U.S. Department of Labor

Occupational Safety and Health Administration
Washington, D.C. 20210

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MEMORANDUM FOR: REGIONAL ADMINISTRATORS

THROUGH: GALEN BLANTON
Acting Deputy Assistant Secretary

FROM: AMANDA EDENS
Acting Director, Directorate of Enforcement Programs
Director, Directorate of Technical Support and Emergency Management

SUBJECT: De Minimus Violation Notices: Blood Laboratory Proficiency Testing and Approval

This memorandum provides guidance to Compliance Safety and Health Officers (CSHOs) on how to evaluate employers' use of clinical laboratories for employee blood lead testing under the general industry lead standard (29 CFR 1910.1025(j) (2) (iii)) and the construction Lead Standard (29 CFR 1926.62(j) (2) (iii)).

The general industry Lead Standard, promulgated in 1978, requires that blood lead testing:

> shall be conducted by a laboratory licensed by the Center for Disease Control, United States Department of Health, Education, and Welfare (CDC) or which has received a satisfactory grade in blood lead proficiency testing from CDC in the prior twelve months.

The construction Lead Standard, promulgated in 1993, requires that employee blood lead testing:

> shall be conducted by a laboratory approved by OSHA.

In developing the Lead Standard, OSHA was concerned with the reliability of blood lead analysis as it impinges on workers' health, particularly with regard to medical removal protection. At the time, CDC was delegated specifically to monitor and evaluate the performance of all laboratories that analyze blood specimens of employees affected by workplace exposure to lead.[1] However, in 1986, CDC stopped licensing laboratories for blood lead analysis, and no longer administered a blood lead proficiency testing program. As a result,

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[1] https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.72.4.404
[2]https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ExemptStatesList.pdf
[3]https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIARO.pdf

OSHA then began its own monitoring program of proficiency testing for laboratories performing occupational blood lead analysis. Until the present, OSHA has continued to monitor proficiency test results for laboratories that request status as an OSHA "approved laboratory." That list is currently published 3 times a year on the OSHA website.

At this time, the U.S. Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), administers a blood lead laboratory monitoring system pursuant to the Clinical Laboratory Improvement Amendments (CLIA) regulations, 42 CFR subpart 493. Under those regulations, any laboratory that tests human blood lead samples for the purpose of medical diagnosis must maintain satisfactory performance in an accepted proficiency testing program and be accredited by a CLIA-approved accreditation organization. CLIA is administered by regions and states. Regional and state contact information is found on the CLIA website.[2,3]

OSHA notes that the CLIA criteria for blood lead proficiency testing constitute the federal government's legal requirements for laboratories performing human blood lead testing. OSHA believes that CMS, through CLIA, is the government entity with the expertise and authority best able to determine clinical laboratories' proficiency for conducting the blood lead analyses required by OSHA's Lead Standards.

For these reasons, henceforth OSHA will view the use of a CLIA-approved blood lead analysis laboratory as fully satisfying the requirements of both 29 CFR 1910.1025(j)(2)(iii) and 1926.62(j)(2)(iii) for employee blood lead testing. OSHA recognition of CLIA-approved lab certification will reduce costs and burdens on employers and at the same time reduce costs and increase efficiency to OSHA, as the agency will no longer duplicate the work that CMS already performs.

Where the laboratory used for employee blood lead testing is CLIA-approved, any technical violation of the Lead Standards' proficiency testing requirements will be treated as a de minimus condition that has no direct relationship to safety or health. A de minimus condition does not result in a citation or penalty and need not be abated.