



November 27, 2007

Sirs,

A revised OESSM should inform the Employer and the representatives of the employer, such as EHS professionals, on the following points:

- Risk Management relates to the quality or acceptability of the work environment.
- Exposure assessment (and management) is a component of the Employer's overall Risk Management program.
- Risk Management relates to the quality or acceptability of the work environment.
- An acceptable work environment is one where the exposure profile, or distribution of exposures, for each worker is adequately controlled or managed.
- An adequately controlled or managed exposure profile for each worker is one where the overwhelming majority of exposures are less than the OEL.
- The quality of the work environment can be expressed as an Exposure Rating.
- The Exposure Rating leads to EHS actions on the part of the Employer.
- Exposure assessment and management is a continuous, ongoing activity.
- The Employer's Risk Management program applies to all substances and mixtures, whether or not each is covered by a regulatory exposure limit.
- In the absence of an exposure limit the Employer - with expert guidance, perhaps obtained through trade and professional organizations or through the use of in-house expertise - should devise a provisional or permanent exposure limit.
- An exposure assessment strategy should be Performance-based.

1 Risk Management relates to the quality or acceptability of the work environment.

Risk of occupational disease is properly managed when workers in the work environment are routinely not overexposed to chemical substances and mixtures. The only way to know if exposures are properly managed (i.e., controlled) - other than completely enclosing a process to the point that exposure at any level is unlikely to impossible - is to routinely do exposure assessments.

2 Exposure assessment (and management) is a component of the Employer's overall Risk Management program.

An exposure assessment and management program (EAMP) is part of the Risk Management function of every company and corporation. Exposures are "assessed" and if found to be excessive, relative to some exposure limit, the potential for exposure is then "managed" or controlled using the hierarchy of controls. It is critical to view the EAMP as a quality control program that has as its goal ensuring that the overwhelming majority of exposures are less than the "specification upper limit", i.e., the exposure limit.^a

Companies are well aware that without an ongoing and effective quality control program the quality of the product or service will most likely deteriorate to be point that the company is affected financially. All quality control programs are designed to rapidly detect a significant shift in the quality of the product. The

^a Often in the U.S. and particularly in the EU the phrase "risk assessment" is used interchangeably with "exposure assessment". Strictly speaking, "exposure assessment and management" is a risk management function and "exposure assessment" applies to the determination of the risk to an exposed population at various levels of exposure.

assessment and control of occupational exposures should be similarly approached. Consequently, the revised OESSM should similarly emphasize that an EAMP should also be designed to have a high power to detect poorly-controlled work environments.

3 An acceptable work environment is one where the exposure profile, or distribution of exposures, for each worker is adequately controlled or managed.

A work environment is acceptable (i.e., has high quality from a quality control point of view) whenever the exposure profile, or distribution of exposures experienced by each worker, is adequately controlled.

4 An adequately controlled or managed exposure profile for each worker is one where the overwhelming majority of exposures are less than the OEL.

An acceptable or controlled exposure profile for each worker - for all TWA-OELs, whether OSHA, MSHA, ACGIH, AIHA, NIOSH - is one where the overwhelming majority of exposures - e.g., 90%, 95%, or 99%, depending upon the toxicity of the substance and/or the severity of the disease endpoint - are less than the OEL.

5 The quality of the work environment can be expressed as an Exposure Rating.

The AIHA exposure rating scheme is an extremely useful mechanism for characterizing the quality or acceptability of a work environment (see Table 1 and Mulhausen and Damiano, 1998 and Bullock and Ignacio, 2006). Employers should set a goal to achieve a Category 2 or better exposure rating. This is consistent with the "continuous improvement" concept found in the various international and chemical industry EHS program management systems that have been published and promoted over the past ten years. NIOSH should promote an identical or similar exposure rating approach.

6 The Exposure Rating leads to EHS actions on the part of the Employer.

The purpose of the exposure rating scheme is the help guide the selection of appropriate actions (see Table 2). These actions are consistent with the Action Limit concept as incorporated into various OSHA 6b regulations, as well as the requirements of the Hazard Communication and Respiratory Protection regulations.

7 Exposure assessment and management is a continuous, ongoing activity.

Like quality control, exposure assessment (and management) is not a one-time proposition. Without audit, surveillance, commissioning, and diagnostic exposure assessments the "quality" of the work environment will most likely deteriorate, leading to excessive risk to the employees (as well as risk to the company, although the risks are of a different sort).

8 The Employer's Risk Management program applies to all substances and mixtures, whether or not each is covered by a regulatory exposure limit.

The 1977 OESSM tended to emphasize the OSHA PELs. The majority of substances and mixtures are not covered by a federal PEL. The Employer should be aware that the obligation to assess and control excessive exposures applies to all toxic and potentially harmful substances and mixtures, not just the few regulated by OSHA.

9 In the absence of an exposure limit the Employer - with expert guidance, perhaps obtained through trade and professional organizations or through the use of in-house expertise - should devise a provisional or permanent exposure limit.

