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Misinterpretation and Misuse of Exposure Limits

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Users of occupational exposure limits (OELs) often fail to distinguish between the complementary processes of risk assessment and exposure (risk) management. The former refers to those activities that lead to the selection of a reasonably protective exposure limit and often includes an analysis of exposure databases and an evaluation of group-based risk. The latter focuses on individual risk, and refers to those actions required of employers to ensure that each employee is unlikely to incur harm to health. This presentation focuses on how this failure to distinguish leads to misinterpretation and misuse of OELs.

A typical OEL definition consists of at least three components: a concentration, an averaging time, and a target (usually the individual worker). OELs are occasionally improperly applied, resulting in a reduction of the expected level of protection. For example, sampling strategies proposed by the American Industrial Hygiene Association (AIHA) and Comité Européen de Normalisation (CEN) permit workers to be aggregated into exposure groups. Under certain circumstances this practice can leave some workers unevaluated and unprotected. Protection is also reduced when the averaging time is extended from a single shift to multiple shifts. Frequently, OELs are misinterpreted as upper limits to exposures averaged over weeks, months, or even years, rather than a single shift.

Much of this confusion can be traced to the desire of some to reconcile research (epidemiology) sampling strategies with compliance sampling strategies. But the two have fundamentally different goals and objectives. Others are simply attracted to alternative OEL interpretations that permit frequent overexposures (i.e., measurements that exceed the OEL), thus making compliance easier.

Given the current limitations of industrial hygiene and occupational epidemiology, and the general unwillingness of employers to routinely collect exposure data, OELs should continue to be defined as upper limits for single shift exposures. The current OEL model, which permits the use of proximate risk management goals to realize long-range objectives, should be retained. There are, however, valid reasons for augmenting this model to include criteria for evaluating compliance with long-range objectives. The augmented OEL model would be applicable to future new and revised OELs. The author suggests that OEL setting organizations consider harmonizing definitions and statistical interpretations for both existing and new OELs, thus minimizing future misinterpretation and misuse.

Historically, organizations that devise and recommend time-weighted average occupational exposure limits (TWA OELs) have consistently defined the TWA OEL as a concentration that should not be exceeded during each shift. The averaging time for each measurement is specified as eight to ten hours, depending upon the source of the OEL. When devising data analysis schemes, the conventional practice among industrial hygienists has been to interpret the TWA OELs as upper percentiles. Consequently, in a nominally controlled work environment single shift excursions above the TWA OEL (overexposures) should be infrequent to rare.[1–6] In contrast, relatively recent articles have recommended that industrial hygienists instead interpret the conventional TWA OEL as upper limits to the long-term average (LTA) exposure experienced by each worker.[7,8] This interpretation is considerably more lenient than that intended by regulatory agencies and OEL setting organizations and, in principle, can lead to the reduced protection of workers.[9–12]

It was noted more than 30 years ago that "it is important that hygienic standards should not be given widely different interpretations."[13] Although there is merit in the idea that a substance that is largely a chronic disease agent should have a LTA OEL, simply redefining existing TWA OELs as LTA OELs will reduce the nominal level of protection afforded by each OEL and therefore is not in the interest of either employers or employees.[14] In light of the current emphasis on the harmonization of occupational exposure databases, the author recommends that an effort be initiated toward the international harmonization of occupational exposure limit definitions and statistical interpretations. Such harmonization would lead to a common understanding of the range of reasonable or intended statistical interpretations that can be applied to occupational exposure limits and, in principle, would facilitate the design of site specific exposure monitoring programs.

