revisions became effective March 1, 2010. The memorandum can be viewed in its entirety by going to the following CMS website for the Appendix C-Interpretative Guidelines and clicking on the link under Related Links inside CMS.

http://www.cms.gov/CLIA/03_Interpretive_Guidelines_for_Laboratories.asp#TopOfPage

**HEW REPLACEMENT CARD INFORMATION**

For those of you who are not familiar with HEW cards, the Social Security Amendments of 1972 authorized the Department of Health and Human Services [formerly, Health, Education and Welfare (HEW)] to provide an exam for people who had laboratory experience but did not meet the CLIA education and training requirements. The HEW exam was given four times between 1975 and 1977, then again in 1979, 1983, and 1987. The exam concentrated on clinical chemistry, microbiology, hematology, and blood banking. Individuals who received an acceptable score on the exam were issued an HEW card, and then were qualified to perform high-complexity testing.

**FOR HEW REPLACEMENT CARDS CONTACT**

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