

DOCUMENTATION OF THE NIOSH VALIDATION

TESTS (DHEW No. 77-185)

David G. Taylor, Richard E. Kupel, John M. Bryant,
U.S. DHEW, NIOSH, Cincinnati, Ohio - April 1977

INTRODUCTION

Early in 1974 the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) announced a joint program to complete the existing workroom level standards promulgated by the U.S. Department of Labor in 1972 (29 CFR 1910.1000). This Standards Completion Program was completed by NIOSH in September 1976. It involved the development of specialized information from which the employer could determine how to comply with the workplace environmental standards. The informational elements in the proposed standards include: informing the employee of hazards, recordkeeping, defining the necessary personal protective equipment, work practices, engineering controls, and environmental and medical monitoring. No attempt was made to change the present permissible exposure limits to chemical substances. Rather, this joint effort provided detailed information to assist the employer in complying with these exposure standards.

The information developed by NIOSH in the program has been set forth in draft technical standards. These documents were reviewed thoroughly by NIOSH and OSHA personnel. In addition, seven professional societies have reviewed the information prior to its being transmitted to OSHA for consideration in promulgating standards.

This document deals specifically with the means by which NIOSH validated existing sampling and analytical methods for monitoring employee exposure to each substance in the regulations. The data reports contained in Appendix B give detailed technical information which support the validation of 216 sampling and analytical methods in the Standards Completion Program. The actual validations were conducted by Stanford Research Institute (SRI) under Contract CDC-99-74-45 with NIOSH. Arthur D. Little, Inc. and Battelle Columbus Laboratories performed validations for NIOSH under sub-contract to SRI. Each contract team set up laboratory facilities and air generation-dilution systems to do complete validations at one-half to two times the OSHA environmental limits shown in 29 CFR 1910.1000, Tables Z-1, Z-2, and Z-3.

The purpose of the validation program is to provide accurate personal sampling and analytical methods in monitoring for non-compliance to the standard by OSHA. The methods are available to others who may want to use them to determine worker exposure to the substances in the OSHA regulations. The validation program was not an attempt to designate the sole procedure by which all worker exposure monitoring must be done. More properly, the validation showed that it is possible

to accurately monitor for the airborne toxic substance. Under the SCP concept, any other analytical methods that an employer may use to measure employee exposure must meet the accuracy requirements set forth in the proposed standard.

Unlike the U.S. Environmental Protection Agency which has a Reference Method for air monitoring, the SCP draft technical standards uniformly designate certain accuracy requirements which must be met for any methods not validated by NIOSH, but are used by an employer for environmental monitoring. There is a sliding scale of proposed requirements depending upon the concentration of the substance. Above the permissible exposure level, the method must come within +25% of the "true" concentration at the 95% confidence level. Above the action level, i.e., one-half the OSHA standard, and up to and including the permissible exposure level, the method must measure within +35% of the "true" concentration. At or below the action level, the method must come within +50% of the "true" concentration. These accuracy requirements refer to the (net) error of the sampling and analytical method used by an employer to measure employee exposure. Should the employer choose to use the NIOSH validated method, the SCP program assures that the method can meet these accuracy requirements.

In conclusion, the technical information presented in this report supports the validation of 216 sampling and analytical methods by NIOSH. An introduction to the Standards Completion Program, a summary of the validation criteria, and the statistical protocol are included. Each of the validated methods is available in the second edition of the "NIOSH Manual of Analytical Methods." In addition, the Sampling Data Sheets (SDS) are available in the "NIOSH Manual of Sampling Data Sheets." The SDS is designed for technical personnel who collect the samples in the field. NIOSH hopes that this information not only supports the completion of the OSHA standards and assists OSHA in its compliance program, but in addition, makes available to the public methods which have received a critical evaluation in the laboratory.

EXPERIMENTAL PROTOCOL

The timing and magnitude of the Standards Completion Program did not allow for collaborative testing of the sampling and analytical methods since approximately 400 methods were scheduled to be validated in a two-year period. Nevertheless, it was deemed important to test both the sampling and the analytical portions of the method. The validation program was designed to evaluate these two parts of the method. Each of the two-part validations was carried out in a single laboratory and although many of the methods have been used in the field previously, no field validations were undertaken.