BACKGROUND

In 1973, shortly after the U.S. Occupational Safety and Health Administration (OSHA) was created, Dr. Stokinger, chair of the American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Value (TLV®) Committee, published a article[15] on how the committee "would have the factory inspector evaluate compliance with (the TLVs)." The procedure suggested was nearly identical to that adopted by OSHA in the early 1970s, and later recommended by NIOSH.[1] If any TWA measurement exceeds the TWA TLV (allowing for a margin of measurement error), then the exposure was not in compliance with the TLV during that shift and a citation is justified. Nearly 30 years later OSHA continues to use this procedure when its inspectors conduct audits of employer compliance with the OSHA permissible exposure limits (PELs).*

The earliest comprehensive treatment given to exposure assessment statistics was perhaps the 1977 NIOSH sampling strategies manual.[1] NIOSH stated that in principle each employer should be 95 percent confident that 95 percent of the exposures for each worker are less than the OEL. However, NIOSH recommended simple decision rules designed to assist small and medium size businesses, having limited resources and little experience using exposure limits, to demonstrate compliance with the OSHA exposure limits. The NIOSH strategy emphasized the collection of one or more single-shift exposure measurements from the most exposed employee(s) of an exposure group, and the direct comparison of each measurement to the TWA OEL. If the exposures of the most exposed employees were in compliance during a single shift, it was reasoned that the other employees in the exposure group were likewise protected during that shift.

The limitations of the "single shift testing" aspect of the NIOSH and OSHA strategies were discussed by Tuggle[16] and Rappaport.[17] While some of this early criticism was not entirely convincing, it did lead to a considerable amount of critical thinking about industrial hygiene sample strategies. The current practice of aggregating workers into exposure groups and evaluating the *group* exposure profile can be traced to a 1979 article by Corn and Esmen.[2] Elements of these and other papers were reflected in the recent American Industrial Hygiene Association (AIHA) monographs[3,4] on exposure assessment, as well as the European Union 1995 exposure assessment standard.[5] Today the assessment of workers aggregated into similar or homogeneous or uniform exposure groups is the cornerstone of modern industrial hygiene practice.

During the 1980s researchers had the opportunity to analyze exposure data sets where two or more repeat measurements were collected from each worker, generally for research purposes. Analysis-of-variance techniques were applied to the data sets and the within- and between-worker components of variability were estimated and compared. This led to criticism that the commonly used observational techniques for aggregating workers into exposures—for example, grouping workers by job title or work area—often did not lead to reasonably homogeneous exposure groups.[18] This, in turn, led to an increased awareness of the circumstances where repeat sampling may be useful for refining exposure group definitions, as well circumstances where within-group heterogeneity is of little importance.[4]

Throughout this period some compliance theorists also suggested that the TWA OELs for chronic disease agents should be interpreted as the long-term mean exposure experienced by each worker (see Figure 1).[17,19] Industrial hygienists have traditionally interpreted the ACGIH TLVs and OSHA PELs for chronic disease agents as upper limits that should not be exceeded, on a shift to shift basis. Were they wrong? Is the correct averaging time for a chronic disease agent TWA OEL longer than a single shift? Hewett[9] reviewed the literature and concluded that the evidence was clear that the TWA OELs issued by the ACGIH, AIHA, OSHA, and NIOSH were and are defined as concentrations, averaged across each single shift, that should not be exceeded.

At its core, an OEL consists of a concentration, an averaging time, and a target. (Most governmental exposure limits are often accompanied by additional criteria or guidance regarding exposure monitoring, medical surveillance, hierarchy of controls, and so forth, that in combination with the OEL minimize

"Daily levels would be allowed to exceed the PEL if they were compensated by other days of low exposure so that μ was below the PEL." Rappaport, 1984

"... 28-week period [to 298 week period] ... is taken as the period of time to calculate the TWA concentration." Corn et al., 1994

"The hypothesis testing strategy focuses on the probability that an arbitrary worker in a job group experiences a long-term mean exposure above the occupational exposure limit (OEL)." Lyles, Kupper, and Rappaport, 1997

FIGURE 1
Selected recommendations regarding the use of TWA OELs.

*Regarding exposure to asbestos, OSHA stated that if employers wish to show that an inspector's measurement is unrepresentative, that they should present a dataset of valid measurements, collected within the past year, for the employee in question. These measurements should show that "on only relatively rare occasions could random fluctuations result in measured TWA concentrations above the PEL. (OSHA, *Federal Register* 51(119):22654, June 20, 1986).

the risk of occupational disease.) The averaging time is a critical concept and refers to period for which an average exposure is calculated. This exposure then becomes a measurement or datum that can, by itself, be compared to the OEL, or with other data be analyzed statistically. Typically, the target of an OEL is the individual worker, although there are instances where the OEL refers to a work environment (e.g., in the United States the cotton dust PEL[20] applies to area samples while in the United Kingdom the vinyl chloride exposure limit[6] applies to the exposure profile of a work environment).

