

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850



**Center for Clinical Standards and Quality/Survey & Certification Group**

**Ref: S&C 17-11-CLIA**

***EXPIRED EFFECTIVE: December 6, 2024***

**DATE:** December 12, 2024

**ORIGINAL POSTING DATE:** December 1, 2016

**DATE:**

**TO:** State Survey Agency Directors

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

**SUBJECT:** ***EXPIRED:*** Advanced Copy –Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (Clinical Laboratory Improvement Amendments (CLIA))

**Memo Expiration Information:**

***Expiration Date:*** December 6, 2024

***Expiration Information:*** Refer to ***QSO-25-10-CLIA: Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services Clinical Laboratory Improvement Amendments (CLIA) - Advanced Copy***

**Memorandum Summary**

**Revisions to Appendix C of the SOM:** The entire document has been revised and updated to include comments and recommendations from:

- Regional Office (RO) and State Agency (SA) surveyors, professional and accrediting organizations (AO);
- Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC);
- CMS Office of General Counsel (OGC); and
- General Accounting Office (GAO) on reporting complaints.

**Deletion**

- D-tags (D2018, D6001, D6002 & 6077).

**It also includes:**

- New D-tags for surveyors; and
- Board certification in dermatology by American Osteopathic Board of Dermatology is equivalent to board certification in dermatology by American Board of Dermatology (ABD)

## **Background**

CMS is issuing this advance copy of the revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. The revisions include edits recommended by RO and SA surveyors, professional and AO's, OGC, and other Health and Human Services (HHS) components.

## **Contact:**

For questions or concerns relating to this memorandum, please contact [LabExcellence@cms.hhs.gov](mailto: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

Attachment- Advanced Copy – Appendix C

## **Resources to Improve Quality of Care:**

*Check out CMS's new [Quality in Focus](#) interactive video series. The series of 10 to 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](#)*

*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.*

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# CMS Manual System

Department of Health & Human  
Services (DHHS)

## Pub. 100-07 State Operations Provider Certification

Centers for Medicare & Medicaid  
Services (CMS)

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Transmittal – Advanced  
Copy

Date:

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### **SUBJECT: Revisions to Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services**

**I. SUMMARY OF CHANGES:** Revisions have been made to reflect comments and recommendations from regional office and State Agency surveyors, professional and accrediting organizations, other Health and Human Services components, and a GAO audit. Changes have also been made to include partial deletions of certain subsections affected and to reflect the recent publication of regulations and updates in technologies within the field of laboratory medicine. Standard level headings have been added to all D-tags for ease of use by surveyors.

**NEW/REVISED MATERIAL - EFFECTIVE DATE\*: 30 DAYS AFTER ISSUANCE**

**IMPLEMENTATION DATE: 30 DAYS AFTER ISSUANCE**

*Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

### **II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)**

**(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

<b>R/N/D</b>	<b>CHAPTER/SECTION/SUBSECTION/TITLE</b>
<b>R</b>	Table of Contents
<b>R</b>	Appendix C/A. Survey Protocols/III. Information Gathering/D. Record Review
<b>R</b>	Appendix C/A. Survey Protocols/VI. Exit Conference
<b>R</b>	Appendix C/A. Survey Protocols/VII. Development of the Statement of Deficiencies/C. Choosing the Appropriate Condition/Example 3.
<b>R</b>	Appendix C/A. Survey Protocols/VII. Development of the Statement of Deficiencies/D. Mandatory Citations
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<b>R</b>	Appendix C /D1000/§493.15 Laboratories performing waived tests
<b>R</b>	Appendix C /D1001/§493.15 Laboratories performing waived tests
<b>R</b>	Appendix C /§493.20 Laboratories performing tests of moderate complexity
<b>R</b>	Appendix C /§493.25 Laboratories performing tests of high complexity
<b>R</b>	Appendix C/§493.37 Requirements for a certificate of waiver
<b>R</b>	Appendix C/§493.47 Requirements for a certificate for provider performed microscopy (PPM) procedures

<b>R</b>	Appendix C/§493.49 Requirements for a certificate of compliance
<b>R</b>	Appendix C/§493.51 Notification requirements for laboratories issued a certificate

	of compliance
<b>R</b>	Appendix C/§493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures
<b>D</b>	Appendix C/D2018/§493.807(b)
<b>R</b>	Appendix C/ PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS/(before & above §493.821 Condition: Microbiology)
<b>R</b>	Appendix C/B. Index/Subpart H/D2074/§493.835 Standard; Syphilis serology
<b>R</b>	Appendix C/B. Index/Subpart H/D2121/§493.851; Standard; Hematology
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R	Appendix C/B. Index/Subpart M/D6069/§493.1425 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6070/§493.1425 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6071/§493.1425 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6072/§493.1425 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6073/§493.1425 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6074/§493.1425 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6075/§493.1425 Standard; Testing personnel responsibilities
R	Appendix C/ LABORATORIES PERFORMING HIGH COMPLEXITY TESTING (before D6076)
R	Appendix C/B. Index/Subpart M/D6076/§493.1441 Condition; Laboratories performing high complexity testing; laboratory director

