OSHA Criteria for Laboratory Proficiency in Blood Lead Analysis

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THE OCCUPATIONAL SAFETY and Health Act of 1970 was aimed primarily, to the extent possible, at assuring that every working man and woman be provided working conditions that are free from recognized hazards. To protect workers exposed to inorganic lead, the occupational health standard for inorganic lead was promulgated on November 14, 1978.

Central to its protective features is the standard's requirement for providing periodic blood lead monitoring of workers whose health is at risk because of their exposure to lead above the action level of 30 $\mu g/m^3$ of air for more than 30 days a year. Elevated blood lead levels of 40 $\mu g/100$ gm of whole blood or more trigger certain other protective measures. Chief among these measures is medical removal protection (MRP): removing workers from excessive exposure to lead until their blood lead levels drop to specified safer levels that permit their return to normal duties.

In developing the lead standard, the Occupational Safety and Health Administration (OSHA) was concerned with the reliability of blood lead analysis as it impinges on workers' health, particularly with regard to MRP. The Centers for Disease Control was delegated specifically to monitor and evaluate the performance of all laboratories that analyze blood specimens of employees affected by workplace exposure to lead.

The OSHA lead standard, 29 CFR 1910.1025(j)(2)(C)(iii), requires that such analyses:

> shall have an accuracy (to a confidence level of 95%) within plus or minus 15 percent or 6 $\mu g/100$ ml, whichever is greater, and shall be conducted by a laboratory licensed by the Centers for Disease Control (CDC) or which has received a satisfactory grade in blood lead proficiency testing from CDC in the prior twelve months.

This statement has led to some confusion on the part of both employers and testing laboratories in complying with the provision. The OSHA-CDC program described here was designed to aid in implementing the standard's requirements for accuracy in blood lead analysis.

CDC has conducted proficiency testing surveys since 1976, in recognition of the toxic effects of lead and of the analytical problems encountered by laboratories in obtaining precise and accurate blood lead results. Participation is mandatory for laboratories licensed for blood lead analysis by the Health Care Financing Administration under the Clinical Laboratory Improvement Act (CLIA). (CDC no longer licenses laboratories.) Other laboratories that are not under Federal jurisdiction are enrolled as voluntary participants.

In a cooperative effort initiated in 1979, CDC has provided support for the lead standard, in conjunction with its blood lead proficiency testing (PbB-PT) program. OSHA has established performance criteria for the PbB-PT program that are equivalent to the level of accuracy required by the lead standard.

Performance Criteria

Employers who are required to provide medical surveillance of workers exposed to lead must use laboratories for blood lead analysis that meet the requirements for satisfactory performance in the CDC's PbB-PT program. CDC conducts quarterly surveys of laboratories in the program, which consists of testing at least three samples of lead-containing bovine blood. To maintain a satisfactory performance rating, a participating laboratory must obtain results within $\pm$ 15 percent of each sample's target concentration, or $\pm$ 6 $\mu g/dl$ for samples with lead concentrations of less than 40 $\mu g/dl$, for 8 out of 9 samples in the most recent 3 consecutive surveys.

An approved laboratory will be dropped from OSHA's list of qualified laboratories if it (*a*) fails to participate in a survey, (*b*) fails to meet the deadline for reporting its results (exceptions can be made for unusual circumstances), or (*c*) reports an incorrect analysis for more

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than one of nine samples in a three-quarter period (that is, less than eight out of nine samples). Approved laboratories may be excused from participating in a survey owing to circumstances beyond their control. However, to remain on the list, they must then document that they did not analyze any patient blood lead specimens during the period in which the test samples would have been processed.

Sample Results

CDC uses selected reference laboratories to establish the lead concentration of each sample. The reference laboratory mean is designated as the target value. These laboratories use reliable methodology such as atomic absorption, anodic stripping, voltametry, or other analytical methods that have been shown to give acceptable results within the 95 percent confidence level.

Each reference laboratory also must demonstrate consistently accurate lead results for at least 1 year before it is selected as a reference laboratory for the CDC program. Beginning with the first quarter of 1981, each sample distributed in the CDC surveys also has been analyzed by the National Bureau of Standards (NBS) by use of the isotopic dilution-mass spectrometry (IDMS) method. The IDMS values from NBS are the most accurate obtainable and serve to define the actual lead concentration in each sample. Thus far, the reference laboratory mean values have shown excellent agreement with the NBS analyses. This agreement permits laboratories to retain survey samples for calibration purposes. Following each survey, CDC furnishes a report to each participant laboratory with an analysis of the survey results and a rating of the laboratory's individual results. Thus, each participating laboratory can relate its performance to that of peer and reference laboratories.

CDC prepares and forwards quarterly a list of laboratories meeting the OSHA criteria to OSHA for verification. The list includes all laboratories that have met the OSHA requirement of a minimum of 8 out of 9 results (89 percent) within acceptable limits over 3 consecutive surveys. An updated "List of Laboratories Approved for Blood Lead Analysis" is circulated quarterly to OSHA's field offices for use in determining compliance with the lead standard in connection with workplace inspections. The list is available from the OSHA national office, regional offices, or field offices.

State Programs

Certain blood lead proficiency testing programs sponsored by State health departments may be considered equivalent to CDC's PbB-PT program if they meet the OSHA performance criteria and are subject to the same or similar participation requirements enforced by CDC. Eligible States are invited to submit information to OSHA for evaluation of their programs. Laboratories with satisfactory performance in State programs determined to be equivalent will be listed as approved for blood lead analysis if they are under *State* rather than *Federal* jurisdiction.

Participation and Consultation

OSHA and CDC encourage laboratories that serve industrial clients and wish to qualify for blood lead analysis to enroll, at no cost to the participants, in the blood lead proficiency testing program. Laboratories that apply for licensing through the Health Care Financing Administration and become certified to do blood lead analysis are automatically included in the program.

Consultation on CDC's PbB-PT program, or on technical problems dealing with the various analytical methodologies, will be offered by CDC to the extent possible. CDC also conducts a limited number of onsite visits relative to problems in quality control, personnel, equipment, and performance when more intensive examinations appear to be necessary to correct deficiencies, as identified by survey results. Similar services may also be available from cooperating State PbB-PT programs.

Summary

The OSHA lead standard, 29 CFR 1910.1025, was established to protect the health of workers exposed to the hazards of lead. The standard lists specific requirements to ensure that blood lead analyses—critical indicators of workers at risk—be performed reliably by laboratories. Employers must use laboratories that meet OSHA performance criteria in blood lead proficiency testing programs monitored by the Centers for Disease Control and certain States. This proficiency testing requires that, as a minimum, laboratories must report the equivalent of eight out of nine samples within acceptable limits for the most recent three quarters or similar period. For compliance purposes, OSHA circulates to its staff a "List of Laboratories Approved for Blood Lead Analysis" each quarter.

NOTE: Further information on enrolling in the CDC program or concerning proficiency testing may be obtained from Dr. Joe Boone, Centers for Disease Control, Bureau of Proficiency Testing, Atlanta, Ga. 30333 (telephone 404: 329–3155). OSHA will respond to questions on laboratory performance requirements relating to compliance with the lead standard from field representatives, industry, and laboratories. Direct inquiries to Dr. Robert E. Donadio, U.S. Department of Labor, OSHA, Division of Occupational Health Programming, 200 Constitution Ave., N.W., Rm. N3608, Washington, D.C. 20210 (telephone 202: 523-8031).