

NIOSH Considers Feedback from Users of its Proposed Occupational Exposure Banding Process

BY LAURALYNN TAYLOR MCKERNAN AND T.J. LENTZ

he rate at which chemicals are introduced into commerce continues to outpace the development of authoritative occupational exposure limits. Occupational exposure banding is a tool that empowers and enables occupational hygienists to address unregulated chemicals. An occupational exposure band is not meant to replace an OEL; rather, it serves as a starting point to inform risk management decisions. Given the utility of an OEB, more occupational hygiene professionals are embracing the proposed NIOSH occupational exposure banding tool and using the occupational exposure banding process to guide their risk

management decisions for chemicals without OELs.

Occupational exposure banding, also known as hazard banding, is a process intended to quickly and accurately assign chemicals to specific categories (bands) that correspond to a range of exposure concentrations. These bands are assigned on the basis of a chemical's toxicological potency and the adverse health effects associated with exposure to the chemical. The output of this process is an OEB. The pharmaceutical sector and some major chemical companies have used occupational exposure banding over the past several decades to establish exposure control limits or ranges for new or existing chemicals that lack formal OELs.

THE NIOSH OCCUPATIONAL EXPOSURE BANDING PROCESS

NIOSH has proposed a process that could be used to apply occupational exposure banding to a broader spectrum of chemicals used in occupational settings. The proposed process uses available, but often limited, toxicological data to determine a potential range of chemical exposure levels that can be used as targets for exposure controls to reduce risk among workers. Through multiple phases of evaluation of the occupational exposure banding process, NIOSH has increased its confidence in the accuracy and reliability of the OEBs. Early adopters of occupational exposure banding, informally referred to as "bandits," have provided and continue to share feedback with NIOSH about the process.

The proposed NIOSH process is organized into three tiers based on the amount of data available and the complexity of the analysis desired (see Figure 1). Each tier requires the user to search for data related to nine health endpoints and compare the data to predetermined NIOSH criteria. Each tier of the process has a different requirement for data sufficiency, which allows a variety of stakeholders to use the exposure banding process in diverse situations. Sequentially, each tier is more intensive than the previous tier in terms of the required analysis and information to band the chemical.

Selection of the most appropriate tier for a specific banding situation also relies on the quantity and quality of the available data. Tier 1 requires relatively little information and only modest specialized user training. A primary goal of the Tier 1 process is to give the user a quick summary of the most important health effects associated with exposure to the chemical of interest, and to quickly identify extremely toxic chemicals to consider for substitution or elimination. Each of the successively higher tiers of the process requires more chemical-specific data to assign an OEB. Tier 2 requires the user to examine a number of publicly available databases and extract relevant toxicological data to be used in a banding algorithm. Tier 3 requires expert judgment to critically evaluate experimental data and discern toxicological outcomes. Users begin with Tier 1 as an initial screening and move to Tier 2 to perform a more thorough evaluation of the chemical. Tier 3 is employed if a data sufficiency requirement for Tier 2 is not met and when expert judgment is available. A draft NIOSH Current Intelligence Bulletin describes the complete proposed methodology; the CIB and supporting documents are available on Regulations.gov at http://bit.ly/draftcib.

APPLYING THE PROCESS

As more occupational hygiene professionals use occupational exposure banding, they have expressed a need for more resources, documentation, and guidance. Existing resources that provide insight and information include a NIOSH occupational exposure banding guidance strategy document, topic pages, Wikipedia pages, and YouTube videos (see page 42 for a list of resources).

With the understanding that the true test of a new

tool is its performance when used, NIOSH has requested and received practical feedback for and evaluation of the proposed occupational exposure banding process. The following are two major themes that have emerged from this feedback:

1. Occupational exposure banding should not be performed for chemicals with existing occupational exposure limits.

Occupational exposure banding is not a substitute for OELs. In fact, OEBs are recognized as the lowest tier of the hierarchy of OELs. Because OELs are derived using quantitative risk assessments based on stronger data requirements, they should be recognized as more authoritative recommendations. While the NIOSH guidance for occupational exposure banding explicitly states that the strategy should not be applied to substances with existing OELs, NIOSH will continue to strengthen its communication efforts to make this point more evident and understood.

2. The proposed NIOSH occupational exposure banding document is complex.

The NIOSH team of subject matter experts has constructed a scientifically robust, consistent, and reliable methodology to determine appropriate exposure bands for chemicals. NIOSH is continuing to develop a suite of practical, userfriendly materials to promote broader understanding and

Figure 1. The three tiers of the NIOSH occupational exposure banding process.

Tier 1—Qualitative

User: Health and safety generalist
A Tier 1 evaluation utilizes GHS hazard statements and categories to identify chemicals that have the potential to

Tier 2— Semi-Quantitative

User: Occupational hygienist

cause irreversible health effects.

A Tier 2 evaluation based on point-of-departure data from reliable sources produces a more robust OEB than a Tier 1 evaluation. Data availability and quality are considered. Users of Tier 2 should be trained in the NIOSH process via web training or in-person training.

