DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: S&C 15-07-CLIA EXPIRED

DATE: December 4, 2025

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: **EXPIRED:** Effect on Microbiology Laboratories Due to the Removal of References to the Clinical Laboratory Standards Institute (CLSI) and to CLSI Documents

Memo Information:
Memo expiration date: 2025-12-04
Original release date: 2014-10-31

Memorandum Summary

- **Notification**: CLSI document references will be removed from the upcoming revision of the Survey Procedures and Interpretive Guidelines (IGs) for Laboratories and Laboratory Services.
- **Guidance:** For Clinical Laboratory Improvement Amendments of 1988 (CLIA) quality control (QC) compliance in each time frame.

A. Background

The May 21, 2004, version of the IGs for Laboratories and Laboratory Services for the CLIA program, which are contained in Appendix C of the State Operations Manual (SOM), contain numerous references to the National Committee for Clinical Laboratory Standards, now known as the Clinical and Laboratory Standards Institute ("CLSI"), and to CLSI standards and guidance documents (collectively "CLSI documents"). These include references to language from specific CLSI microbiology documents at the following places:

- D5477; and,
- D5507.

Additional references to CLSI microbiology documents are contained in S&C-09-06 (http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter09-06.pdf).

B. Removal of CLSI References in Upcoming IGs Revision

The next revision of the IGs for Laboratories and Laboratory Services is scheduled for publication later this calendar year. **Please note that all references to CLSI and to CLSI documents will be removed from this upcoming revision of the IGs.** After the implementation date of the revised IGs, S&C-09-06 will be superseded by the revised IGs and no longer be effective.

The following sections of this memorandum address the references to CLSI and CLSI documents that specifically pertain to microbiology and provide advance guidance in anticipation of the new Appendix C provisions that will apply to specific scenarios and time frames.

C. Individualized Quality Control Plan (IQCP)

As discussed in S&C 13-54-CLIA (http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf), Centers for Medicare & Medicaid Services (CMS) anticipates adopting a new equivalent quality control program under §493.1250 which would be called the IQCP. As stated on pages 1 and 2 of S&C 13-54-CLIA, there will be an IQCP Education and Transition Period to allow laboratories an opportunity to learn about IQCP and implement the laboratories' chosen QC policies and procedures, which will begin on January 1, 2014, and conclude on January 1, 2016. For specific information on IQCP, refer to S&C 13-54-CLIA or direct your questions to the IQCP mailbox IQCP@cms.hhs.gov.

D. Timeline

1. Guidance for Laboratories and Surveyors Prior to the Implementation Date of the Anticipated Revised IGs for Laboratories and Laboratory Services and During the IQCP Education and Transition Period

Until implementation of any revisions to the current IGs, laboratories and surveyors can continue to meet their QC obligations in accordance with the Appendix C provisions that reference CLSI microbiology information under the May 21, 2004, version of the IGs and in S&C-09-06. During the time frame that follows the issue date of this memorandum and the publication of the revised IGs for Laboratories and Laboratory Services, microbiology laboratories will have 3 options for CLIA QC compliance:

- Follow all applicable CLIA QC regulations;
- Follow Appendix C's alternate QC requirements, including, where applicable, referenced CLSI-authored microbiology materials; or
- Implement IQCP. (See information in section C of this memorandum.)
    - Laboratories may choose to use the CLSI microbiology information contained in the current IGs and in S&C-09-06 to assist with their IQCP risk assessment, but the CLSI microbiology information alone will not fulfill every requirement for IQCP contained in S&C 13-54-CLIA.

As stated on page 3 of S&C 13-54-CLIA, during the IQCP Education and Transition Period, CMS will generally follow a policy of educational surveys for QC requirements. These include microbiology QC requirements.

2. **Guidance After the Implementation Date of the Anticipated Revised IGs for Laboratories and Laboratory Services through the Remainder of the IQCP Education and Transition Period**

   Microbiology laboratories will have 2 options for CLIA QC:

   - Follow all applicable CLIA QC regulations; or
   - Implement IQCP. (See information in section C of this memorandum.)

   CMS Surveyors:

   - As stated on page 3 of S&C 13-54-CLIA, during the IQCP Education and Transition Period, CMS will generally follow a policy of educational surveys for QC requirements. These include microbiology QC requirements.
   - When a surveyor encounters a situation in which a laboratory is performing QC using the CLSI information contained in the current IGs or in S&C-09-06, the surveyor would document the non-compliance by sending the letter contained in Attachment 1 (Letter for CoC Laboratories Which Have Been Doing QC That Does Not Meet CLIA Requirements Due to CLSI Being Removed from the IGs).

     This letter explains that the laboratory must come into compliance by either following the CLIA regulations as written, or by implementing IQCP.
   - When a surveyor encounters a situation in which a laboratory has already implemented IQCP that does not fully conform to the IQCP procedure in S&C 13-54-CLIA, the surveyor would document this by sending the letter contained in Attachment 3 of S&C 13-54-CLIA.

