



**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[CDC-2019-0111, NIOSH-332]

**Request for Information on Toxicological and Physicochemical Data of Engineered Nanomaterials to Evaluate in Developing Categorical Occupational Exposure Limits (OELs)**

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Request for information.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) intends to evaluate the scientific data on engineered nanomaterials (ENMs) to develop categorical occupational exposure limits (OELs) based on the available scientific evidence regarding the hazard or safety of these materials. NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible adverse health risks of occupational exposure to ENMs.

**DATES:** Electronic or written comments must be received by [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by CDC-2019-0111 and Docket Number NIOSH-332, by either of the two following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>.

Follow the instructions for submitting comments.

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MSC34, 1090 Tusculum Avenue, Cincinnati, OH 45226.

**Instructions:** All information received in response to this notice must include the agency name and docket number [CDC-2019-0111; NIOSH-332]. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. All electronic comments should be formatted in Microsoft Word. Please make reference to CDC-2019-0111 and Docket Number NIOSH-332.

**FOR FURTHER INFORMATION CONTACT:** Nathan M. Drew, MS, NIOSH, MSC14, 1090 Tusculum Avenue, Cincinnati, OH 45226, telephone (513) 533-8352.

**SUPPLEMENTARY INFORMATION:**

In 2017, NIOSH contributed to the International Organization for Standardization (ISO) technical report on frameworks for developing OELs for nano-objects [ISO 2016]. In 2019, NIOSH published a Technical Report on occupational exposure banding guidance [NIOSH 2019]. The information presented in these

Technical Reports represents the most recent update of the scientific rationale and methodology for establishing hazard values for chemicals, which includes ENMs.

The development of an OEL for an individual chemical involves a critical review of the available scientific data in humans and animals to identify relevant studies and to characterize the various lines of evidence that can support the derivation of the OEL. NIOSH requests information for ENMs to include human, animal, and cellular toxicology data, including but not limited to: acute, subchronic, or chronic data; the physicochemical characterization of those ENMs; and other information about the biological mechanisms and toxicological effects of ENMs. NIOSH is also seeking information on studies that include evaluating the dose-response relationships between exposure to ENMs and the development of adverse lung effects including inflammation, fibrosis, or neoplasia. Supporting information for published studies should include a full citation. For unpublished studies please include authors, affiliations, year, and any context on how the data were collected.

NIOSH will publish a Technical Report which describes the data, methods, and findings for the development of categorical OELs for ENMs, which may include relevant information submitted in

response to this request. The draft Technical Report will be made available for public comment in a subsequent notice.

**References:**

[ISO 2016] Nanotechnologies - Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs). International Organization for Standardization (ISO) Technical Report. ISO/TR 18637, published November 21. ISO, Geneva, Switzerland.

[NIOSH 2019] Technical report: The NIOSH occupational exposure banding process for chemical risk management. By Lentz TJ, Seaton M, Rane P, Gilbert SJ, McKernan LT, Whittaker C. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2019-132

**John J. Howard,**

*Director,*

*National Institute for Occupational Safety and Health,*

*Centers for Disease Control and Prevention.*

[FR Doc. 2019-27169 Filed: 12/16/2019 8:45 am; Publication Date: 12/17/2019]