Tier 3—Expert Judgment

User: Toxicologist or experienced occupational hygienist Tier 3 involves integrating all available data and determining the degree of conviction of the outcome.

application of its proposed occupational exposure banding process. The latest product is the NIOSH occupational exposure banding e-tool. This draft website allows users to band a chemical online using recommended resources. The tool includes a user-friendly interface that allows users to complete the Tier 1 and Tier 2 processes for occupational exposure banding. Since its inception last year, approximately 250 people have used the proposed e-tool to assess chemicals and assign them to an OEB.

AIHA'S ROLE

AIHA was an early champion of the occupational exposure banding effort, and plays an important role in integrating OEBs within the industrial hygiene profession. Last year, AIHA created a body of knowledge workgroup to review occupational exposure banding methodologies and identify the knowledge, skills, and abilities competent practitioners need to perform occupational exposure banding. The team has drafted a BoK document that is currently undergoing further review. AIHA will use this document to establish a framework for the development of educational programs and to improve the state of professional IH knowledge related to occupational exposure banding.

In addition, the AIHA Exposure and Control Banding Committee is continuing its efforts to further enhance banding throughout the profession. The committee provided critical feedback to NIOSH on its proposed occupational exposure banding methodology. The committee is also brainstorming ways that AIHA members could benefit from sharing resources on occupational exposure banding. Leaders within the Exposure and Control Banding Committee have begun discussions about occupational exposure banding on Catalyst, the AIHA online community. Catalyst will be the starting point to garner case studies and promote tools for use by the AIHA membership.

A BLUEPRINT FOR RISK MANAGEMENT

Although occupational exposure banding holds great promise for the IH profession, it has potential limitations. As with any analysis, the outcome of the NIOSH occupational exposure banding process depends on the quantity and the quality of data available. Furthermore, for some chemicals, the amount of quality data may not be sufficient to derive an OEB. It is important to note that a lack

RESOURCES

NIOSH: "NIOSH Occupational Exposure Banding e-Tool (Draft)," http://bit.ly/oebetool.

NIOSH: "Occupational Exposure Banding," http://bit.ly/oebpage.

NIOSH: "The NIOSH Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards - External Review Draft," http://bit.ly/oebguidance (PDF, March 2017).

Regulations.gov: "Current Intelligence Bulletin: The Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards," http://bit.ly/draftcib.

The Synergist: "The NIOSH Decision Logic for OEBs: Applying Occupational Exposure Bands," http://bit.ly/oeblogic (March 2016).

Wikipedia: "Occupational Exposure Banding," http://bit.ly/oebwikipedia.

of data does not indicate that a chemical is safe.

Feedback from "bandits" has played a significant role in refining the proposed occupational exposure banding process. NIOSH gratefully acknowledged over 75 professionals in its proposed occupational exposure banding document. Knowledge gained from this feedback includes that some users are completing only the Tier 1 process and using it solely as a screening tool. Other professionals feel that the Tier 2 process is insightful as a basic assessment, and so complete this process whenever a new chemical is introduced at their work site. Other users conduct the Tier 2 process to get up to speed on a chemical before they embark on a full research study. Still other users draw on their own raw data to conduct in-depth analyses during the Tier 3 process. All of these applications have significant merit, some of which were beyond our original intentions when deriving the proposed NIOSH occupational exposure banding process.

NIOSH designed its proposed occupational exposure banding process to identify potential health effects and target organs, as well as health risks that impact health communication; inform decisions regarding control interventions and medical surveillance; and provide critical information quickly. One major benefit of the process is that the amount of time and data required to categorize a chemical into an OEB is far less than that required to assign a chemical an OEL. However, there is greater uncertainty surrounding an OEB compared to an OEL produced by a rigorous risk assessment. The proposed NIOSH occupational exposure banding process represents one possible approach for assessing chemical hazards and prioritizing control efforts. While not the only technically sound approach, it provides a blueprint for occupational hygienists to begin making risk management decisions. 9

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Acknowledgments: The team developing the NIOSH occupational exposure banding process also includes Stephen J. Gilbert, MS; George Holdsworth, PhD; Andy Maier, PhD, CIH, DABT; Pranav Rane, MPH; Melissa Seaton, MS; and Christine Whittaker, PhD. Donna Heidel (formerly of NIOSH) was also instrumental for this process.

This article was written in memory of Dr. George Holdsworth, an integral and influential part of the NIOSH occupational exposure banding team. The team is grateful for his many contributions and will miss his intellect, professionalism, kindness, and humor.

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Volume 29 Number 5

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The Synergist (USPS #009-332) is published monthly except a combined June/July issue by the American Industrial Hygiene Association, 3141 Fairview Park Drive, Suite 777, Falls Church, VA 22042 for \$50 per year for members; nonmembers may subscribe for \$315/yr. International nonmembers may subscribe for \$415/yr (U.S. funds). Periodicals postage paid at Merrifield, Virginia, and additional mailing offices. POSTMASTER: Send address changes to The Synergist, American Industrial Hygiene Association, Attn: Customer Service, 3141 Fairview Park Drive, Suite 777, Falls Church, VA 22042. ISSN 10667660.

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