3. **Guidance After the IQCP Education and Transition Period Has Ended**

   - Microbiology laboratories will have the same two options for CLIA QC that were available during the IQCP Education and Transition Period (i.e., follow all applicable CLIA QC regulations or implement IQCP).
   - Surveyors will be able to cite deficiencies on the CMS-2567 for non-compliance.

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Attachments: Attachment 1: General Letter for CoC Laboratories Which Have Been Doing QC That Does Not Meet CLIA Due to CLSI Being Removed From the IGs
Attachment 2: Guidance for the Laboratory & Surveyor Concerning the Removal of CLSI **Microbiology References** in the IGs for Laboratories and Laboratory Services

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.
Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Receive email notification for memos:

Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

Attachment 1

GENERAL LETTER FOR CoC LABORATORIES WHICH HAVE BEEN DOING QC THAT DOES NOT MEET CLIA DUE TO CLSI BEING REMOVED FROM THE IGS

Dear Laboratory Director,

The (State Agency) Clinical Laboratory Improvement Amendments (CLIA) staff performed a CLIA survey of your laboratory on (date) for certification purposes. At the time of your survey, the surveyor observed certain quality control (QC) practices that did not fully meet the CLIA regulations.

********List the specific D-tags 493.1256(e)(4)(i-iii), D5477; and/or 42 CFR §493.1261(b)(1-2), D5507 not met by the laboratory here. Include a description of each regulatory citation in clear language to accompany the citation and clarify it.********

We are issuing this non-compliance notice as an advisory, rather than a formal enforcement action (Form CMS-2567), as part of an educational effort. The following information is provided to help you ensure your laboratory's CLIA compliance by its next routine biannual recertification survey. You should start planning now to allow sufficient time to implement the necessary changes by the time of your next survey.

All other applicable, unmet CLIA requirements are cited on the Statement of Deficiencies and Plan of Correct (Form CMS-2567) and must be corrected timely.

Background

The May 21, 2004, version of the Interpretive Guidelines for Laboratories and Laboratory Services (IGs) in Appendix C of the State Operations Manual (SOM) contained numerous references to the National Committee for Clinical Laboratory Standards, now known as the Clinical and Laboratory Standards Institute ("CLSI") and to CLSI standards and guidance documents (collectively "CLSI documents"). The current [date] version of the IGs no longer contains any references to CLSI or CLSI documents.

You must follow all applicable CLIA QC regulations or implement the Individualized Quality Control Plan (IQCP). The policies and procedures for IQCP are contained in the optional IQCP IGs, which are available on the CLIA web site at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html.

The IQCP Education and Transition Period will end on January 1, 2016. Beginning January 2, 2016, Microbiology laboratories will have the same 2 options for CLIA QC as were available during the IQCP Education and Transition period (i.e., follow all applicable CLIA QC regulations or implement IQCP). Microbiology QC procedures that do not meet one of these two options will be considered out of compliance, and the laboratory will be cited accordingly (Form CMS-2567). Therefore, by the time your laboratory receives its next routine biennial CLIA survey, the IQCP Education and Transition period will be over and your laboratory will be expected to be in compliance with one of these two options.

If you have any questions or concerns, please contact [insert SA contact information].

Sincerely,

Attachment 2

GUIDANCE FOR THE LABORATORY & SURVEYOR CONCERNING THE REMOVAL OF CLSI MICROBIOLOGY REFERENCES IN THE IGS FOR LABORATORIES AND LABORATORY SERVICES

	Beginning With the Issuance of this Memorandum Until the Publication of the Revised IGs	**Post Publication of the New IGs Through the Remainder of the IQCP Education and Transition Period**	**After the IQCP Education and Transition Period has Ended**
Laboratory	• Follow all applicable CLIA QC regulations; • Follow Appendix C's alternate QC requirements, including, where applicable, referenced CLSI-authored microbiology materials; or • Implement IQCP o Laboratories may choose to use the CLSI microbiology information contained in the current IGs and in S&C-09-06 to assist with their IQCP risk assessment, but the CLSI microbiology information alone will not fulfill every requirement for IQCP contained in S&C 13-54-CLIA	• Follow all applicable CLIA QC regulations or • Implement IQCP.	• Follow all applicable CLIA QC regulations or • Implement IQCP
Surveyor	CMS will generally follow a policy of educational surveys for QC requirements. These include microbiology QC requirements. If the laboratory has already implemented IQCP that does not fully conform to the IQCP procedure in S&C 13-54-CLIA, document this by sending the letter contained in Attachment 3 of S&C 13-54-CLIA	• CMS will generally follow a policy of educational surveys for QC requirements. These include microbiology QC requirements. • If the laboratory is performing QC using CLSI information contained in the current IGs and in S&C-09-06, document the non-compliance by sending the letter contained in Attachment 1. • If the laboratory has already implemented IQCP that does not fully conform to the IQCP procedure in S&C 13-54-CLIA, document this by sending the letter contained in Attachment 3 of S&C 13-54-CLIA.	Cite deficiencies on the CMS-2567 for non-compliance