

October 27, 2021

Ms. Monique Spruill
Director, Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Semi-Annual Competency Requirement (42 CFR 493.1451(b)(9))

Dear Ms. Spruill:

The undersigned organizations respectfully request that the Centers for Medicare & Medicaid Services (CMS) explicitly permit delegation of the semi-annual competency requirement specified in 42 CFR 493.1451(b)(9).

The existing regulations provide that “the technical supervisor is responsible for... evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.”¹ The regulations specifically permit the director or technical supervisor to delegate to the general supervisor the annual evaluations of testing personnel,² but are silent on the delegation of the semiannual competency evaluation.

CMS’ CLIA Brochure entitled, “What Do I Need to Do to Assess Personnel Competency” explains that “[t]he Technical Supervisor for high complexity testing (42 CFR 493.1451(b)(8)) is responsible for performing and documenting competency assessments. This responsibility can be delegated, in writing, to a General Supervisor as long as the GS meets the regulatory qualifications as a GS for high complexity testing.”³

On September 28, 2017, AABB received an email from Penelope Meyers, Technical Director/CLIA, Division of Laboratory Services at CMS, that included written responses to several questions submitted on behalf of AABB members seeking clarification to support compliance efforts. The following question and answer, which was shared during the Association’s annual meeting, includes CMS’ interpretation regarding the delegation of the semi-annual competency assessment:

¹ 42 CFR 493.1451(b)(9).

² 42 CFR 493.1463(b)(4).

³ https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

Question #5

Semi-Annual Competency Assessment

Background: 42 CFR 493.1451(b)(9), which states that the technical supervisor (of any specialty) will perform competency evaluation semiannually during the first year and annually thereafter. It allows delegation to a general supervisor in 42 CFR 493.1463(b)(4). This allows delegation of the annual competency evaluations, but it doesn't say semi-annual.

For the 6-month competency evaluation, would a general supervisor be able to do that evaluation?

Although not specified in the regulation, we have allowed the general supervisor to perform the semi-annual evaluation.

Similarly, the following question and answer was presented during the "Ask the FDA and CMS/CLIA session at AABB's October 16, 2018 Annual Meeting:

Question 42: Does the technical supervisor have to sign off initial training and competency of new staff; or can that be delegated to the general supervisor based on §493.1463 (b)(4) which lists the responsibilities of the General Supervisor (GS) as: "Annually evaluating and documenting the performance of all testing personnel."

CMS Response: "If the TS delegates, in writing, the responsibility for performing and documenting competency assessments to the GS, then it's the GS's written responsibility to perform and document the competency assessment."

In contrast to these communications from CMS, the Agency recently indicated that the semi-annual assessment of competency must be directly observed by the technical supervisor and cannot be delegated.

CMS' conflicting guidance on the delegation of the semi-annual evaluation is confusing and leaves the regulated community unclear about how to comply with the regulations. CMS' most recent interpretation that the semi-annual competency requirement must be performed by the technical supervisor is overly burdensome and unnecessary to protect the public health. The general supervisor provides the day-to-day supervision of testing personnel and reporting of lab results, has the relevant training and expertise, and is qualified to perform both the semi-annual and annual competency assessments.⁴ Since the semi-annual evaluation is the same as the annual evaluation, CMS should explicitly permit the technical supervisor to delegate both assessments to the general supervisor.

Importantly, blood banks, blood centers and other laboratories performing high complexity testing are experiencing significant workforce shortages, which have been exacerbated by the COVID-19 public health emergency. These organizations should be commended for continuing to ensure patient care and safety while managing disruptive vacancies. As a result of the workforce shortages, blood banks, blood centers and laboratories

⁴ 42 C.F.R. 493.1461.

need all staff to be able to operate to the full extent of their education and training. This includes permitting the technical supervisor to delegate the semi-annual assessment to the general supervisor.

Our organizations request that CMS recognize the workforce challenges resulting from the ongoing COVID-19 public health emergency by immediately modifying its most recent interpretation of the semi-annual competency assessment and explicitly permitting the technical supervisor to delegate this function to the general supervisor. Additionally, we urge CMS to revise the regulations and related sub-regulatory guidance accordingly.

If you have any questions or need additional information, please contact Leah Stone at lmstone@aabb.org or 301-215-6554.

Sincerely,

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