If the number of measurements per worker or exposure group is small, then each measurement or datum should be compared to the OEL.[5] If the sample size is large, say six or more measurements, then statistics such as the upper percentile (e.g., 95th percentile or its upper confidence limit)[2–5] can be compared to the OEL. Since in most work environments there is always a finite probability of a random exposure exceeding the TWA OEL[21] the idea that a nominally controlled worker exposure profile is one where the exceedance fraction is low (e.g., 5% or less) has become commonplace.[1,3–5]†

Unfortunately, this upper percentile statistical interpretation of the TWA OELs did not fit well with the proposals for the collection and statistical analysis of large datasets of where each worker was sampled more than once. Proponents of these sampling strategies have proposed instead a variety of alternative statistical interpretations for the TWA OEL concept, and encourage employers to interpret TWA OELs as the average concentration over some ill-defined, broad span of time.

MISUSE AND MISINTERPRETATION OF OELS

I have previously argued that TWA OELs are misused and misinterpreted when they are used as limits for the long-term average exposure.[10–12,14] By extending the averaging time from the original single shift to longer periods the user has basically created a different OEL that, in principle, does not provide the same level of protection as the original. In part this is because this alternative interpretation permits daily TWA exposures to frequently exceed the TWA OEL.[17,19]

Recommendations for an alternative averaging time range from one week[22] to one year[23] to as long as five[19] or even fifteen years.[22] In a few cases, these alternative definitions are simply self-serving, permitting the employer to justify ignoring current high exposures by averaging them with previous, lower exposures. Others[8] thoughtfully argue that employers should abandon "compliance testing" and cease comparing each full-shift TWA measurement to the TWA OEL, adopting instead strategies where workers are sampled repeatedly each year of observation.

There are several published examples where TWA OELs have been interpreted as if they were LTA OELs. The substances involved include nickel,[7] styrene,[24] benzene,[25] asbestos,[19] coal dust,[25] welding fumes,[25] and crystalline silica.[22] In these instances new definitions of "overexposure" have been created. For example, "overexposure" has been used to refer to either an individual worker mean exposure or to the mean of an entire exposure group, plant, or mine exceeding the TWA OEL. To some "overexposure" refers to the probability that a random worker's true mean exceeds the OEL or the condition where a worker's cumulative exposure exceeds the product of the OEL and 45 years. Such definitions lead to a variety of questions that have not been adequately examined. For example:

- What should be the averaging time for a generic LTA OEL? Should it be one week, six months, one year, several years?
- Should a long-term average be calculated for each worker, for an exposure group, or work environment?
- Can the dose-rate be ignored? How does one protect workers against short-term effects with only a LTA OEL as a comparison metric?‡
- Should the same workers be repeatedly sampled? If so, how do we ensure that compliance decisions will be protective of all workers, measured or unmeasured?
- How many measurements should be collected each week, month, or year?

Regarding the latter issue, computer simulations show that huge sample sizes, as well as extremely low exposures, may be needed to pass the compliance scheme proposed by one group of long-term average interpretation advocates.[24] Few companies have the resources to do such sampling, and indeed is such a level of effort needed. As suggested by Hewett,[11] such extensive sampling may not be necessary to make the same valid risk management decision. And then there is the timeliness issue. When does one intervene as the number of single shift overexposures accumulate? It is unlikely that deleterious changes in the work environment will be rapidly detected when using strict "long-term averaging" scheme. Last, it is unclear if these new compliance schemes leave any room for professional judgment and the use of diagnostic sampling techniques.[7,8]

Risk Assessment v. Risk Management

Part of the reason that compliance theorists are drawn to the long-term average interpretation of TWA OELs can be attributed to a failure to distinguish between the complementary concepts of risk assessment and risk management. The phrase "risk assessment" is often used to refer to the process leading to recommendation of a protective OEL. The risk assessor needs accurate

