NIOSH Comments to EPA

COMMENTS OF THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH ON THE ENVIRONMENTAL PROTECTION AGENCY'S REQUEST FOR COMMENTS; NOTICE ON PROPOSED GUIDELINES FOR EXPOSURE-RELATED MEASUREMENTS

FRL-3484-8

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

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INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) has reviewed the Environmental Protection Agency's (EPA's) "Proposed Guidelines for Exposure-Related Measurements" [53 FR 48830]. Generally, we find the measurement (sampling plan, field activities, analytical methods) and data handling methodologies to be in agreement with those used in NIOSH in the evaluation of occupational environments. NIOSH recently commented on the Occupational Safety and Health Administration's (OSHA's) advance notice of proposed rulemaking on a generic standard for exposure monitoring (29 CFR Part 1910, Docket No. H-029). These comments (Enclosure 1) contain many considerations which may be relevant to the EPA guideline.

RETROSPECTIVE EXPOSURES

The proposed guidelines emphasize the importance of developing well-designed studies to assess current exposures so that a prospective assessment of future exposure and risk can be estimated. Unfortunately, there is a disparity in information given on the importance and need for a well-designed study that permits an assessment of past exposures necessary for establishing a relationship between specific exposure and the observed health risk. A considerable amount of human health data used for conducting risk analysis are derived from mortality and morbidity studies of occupational populations. Excess mortality and morbidity observed in these studies of workers are often a result of past exposure conditions that may have changed with time. Thus an assessment that reliably estimates past exposure conditions is essential, and the design of a study should incorporate measures to assess past workplace conditions (e.g., chemicals used, changes in processes, type of engineering controls, and use of personal protective equipment) and work practices (e.g., changes in job responsibilities) of the study population. EPA provides some guidelines for making measurements which can be used for "Direct," "Reconstructive," and "Predictive" exposure assessments, but does not adequately describe how these data (or combination of these data) are to be used for making inferences of past exposures. NIOSH has conducted several epidemiologic and industrial hygiene studies that used different study designs for determining historic exposure conditions, including the identification of hazardous substances and an estimate of their exposure.

The comprehensiveness of the assessment depended on the availability and quality of past workplace and work practice data. Examples of five different approaches for determining and estimating past exposures are

illustrated in the attached reports. The paper entitled "Development of a model for use in estimating exposure to ethylene oxide in a retrospective cohort mortality study" (Enclosure 2) is an objective method for estimating average levels of exposure to ethylene oxide in the absence of industrial hygiene data. The paper entitled "Quantitative risk assessment of lung cancer in U.S. uranium miners" (Enclosure 3) uses several statistical models on radon exposure data from the U.S. cohort of uranium miners to make quantitative risk estimates for various levels of cumulative exposures.

The NIOSH report entitled "Industrial hygiene report--Homestake Mining Company" (Enclosure 4) is an example of a study in which a comprehensive assessment was made to determine historic concentrations of asbestos and arsenic using several statistically based analogies with current exposure data. The reports, "A retrospective cohort mortality study of males mining and milling attapulgite clay" (Enclosure 5) and "A case-control study of leukemia at a naval nuclear shipyard" (Enclosure 6), represent less sophisticated study designs where estimates of exposure were made using either exposure categories (low, medium, high) for a specific agent or with the association of a specific agent(s) to a job classification or process.

The following comments and suggested changes relate to specific sections of the proposed guidelines:

1.1.1 Intended Audience

Two of the more important disciplines--Industrial Hygienist and Epidemiologist--would be essential in a multidisciplinary approach to exposure assessment.

1.3.1 Direct Measurement of Exposure

The TEAM studies done by EPA to assess carbon monoxide are presented as examples of direct exposure assessment. NIOSH has collected a broad base of direct exposure assessment data through the Industrywide Studies, Health Hazard Evaluation, and Control Technology Assessment programs. EPA is directed to these sources as examples of a variety of activities that would have useful data.

2.3 Developing a Sampling Strategy

First paragraph - Recognition of "mixed" exposures is important for: 1) determining interferences that may occur during sampling analysis, 2) determining the need to sample other chemical, physical, or biological agents that may interact in a compound manner or result in a synergistic effect.

2.5.2 Sampling Location and Frequency

The discussion of the sampling frequency needs to be expanded to include the idea that the frequency of sampling is largely determined by the variability of the exposure being characterized. This would include variability in composition, as well as variability of concentration about a central value (Enclosure 1).

2.5.3 Sampling Duration

The toxic effect produced by the chemical should be considered in deciding the sampling duration. For example, short-term peak samples may need to be collected for substances with severe acute effects. Also, the process which produces the exposure may be short in duration.

2.6.4 Reporting Data Near the Detection Limit

Although both the limit of detection (LOD) and the limit of quantitation (LOQ) are defined operationally and used appropriately, NIOSH suggests the following wording for the last paragraph of 2.6.4 to read:

> "The American Chemical Society defines the LOD as the amount or concentration of a substance which would give rise to a measurement that is three times the standard deviation of the population of blank measurements above the mean value for the blank. The LOQ is similar except that ten times the standard deviation of the blank measurement is employed."

Under item 3 of 2.6.4, a minor change in wording should be made. The first paragraph should be revised to read:

> "If the measured value is greater than the LOQ, report the value and index of its uncertainty."

The term "uncertainty" should be defined, such as the standard deviation or the 95% confidence interval. The confidence level or limit should also be defined in the glossary.