In the absence of an exposure limit one must be devised in order to assess and manage occupational exposures (Paustenbach, 1994; Mulhausen and Damiano, 1998; Bullock and Ignacio, 2006). Control Banding principles could be used as a first approximation.

10 An exposure assessment strategy should be Performance-based.

An exposure assessment strategy should be designed with a goal in mind, and the goals are different for the different types of exposure assessment surveys: e.g., audit, baseline/initial, surveillance, termination/reduction, diagnostic, commissioning (for a new process or piece of equipment), or research (i.e., as during epidemiological study).

For a baseline survey (or the "initial" survey as it is referred to in many of the OSHA 6b regulations)^b the goal should be to detect a poorly-controlled exposure profile (i.e., a Category 4 exposure) *if it exists*. If this is the goal, the strategy should have a high power to detect such an exposure profile. See Hewett (2006) for guidance on designing performance-based strategies.

The OESSM focused on audit surveys, where the goal is to determine if exposures are acceptable *only on the day of the survey*. This quite different from and much less rigorous than a survey designed to determine if the exposure profile (i.e., the distribution of exposures across a wide range of days, such a quarter, half or full year) is acceptable or unacceptable.

There are many other issues, but the above represent the major points that I wish to make. Please review my several publications and chapters for additional information (see the reference list).

There will be those that will try to get NIOSH to agree to or tacitly accept the proposition that TWA-OELs have been and should be defined and interpreted as upper limits on the long-term, multi-year, or even lifetime average exposure of each worker. This concept, when first advanced (to my knowledge) in the 70's and 80's by the petroleum/chemical industry and their funded academicians, was aimed at persuading OSHA to define the proposed benzene PEL as the upper limit to the average exposure calculated across a number of shifts, rather than across a single shift. Had OSHA accepted the long-term average definition exposures to benzene would probably not have decreased by much and enforcement would have been virtually impossible. However, OSHA, in the benzene standard preamble, critiqued and correctly rejected this proposition. For additional information on the use and interpretation of TWA-OELs see my several publications and letters-to-the-editor in the reference list, as well as the publications and white papers of the AIHA on exposure assessment.

I anticipate that the process of revising the OESSM will cover several years with other opportunities for reviewing draft materials and for submitting comments. I regret not being able to participate in the recent workshop on revising the OESSM and will make an effort to attend any future workshop.

Thanks for considering my comments.

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^b For example: 29 CFR 1910.1052(d)(2) Initial determination "Each employer whose employees are exposed to MC [i.e., methylene chloride] shall perform initial exposure monitoring to determine each affected employee's exposure..."

References

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11 TABLES

Table 1: AIHA exposure rating scheme. An exposure category can be assigned to a SEG or SEG-task whenever the true 95th percentile exposure ($X_{0.95}$) falls within the specified range.

Exposure Category	Rule-of-thumb Description*	Qualitative Description	Recommended Statistical Interpretation**	Notes
0	Exposures are trivial to non-existent - employees have little to no exposure, with little to no inhalation contact.	Exposures, if they occur, infrequently exceed 1% of the OEL.	$X_{0.95} \leq 0.01 \cdot OEL$	1
1	Exposures are <i>highly-controlled</i> - employees have minimal exposure, with little to no inhalation contact.	Exposures infrequently exceed 10% of the OEL.	$0.01 \cdot OEL < X_{0.95} \leq 0.1 \cdot OEL$	2
2	Exposures are <i>well-controlled</i> - employees have frequent contact at low concentrations and rare contact at high concentrations.	Exposures infrequently exceed 50% of the OEL and rarely exceed the OEL.	$0.1 \cdot OEL < X_{0.95} \leq 0.5 \cdot OEL$	2,3,4
3	Exposures are <i>controlled</i> - employees have frequent contact at low concentrations and infrequent contact at high concentrations.	Exposures infrequently exceed the OEL.	$0.5 \cdot OEL < X_{0.95} \leq OEL$	2,4
4	Exposures are <i>poorly-controlled</i> - employees often have contact at high or very high concentrations.	Exposures frequently exceed the OEL.	$X_{0.95} > OEL$	4

* The "Rule-of-thumb" descriptions were adapted from the AIHA.

** $X_{0.95}$ = the true group 95th percentile exposure

1 Category 0 was added to distinguish between highly-controlled exposures and situations where exposures are either nonexistent or trivially low. It was included in the 1991 AIHA rating scheme .

2 "Infrequently" refers to an event that occurs no more than 5% of the time.

3 "Rarely" refers to an event that occurs no more than 1% of the time.

4 "High concentrations" are defined as concentrations that exceed the TWA OEL.

Table 2: Typical actions or controls that result for each Final Rating.

Final Rating	Action or Control
0	no action
1	general or chemical specific hazard communication
2	chemical specific hazard communication
3	+ exposure surveillance, medical surveillance, and work practice evaluation
4	+ respiratory protection, and engineering controls; validate that the respiratory protection is appropriate
4+	immediate engineering controls or process shutdown; validate that the respiratory protection is appropriate