



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-11- CLIA

DATE: December 1, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: 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))

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 related to this memorandum, please contact Minnie Christian at 410-786-3339 (minnie.christian@cms.hhs.gov.) or Daniel Cajigas at 410-786-0793 (daniel.cajigas@cms.hhs.gov).

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Effective Date: Immediately. This information is current policy and becomes effective no later than 30 days after the release of the memorandum. The Interpretive Guidelines should be distributed to all CLIA Survey and Certification staff, their managers, SAs, and State RO training coordinators within 30 days of this memorandum. There may be minor revisions in the final document that are not included in this advance copy.

/s/

David R. Wright

Attachment- Advanced Copy – Appendix C

cc: Survey and Certification Regional Office Management

The contents of this letter support activities or actions to improve patient or resident safety and increase quality and reliability of care for better outcomes.

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human
Services (DHHS)
Centers for Medicare & Medicaid
Services (CMS)

Transmittal – Advanced
Copy

Date:

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.)

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

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

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**