† In contrast, a *well-controlled* exposure profile is one where the true 95th percentile exposure does not exceed 50 percent of the TWA OEL. Exposures can be considered *highly-controlled* if the true 95th percentile exposure does not exceed 10 percent of the OEL.[4]

‡ It is well known that excessive exposures to many so-called chronic disease agents, for example, silica, lead, benzene, cadmium, and nickel, to name a few, can over a period of hours, several shifts, weeks, months, or years—depending upon the substance—result in poisoning and/or irreversible disease.

job exposure matrices so that accurate cumulative or long-term (working lifetime) average exposures can be calculated. This data is then fed into an exposure-response analysis where the lifetime risk for *a hypothetical worker* is estimated for different exposure levels. Critical to this process is the estimation of long-term, usually working lifetime, exposures. The resulting risk statements are also often expressed in relation to working lifetime average exposure.[14]

Risk management, on the other hand, is an entirely separate process that has often been compared to quality control. The OEL is used as a metric to determine if *current* exposures, that is, the current exposure profiles, are reasonably and effectively managed. OEL sponsoring organizations expect that when a worker's TWA exposures are consistently and regularly maintained below the TWA OEL, that the long-term average exposure will be much less than TWA OEL. Consequently, the actual risk to that worker should also be much less than the residual risk estimated in the exposure-response analysis.[14,21] In addition, ensuring that single shift exposures do not or rarely exceed the TWA OEL helps ensure that the dose rate is also limited or minimized.

These notions are not restricted to the United States. The United Kingdom guidelines on exposure limits[6] define the averaging time for a TWA exposure limit as normally eight hours. The European Union standard EN 689 for assessing workplace exposures[5] discusses the "8-hour reference period" and notes that for small sample sizes that each TWA is compared to the OEL. If the sample size is six or more, then one can calculate and compare the sample (i.e., point estimate) exceedance fraction to a 5 percent criterion.

A PROPOSAL FOR HARMONIZATION

Given the current limitations of industrial hygiene and occupational epidemiology, particularly those related to resources, TWA OELs should continue to be defined as upper limits for single shift exposures. The current OEL model, which permits the use of proximate risk management goals to realize long-range objectives, should be retained. There are, however, valid reasons for augmenting this model to include criteria for evaluating compliance with long-range objectives. The augmented OEL model would be applicable to future new and revised OELs. I propose that the occupational health community develop international guidelines for the following concepts for chronic disease agents: dual OELs, OEL definitions, OEL statistical interpretations, and OEL compliance.

Dual OELs

Chronic disease agents should have both a TWA OEL and a LTA OEL.[10–12,14] The TWA OEL would be used to limit dose rate and as a metric for evaluating exposure management on a day-to-day basis. For example, maintenance of the true 95th percentile of each worker's exposure profile to the TWA OEL will directly limit excessive, single-shift exposures and at the same time indirectly limit long-term average exposure.[10,26] The LTA OEL would be used to ensure, as exposure data is accumulated on a year to year basis, that the long-term goal is indeed being achieved for each worker.

OEL Definitions

The TWA OEL would be defined as a concentration that *should not* be exceeded for *each* shift. The LTA OEL would be specified as an annual average that *must not* be exceeded. Numerically the LTA OEL is always less than the TWA OEL. I suggest that it be no more than 50 percent of the TWA OEL, and for some substances as low as 10 percent to 25 percent.[27] It may be expedient to simply establish a fixed ratio for the TWA OEL and LTA OEL, applicable to all chronic disease agents. For example, the AIHA[3,4] suggested that it is reasonable to define a provisional LTA OEL as one-third of the TWA OEL.

OEL Statistical Interpretations

When designing exposure sampling strategies, the employer should interpret the TWA OELs as an upper percentile (e.g., 95th percentile) for each worker's exposure profile. The LTA OELs should be interpreted as the upper limit for each worker's annual average exposure. The employer can then design a site specific sampling strategy using guidance from a variety of sources.