3.2 Relevance of Measurement Data for the Intended Exposure Assessment

In Table 3.1, because industrial hygiene studies are only mentioned under Breathing Zone Measurements for "Predictive" Exposure Assessments (defined as area samples collected at breathing zone height), the impression is given that most industrial hygiene measurements are of this type when, in fact, it is far more likely that they are what EPA calls Direct Measurements (Personal Samples). The table only offers two EPA studies as examples of studies that use direct measurements.

3.2.4 Measurements and Modeling

NIOSH recognizes the importance of exposure modeling; however, we also recognize that there are many variables that can affect accuracy. For example, the Greife et al. paper (Enclosure 2) indicates 23 variables that affect the exposure levels of ethylene oxide. We have seen that in some cases, worker exposure variability caused by changes in work practices far exceeds variability of the process and engineering controls as a determining factor of employee exposure (Enclosure 7). As stated in the NIOSH comments to DOL on a generic standard for exposure monitoring (Enclosure 1), the modeling that is applicable is that based on actual sampling data and should be used to predict future exposures in the same area where the data was collected.

NIOSH agrees that exposure monitoring and modeling are complementary; however, it has not been demonstrated that the use of models to verify data collected by new analytical methods is a valid procedure.

3.3.2 The Role of Limit of Detection (LOD) Values in Measurements Used to Estimate Exposure

NIOSH has observed that concentrations of airborne contaminants are generally much lower today than those encountered 15 or 20 years ago. Lower average concentrations result in a higher percentage of nondetectable values. Therefore, NIOSH suggests that the statistical handling of sample data with nondetectable values is very important, particularly with regard to estimation of exposure levels and inferences that are drawn from these estimations.

Enclosure 8 is a draft article that has been submitted by NIOSH scientists. This article summarizes several methods for estimating the mean and standard deviation of exposure monitoring data when various proportions of the sample values are nondetectable (i.e., less than the LOD).

NIOSH suggests that this reference be added to the list that is cited by EPA in Section 3.3.2, and that EPA define in its glossary the term "nondetectable" to be a sample value less than the LOD.

Glossary of Terms

Some additions and changes are recommended as indicated:

> Accuracy - "The extent of agreement between a measured value and the true value of the test parameter for the population under examination."

Blank - "The measured value of a sample or component thereof (e.g., an unexposed sampling media, or an aliquot of the reagents used in the analytical procedure) in the absence of added analyte."

Limit of Detection (LOD) - The amount or concentration of a substance which would give rise to a measurement that is three times the standard deviation of the population of blank measurements above the mean value for the blank.

Limit of Quantitation (LOQ) - The amount or concentration of a substance which would give rise to a measurement that is ten times the standard deviation of the population of blank measurements.

Nondetectable - Any sample level less than the LOD.

Sample - The definition offered implies that the sample is representative of the population. It may not be. A better definition is: "A part of the population under study."

Statistical Control - "There is statistical evidence that the critical variables in a measurement process are being controlled to such an extent that the system yields data which is reproducible within well-defined limits."

Enclosures and/or attachments that are not included are available free of charge from the NIOSH Docket Office (513/533-8450).

LIST OF ENCLOSURES

1. NIOSH [1988]. Comments of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration's Advance Notice on proposed rulemaking on generic standard for exposure monitoring. Cincinnati, OH: Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

2. Greife A, Hornung RW, Stayner LG, and Steenland KN [1988]. Development of a model for use in estimating exposure to ethylene oxide in a retrospective cohort mortality study. Scand J Work Environ Health 14(1):29-30.

3. Hornung RW and Meinhardt TJ [1987]. Quantitative risk assessment of lung cancer in U.S. uranium miners. Health Physics 52(4):417-430.

4. Zumwalde R, Ludwig H, and Dement J [1981]. Industrial hygiene report: Homestake Mining Company, Lead, South Dakota. Cincinnati, OH: Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

5. Waxweiler RJ, Zumwalde RD, Ness GO, and Brown DP [1988]. A retrospective cohort mortality study of males mining and milling attapulgite clay. Am J Ind Med 13:305-315.

6. Stern FB, Waxweiler RA, Beaumont JJ, Lee ST, Rinsky RA, Zumwalde RD, Halperin WE, Bierbaum RJ, Landrigan PJ, and Murray WE [1986]. Original contribution: A case-control study of leukemia at a naval nuclear shipyard. Am J Epidemiol 123(6):980-992.

7. Gressel MG and Fischbach TJ [1988]. In-depth survey report: design of improved workstations for handling dry chemical powders at B.F. Goodrich Company, Industrial Plastics Division, Marietta, Ohio, August 10-14 and August 17-21, 1987 (Report No. 169-11). Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, NTIS Publication No. PB-88-236880.

8. Hornung RW and Reed LD [submitted to Appl Ind Hyg for publication]. Estimation of average concentration in the presence of nondetectable values.

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony includes considerations which may be relevant to the Environmental Protection Agency Guideline for exposure related measurements. The proposed guidelines emphasize the importance of developing well designed studies to assess current exposures so that a prospective assessment of future exposure and risk can be estimated. The comprehensiveness of an assessment depends on the availability and quality of past workplace and work practice data. Two of the more important disciplines, industrial hygienist and epidemiologist, would be essential in a multidisciplinary approach to exposure assessment. The testimony also considers direct measurement of exposure, developing a sampling strategy, sampling location and frequency, sampling duration, reporting data near the detection limit, the relevance of measurement data for the intended exposure assessment, measurements and modeling, and the role of limit of detection values in measurements used to estimate exposure.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Testimony, Lemen-R-A, Epidemiology, Risk-analysis, Sampling-equipment, Sampling-methods

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