June 13, 2017

National Institute for Occupational Safety and Health
NIOSH Docket Office
C/O Melissa Seaton
1090 Tusculum Avenue, MS C–34
Cincinnati, Ohio 45226–1998


Dear Ms. Seaton:

The American Society of Safety Engineers (ASSE) is pleased to submit our comments concerning the National Institute for Occupational Safety and Health (NIOSH) Draft Current Intelligence Bulletin entitled The Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards published in the March 10, 2017, Federal Register (Vol. 82 No. 49, page 13811).

ASSE is the oldest and largest society of safety professionals in the world. Founded in 1911, ASSE represents more than 37,000 dedicated safety, health, and environmental professionals. Our members are experts in managing workplace safety and health in every industry, in every state, and around the globe. ASSE is also the Secretariat for various voluntary consensus standards related to best practices in occupational safety and health.

We commend NIOSH for proposing a standardized system of chemical hazard assessments for those compounds for which no established occupational exposure limit (OEL) currently exists by building on existing qualitative and quantitative chemical hazard assessments. Hazard classification and category-based systems have been used in the pharmaceutical industry, and category-based systems are the basis for the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Given the absence of established Permissible Exposure Limits (PELs) by the Occupational Safety & Health Administration (OSHA), employers and the safety and health professionals who assist them in protecting workers can benefit from the use of this and other guidance on occupational exposure banding (OEB).
Concerns & Recommendations:

ASSE has three concerns with the Guidance Document as currently written:

1. The process may be complex to the point of untenability and leaves too much room for variability;
2. It may inadvertently impose unintended legal obligations on users;
3. Focusing on exposure banding to the exclusion of control banding may be a missed opportunity.

1. The Guidance Document is exceedingly complex: As written, the proposed banding process is very complex (resulting in a 140-page long guidance document) and may not be intuitive or end-user friendly. This complexity may preclude many practicing occupational safety and health professionals with limited experience in chemical hazard assessments or toxicology from being able to correctly utilize this methodology. This concern is amplified for the many small- and medium-sized enterprises (SMEs) without highly qualified safety and health professionals on staff or retainer.

Specifically, while the Tier 1 approach offers a relatively straight-forward process, limiting Tier 1 assessments to bands C through E may be overprotective when prioritizing resources and is generally discouraged for many substances by NIOSH. With the Tier 2 approach, the detailed guidance may be too complex even for many safety and health professionals. In the preliminary evaluation of the Tier 1 and Tier 2 protocols, the Guidance Document indicates that assessing the band of a single chemical took users anywhere from several hours to several days. The process requires developing a means for verifying compliance with the OEB, which may require the rigor and cost of a competent sampling and analytical strategy. This may significantly tax the resources of many firms. The level of expertise and time commitment required for these approaches will be beyond the resources available to most SMEs.

A statement from the Guidance Document regarding the preliminary evaluation of the Tier 1 and Tier 2 protocols conducted with trained users underscores this issue: "Key details explained in the document were often missed by only using the training slides, and this created problem for users and is reflected in variability in the banding. This points to a need for a more streamlined and usable process." (page 104, line 23).

Additionally, the process provides allows for too much variability among users. The Guidance Document states: "Some stakeholders may select a guide value of 10% of the OEB range." (page 78, lines 4-6). Beyond the variability inherent in suggesting a range, this suggests that the assessor may determine acceptability based on a personally-defined percentage of what he determines to be acceptable. Another example of variability entering the process is the allowance given in Tier 2 for users to determine alternate endpoints based on personal background and experience.

While there are more than 80,000 hazardous chemicals currently used in the United States, only a small percentage of those chemicals are used in any significant quantity. ASSE believes that NIOSH could minimize variability in the exposure banding of the chemicals most commonly used in industry by publishing OEBs for a population (e.g.100) of those
chemicals. Candidate chemicals would be those with no current recognized OEL. Such an approach would provide sound exposure banding data for commonly used chemicals and provide NIOSH an opportunity to optimize the Guidance Document.

**Recommendations:**

i. Develop companion training materials for users with limited knowledge of chemical hazard assessments;

ii. Solicit targeted feedback from SMEs;

iii. Limit variability in banding decisions of commonly used substances by developing OEBs for a population (e.g. 100) of the chemicals commonly used in industry that do not have existing OELs.