<b>D</b>	Appendix C/B. Index/Subpart M/D6077/§493.1443 Standard; Laboratory director qualifications
<b>R</b>	Appendix C/B. Index/Subpart M/D6078/§493.1443 Standard; Laboratory director qualifications
<b>R</b>	Appendix C/B. Index/Subpart M/D6079/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6081/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6082/§493.1445 Standard; Laboratory director

	responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6083/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6085/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6086/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6087/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6088/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6089/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6090/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6091/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6092/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6093/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6094/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6095/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6096/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6097/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6098/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6099/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6100/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6101/§493.1445 Standard; Laboratory director responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6102/§493.1445 Standard; Laboratory director responsibilities

R	Appendix C/B. Index/Subpart M/D6107/§493.1445 Standard; Laboratory director responsibilities
R	Appendix C/B. Index/Subpart M/D6108/§493.1447 Condition: Laboratories performing high complexity testing; technical supervisor
R	Appendix C/B. Index/Subpart M/D6109/§493.1449 Standard; Technical supervisor qualifications
R	Appendix C/B. Index/Subpart M/D6111/§493.1449 Standard; Technical supervisor qualifications
R	Appendix C/B. Index/Subpart M/D6112/§493.1451 Standard; Technical supervisor responsibilities

R	Appendix C/B. Index/Subpart M/D6113/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6114/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6115/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6117/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6118/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6119/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6121/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6122/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6123/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6124/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6125/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6126/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6127/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6128/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6129/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6130/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6131/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6132/§493.1451 Standard; Technical supervisor responsibilities
R	Appendix C/B. Index/Subpart M/D6133/§493.1451 Standard; Technical supervisor responsibilities

<b>R</b>	Appendix C/B. Index/Subpart M/D6134/§493.1453 Condition: Laboratories performing high complexity testing; clinical consultant
<b>R</b>	Appendix C/B. Index/Subpart M/D6135/§493.1455 Standard; Clinical consultant qualifications
<b>R</b>	Appendix C/B. Index/Subpart M/D6136/§493.1457 Standard; Clinical consultant responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6137/§493.1457 Standard; Clinical consultant responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6138/§493.1457 Standard; Clinical consultant responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6140/§493.1457 Standard; Clinical consultant

	responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6141/§493.1459 Condition: Laboratories performing high complexity testing; general supervisor
<b>R</b>	Appendix C/B. Index/Subpart M/D6142/§493.1461 Standard; General supervisor qualifications
<b>R</b>	Appendix C/B. Index/Subpart M/D6144/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6145/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6146/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6147/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6148/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6149/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6150/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6151/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6152/§493.1463 Standard; General supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6153/§493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor
<b>R</b>	Appendix C/B. Index/Subpart M/D6155/§493.1469 Standard; Cytology general supervisor qualifications
<b>R</b>	Appendix C/B. Index/Subpart M/D6157/§493.1471 Standard; Cytology general supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6158/§493.1471 Standard; Cytology general supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6159/§493.1471 Standard; Cytology general supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6160/§493.1471 Standard; Cytology general supervisor responsibilities
<b>R</b>	Appendix C/B. Index/Subpart M/D6161/§493.1471 Standard; Cytology general supervisor responsibilities

R	Appendix C/B. Index/Subpart M/D6162/§493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist
R	Appendix C/B. Index/Subpart M/D6163/§493.1483 Standard: Cytotechnologist qualifications
R	Appendix C/B. Index/Subpart M/D6166/§493.1485 Standard; Cytotechnologist Responsibilities
R	Appendix C/B. Index/Subpart M/D6167/§493.1485 Standard; Cytotechnologist Responsibilities
N	Appendix C/B. Index/Subpart M/D6168/§493.1487 Condition; Laboratories performing high complexity testing; testing personnel
R	Appendix C/B. Index/Subpart M/D6170/§493.1489 Standard; Testing personnel qualifications

R	Appendix C/B. Index/Subpart M/D6174/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6175/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6176/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6177/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6178/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6179/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6181/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6182/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart M/D6183/§493.1495 Standard; Testing personnel responsibilities
R	Appendix C/B. Index/Subpart Q--Inspection (before D8100)
R	Appendix C/B. Index/Subpart Q/D8100/§493.1771 Condition: Inspection requirements applicable to All CLIA-certified and CLIA-exempt laboratories
R	Appendix C/B. Index/Subpart Q/D8103/§493.1773 Standard; Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories
R	Appendix C/B. Index/Subpart Q/D8401/§493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation

**III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.**

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>

	<b>Recurring Update Notification</b>
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**\*Unless otherwise specified, the effective date is the date of service.**