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Subject:	Comments on NIOSH Pub 77-173, Docket #NIOSH-091
Attachments:	NIOSHcommentsresamplingstratbook1977.doc

Attached you will find comments submitted by the Center to Protect Workers' Rights (CPWR) on NIOSH publication 77-173. Thank you for the opportunity to provide our input on the utility of this document and how this or similar publications can be improved.

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NIOSH Docket #NIOSH-091
Comments on "Occupational Exposure Sampling Strategies Manual, NIOSH Document No.: DHHS(NIOSH) Publication Number 77-173

The *Occupational Exposure Sampling Strategy Manual* (1977) was an important document in its time which motivated considerable work during the 1980s and 1990s. The manual states on page 37 that the intended objective of the sampling strategy is to identify whether any workers are exposed above the action level (AL) regardless of whether or not a random sampling or maximum risk employee approach is used. If this is accepted as a reasonable approach to protect workers then the use of standard statistical inference procedures (as outlined in the manual) for the non random (maximum risk employee) approach has some problems. The manual seems overly concerned with the variability that the sampling and analytical procedure introduces rather than the actual variability of the exposure itself.

In general, this document focuses primarily upon the narrow issue of compliance, based upon a single measurement exceeding the OSHA PEL (or AL). In this context, the authors devoted most of their attention to the potential that random assay error might affect the assessment process, an issue that is now viewed as a relatively minor source of exposure variability today. Larger sample sizes would easily solve the problem.

A more important issue addressed by the authors was the inter-day variation in exposure levels experienced by a worker. Recognition of this *within-worker variability* led to the development of ALs of half the corresponding PELs and to the practical recommendation (in Section 4.4) that employers limit the exceedance (the probability that a random 8-hr TWA would exceed the PEL) to 5%. It is important to understand that both of these recommendations assume that, whereas exposures can vary randomly *within* workers (from day to day) in a group, exposures do not vary *between* workers (on average) in the group. We now know this latter assumption (of no between-worker variability) is generally incorrect for occupational groups. The presence of significant between-worker variability in an occupational group fundamentally alters the nature of the assessment problem and has been the subject of much research in the last two decades. For example, the whole concept of *overexposure* changes when it is recognized that some workers in a given group can have much greater average and cumulative exposures than others.

There are many other issues of relevance to the assessment of occupational exposures that were not addressed in the 1977 NIOSH document. These include

- the impact of exposure variability on the interpretation of PELs,
- the integration of exposure assessment and control,
- the juxtaposition of compliance and health risk,
- incentives for increasing sample sizes in exposure assessment,

- minimizing biases in assessing exposures,
- the utility of deterministic models of exposure
- control banding, and
- task-based exposure assessments.

There has been a lot of work in the area of statistics, sampling and general approaches to exposure assessment since 1977 and there is much room for improvement in the document. Prior to any revision an expert panel should be convened to consider the scope and objectives of such a document and whether or not the current document can be easily revised or if an entirely new guidance document is warranted. The following points should be considered by such a panel in formulating recommendations for a new guidance document that reflects our current understanding of exposure assessment and provides useful sampling strategies for health hazard assessment, compliance and evaluation of control technologies for reducing occupational exposure to hazardous agents:

1) Exposures are not stationary – the mean and variance change with time, sometimes over short intervals. Current statistical exposure methodology generally neglects this, resulting in biased exposure results, and very limited inferences. Time-series analysis needs to be incorporated into the sampling strategy.
2) Statistical methods capable of incorporating knowledge both *a priori* and as it is learned, need to be explored. Bayesian methods are one example.
3) Exposure distributions are often not lognormal, or can be better fit with more appropriate distributions particularly for inference purposes. Beta distributions and 4-parameter lognormal models are cases in point.
4) Exposures that are highly variable require very large sample sizes to characterize adequately using traditional random sample approaches. This is especially relevant in the construction industry where there are many different tasks involved under very different conditions. The task based sampling approach shows promise, but effective statistical techniques need to be developed for this type of assessment. This relates strongly to item (2) above.
5) It is extremely important that the objective of any sampling strategy be defined clearly and quantitatively so that hypotheses can be tested and/or inferences logically defended.
6) Computer capabilities and access to sophisticated statistical techniques have increased so dramatically since 1977 that some consideration of this needs to be included in any revision of the sampling manual. Software resources should be brought to bear on the problem.
7) Use of leading indicators to predict future exposures where tasks and materials are rapidly changing such as in construction.

References

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