

Scott Walker
Governor

Kitty Rhoades
Secretary



State of Wisconsin
Department of Health Services

DIVISION OF QUALITY ASSURANCE

1 WEST WILSON STREET
P O BOX 2969
MADISON WI 53701-2969

Telephone: 608-266-8481
FAX: 608-267-0352
TTY: 888-241-9432
dhs.wisconsin.gov

Date: April 10, 2013

DQA Memo 13-009

To: [Clinical Lab Improvement Amendments](#)

CLIA 01

From: Cremear Mims, Director
Bureau of Health Services

Via: Otis Woods, Administrator
Division of Quality Assurance

Assessing Personnel Competency in Clinical Laboratories

The purpose of this memo is to remind clinical laboratories of the memo distributed by the Centers for Medicare and Medicaid Services (CMS) on December 21, 2012, S&C-13-07 CLIA regarding the release of Brochure #10, "What Do I Need to Do to Assess Personnel Competency"?

This memo can be found at the following link: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-07.pdf>

42 CFR, Part 493, Subpart M of the Code of Federal Regulations is not new; however, CMS is clarifying the laboratory's responsibility to ensure compliance with these requirements. Brochure #10 provides additional information to assist the laboratory in meeting the requirements in Subpart M. Brochure #10 can be found at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html.

As mentioned in the S&C Memo, State and Regional surveyors are required to make compliance determinations as to whether individuals have had their competency assessed according to the personnel requirements stated in 42 CFR, Part 493, Subpart M. Laboratories are expected to be in compliance with the federal regulations; therefore, CLIA surveyors will issue appropriate deficiencies based on survey findings.

Please direct questions regarding this memo to the Bureau of Health Services, Supervisor at (414) 227- 4556 or via email at dhsdqaclia@wi.gov