January 2013

Compliance Alert:
Important Information for All Laboratories

The Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for enforcing CLIA[1] regulations, recently posted to its website a brochure titled "What Do I Need to Do to Assess Personnel Competency?"[2]

This document clarifies CMS's current thinking regarding CLIA regulations related to competency assessment and is applicable to the transfusion service and to *all* hospital laboratory departments. Our Quality Source consulting team has summarized the important elements of the brochure below. This summary is based on the brochure and information available in January 2013 and is subject to change. Please visit the CMS website[3] for the most current information.

1. Who must have competency assessed?

CLIA explicitly requires that all testing personnel have their competency assessed semi-annually during the first year of testing patient specimens and annually thereafter. This includes any supervisory personnel who perform testing.

CMS now states that if anyone other than the laboratory director (that is, the person listed on the CLIA certificate) performs in the following roles, he or she must have their competency assessed based on their federal regulatory responsibilities:

- Clinical consultant
- Technical consultant (moderate complexity testing)
- Technical supervisor (high complexity testing)
- General supervisor

In particular, this means that if the laboratory director does not function as the technical consultant and/or technical supervisor, the individuals in those positions must have their competency assessed to fulfill the following responsibilities:

- Available to provide consultation
- Select appropriate test methods
- Assure performance specifications are established
- Ensure enrollment and participation in Proficiency Testing
- Ensure QC program is in effect and adequate
- Resolve technical problems
- Identify training needs
- Evaluate competency of testing personnel

NOTE: A yearly personnel evaluation does NOT suffice as a documented competency assessment.

continued

Website references:

1. CLIA on CMS: cms.hhs.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia
2. CMS CLIA Competency Assessment Brochure: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf
3. CMS: cms.gov/

Regulatory Qualification Requirements (42 CFR Ch. IV):

4. Technical Consultant (§493.1411): www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec493-1411.pdf
5. General Supervisor for high complexity testing (§493.146): www.gpo.gov/fdsys/pkg/CFR-2002-title42-vol3/pdf/CFR-2002-title42-vol3-sec493-1461.pdf

2. How must the competency of testing personnel be assessed?

The following six procedures must be performed for the competency assessment of all testing personnel *for each test that the individual is approved by the laboratory director to perform:*

- Direct observation of routine patient test performance
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records
- Direct observations of performance of instrument maintenance and function checks
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
- Assessment of problem solving skills

NOTE: Competency assessments for tests performed simultaneously on the same testing platform can be combined as long as there are no unique aspects, problems or procedures associated with any tests on the test platform.

3. When must annual competency assessments occur?

All six procedures of competency assessment do NOT need to be performed at the same time each year. The laboratory may coordinate the competency assessment with its routine practices and procedures to minimize impact on workload.

4. Who can assess competency?

For moderate complexity testing, the Technical Consultant or other personnel meeting the regulatory qualification requirements for Technical Consultant[4] can assess competency.

For high complexity testing, the Technical Supervisor has the responsibility for performing competency assessment. This responsibility can be delegated, *in writing,* to a General Supervisor, as long as the General Supervisor meets the regulatory qualifications as a General Supervisor for high complexity testing.[5]

NOTE: Peer testing personnel who do not meet the regulatory qualifications of a Technical Consultant, Technical Supervisor or General Supervisor CANNOT be designated to perform competency assessments. (A Technical Supervisor in immunohematology must be an MD or DO, either board certified in clinical pathology or having at least one year of laboratory training or experience, or both, in immunohematology.)

5. Can Proficiency Testing (PT) performance be used to assess competency?

PT performance can be used as part of competency assessment. However, it fulfills only one element of competency assessment. All six required procedures must be incorporated into the competency assessment process.

NOTE: PT samples should NOT be shared among other testing personnel until the results of the PT challenge have been received from your PT provider.

6. Can training evaluations be used in place of a competency assessment?

Documentation of training DOES NOT satisfy the requirement for documented competency assessment. There must be separate evidence that testing personnel were trained, and then that their competency was assessed and found acceptable.

If you have questions regarding the information provided above or additional compliance questions, please contact our blood center's Technical Director or email our Quality Source consulting team at qualitysource@bloodsystems.org.