OEL Compliance

There should be agreement on what it means to be in compliance with both the TWA OEL and LTA OEL. For example, a nominally controlled exposure profile for a worker would be one where the true fraction of single-shift TWAs above the TWA OEL is low, and the true annual mean is less than the LTA OEL.

The opposite of compliance is overexposure. I propose that we retain the traditional notion of overexposure. If any TWA measurement exceeds the TWA OEL, then an *overexposure*, relative to the TWA OEL, has occurred and should be investigated. If current or fairly recent exposure data suggest that the overexposure is a random happening in an otherwise controlled work environment, then it is reasonable to take no action beyond merely documenting the investigation. However, if no explanation can be suggested for the over-exposure(s), then one should conclude that a systematic change of some sort *may* have occurred. Follow up actions may consist simply of adjustment to existing controls, installation or modification of controls, or a comprehensive evaluation of individual work practices. Afterwards, additional measurements are usually necessary to verify the need for additional controls or to evaluate the effectiveness of any intervention.

The true mean of a worker's annual exposure profile must be less than the LTA OEL. If the current *sample* mean of a worker exceeds the LTA OEL, then a potential *overexposure*, relative to the LTA OEL, has occurred, and the situation should be investigated, as described above. The annual average exposure should not be permitted to exceed the LTA OEL.

In the U.K. the "maximum exposure limit" for vinyl chloride is 7 ppm (using the 8-hour TWA reference period. This single shift limit is subject to an "overriding annual exposure limit of 3 ppm":

> "Exposure should be recorded as the time-weighted average of vinyl chloride in the atmosphere of a working area over a period of one year. At enclosed vinyl chloride polymerisation plants continuous or permanent sequential sampling method must be used. Where discontinuous measurements are made, the frequency of measurements and the number per year should be such that it is possible to state with [a] statistical confidence coefficient of at 95 percent that the true mean annual concentration did not exceed the annual maximum exposure limit."

Source: U.K. Health and Safety Executive EH 40/99 Occupational Exposure Limits 1999.

FIGURE 2
The United Kingdom standard for vinyl chloride.

These concepts are not new. The United Kingdom vinyl chloride standard (see Figure 2) already has both a TWA OEL and an annual LTA OEL. Investigation of each overexposure is standard practice with most IHs, and is required by the United States and United Kingdom[6] regulations, as well as the regulations of other countries. For example, in the United Kingdom the Health and Safety Executive[6] advises employers that "(if the Occupational Exposure Standard) is exceeded, the reason must be identified." In the United States the AIHA[4] recommends that "all exposures above an OEL be investigated." The ASTM Committee E-34 on Occupational Health and Safety recommended for silica that when the OSHA PEL is exceeded "a root cause analysis should be conducted for all exposures in excess of the PEL that can not be accounted for."[28] OSHA regulations require that each overexposure be investigated, and that necessary steps be taken to minimize the likelihood of future overexposures.

Advantages to Harmonization

Dual limits for substances where the *primary* disease outcome is a chronic effect would likely lead to improved management of chronic disease risk. The TWA OEL would be used to assess measurements as they are collected, e.g., the analysis of data from baseline surveys and audits. Compliance with the TWA OEL would help limit dose-rate. This is a important consideration, since for most substances the effects of high short-term (days, weeks, months) exposures are often unknown, suggesting that the precautionary principle be applied. The LTA OEL, where the averaging time is no more than one year, or perhaps two in documented highly stable work environments, is used to determine if the long-range goal is actually being achieved and to evaluate datasets containing repeat measurements.

Dual limits would facilitate the design of *efficient* and *effective* exposure assessment strategies. For example, small and medium-size businesses might be inclined to adopt efficient maximum exposed employee based strategies, or task or process control strategies. Larger businesses or trade organizations may adopt research oriented strategies that are based on random sampling strategies where repeat measurements are collected from each worker.

CONCLUSIONS/RECOMMENDATIONS

Managing risk for chronic disease agents could be improved if both a TWA OEL and LTA OEL were available. The United States and European bodies that recommend or establish exposure limits—both governmental and professional—should establish guidelines regarding definitions and statistical interpretations of occupational exposure limits for chronic disease agents.

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