2. **The Guidance Document leaves many legal questions open:** ASSE recognizes that this guidance would be non-regulatory. However, as it is written, it is fraught with potential legal implications and possible misalignments with existing industry or various trade group approaches to exposure risk assessments. The Guidance will not exist in a vacuum but may be used in relation to established OELs and the information provided by manufacturers. To the extent that this information conflicts (which is common) and could trigger different banding responses depending upon which OELs are relied upon, an employer could inadvertently provide a lesser level of protection for workers than is necessary.

Moreover, many companies currently develop internal OEBs (such as pharmaceutical companies developing OEBs for their proprietary chemicals) which are much easier to administer and use. However, the NIOSH approach is more protective than many published OELs. Given results that differ, should organizations use OEBs, or a percent of the OEB (page 78, lines 4-6), instead of OELs? Are there legal implications for organizations that don’t control exposures to the more protective OEB in these cases?

Other legal questions include:

- Is there a legal risk for using the process detailed in the Guidance Document, or an equivalent risk of not using the process?
- Is there a legal obligation or duty of care risk for a user to stop his assessment at Tier 1?
- Is there a risk if the user proceeds to Tier 2 and does not select the most protective endpoint due to lack of experience or understanding?
- Is there a risk if the user stops at Tier 2 and doesn’t proceed to Tier 3, when appropriate?

**Recommendations:**

- State clearly that the process represents one possible approach for assessing chemical hazards and prioritizing control efforts, and is not the only technically-sound approach;
- Clarify that the proposed OEB guidance is not intended to replace or challenge the validity of existing, recognized OELs;
- State clearly that the guidance is meant to be used by qualified professionals and is not meant to be the only available tool for employers to demonstrate compliance with codes, regulations, or standards of care.
3. **The Guidance Document misses an opportunity to integrate exposure banding and chemical banding.** While characterizing and prioritizing chemical hazards is valuable, there is a greater need for guidance on controlling exposure to those chemical hazards. These two approaches ought to be integrated.

The Guidance Document makes few references to control strategies, other than using an exposure banding process to identify priority candidate chemicals for elimination or substitution. While these are recognized as the most effective methods for controlling chemical exposures, such strategies are not always possible in industry. In addition, there are some chemicals (e.g.: hydrogen fluoride, or HF) that present very serious health hazards, but equally or of greater concern, serious physical hazards (i.e. flammability, shock reactions, etc.). Banding these substances into an inhalation exposure range alone may obscure the recognition of other (equally important) risks.

ASSE recognizes there are shortcomings in existing control banding strategies, and these are pointed out in the Guidance Document. However, simple guidance based on hazards could be integrated into the exposure banding process. Some organizations that are currently using exposure banding processes also include basic control strategies beyond enclosure and ventilation.

**Recommendations:**
- Integrate additional control banding concepts;
- Direct users toward additional information on chemical hazard prevention beyond inhalation techniques.

**Conclusion**

ASSE has long been a supporter of control banding and commends NIOSH on its efforts to develop the Guidance Document. This support was again reiterated in ASSE’s May 2017 OSHA Reform Blueprint:

*With the current rulemaking process, it is impossible for OSHA to develop individual standards for each substance and agent. The control of chemical and physical hazards in the workplace is especially acute for small- and medium-sized employers.*

*The technique of occupational hazard banding allows stakeholders to assess exposures and risks across broad chemical and physical hazard categories and establish predetermined hazard control strategies (or bands) based on the assessed risk. Occupational hazard banding has also been found to be a cost-effective method of protecting workers from chemical hazards because it focuses primarily on the implementation of control measures versus the traditional monitoring and assessment methodologies. NIOSH is in the process of gathering public comments on their own draft guidance on occupational exposure banding. ASSE urges OSHA to partner with NIOSH to commence a full review and collection of the available data to demonstrate the feasibility using this innovative technique in the future regulation of chemical and physical workplace hazards.*

*Occupational hazard banding has been adopted by progressive European countries and global pharmaceutical companies and has been demonstrated to successfully control workplace exposures, particularly in large companies. However, the control of chemical and physical hazards in the workplace is especially acute for small- and medium-sized employers and it is clear that*
additional compliance assistance and expertise in chemical control strategies and the implementation of best practices is necessary to protect workers in those enterprises.

We appreciate the opportunity to comment on guidance which may help fill a critical gap in workplace protections, and pledge our assistance in working with you toward a final document that is both feasible and effective.

Thank you for your consideration of our position.

Respectfully submitted:

Thomas F. Cecich, CSP, CIH