



This document is scheduled to be published in the Federal Register on 05/01/2015 and available online at <http://federalregister.gov/a/2015-10295>, and on FDsys.gov

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2015-0020; NIOSH 156-A]

Request for the Technical Review of 14 Draft Immediately Dangerous to Life or Health (IDLH) Value Profiles

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 and comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is conducting a public review of the draft immediately dangerous to life or health (IDLH) values and support technical documents, entitled IDLH Values Profiles, for 14 chemicals. NIOSH is requesting technical reviews of the draft IDLH Value Profiles.

DATES: Electronic or written comments on the 14 documents contained within Group A must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by CDC-2015-0020 and docket number NIOSH 156-A, by either of the two following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.
Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, OH 45226.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2015-0020; NIOSH 156-A]. All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. All electronic comments should be formatted as Microsoft Word. For access to the docket to read background documents or comments received, go to www.regulations.gov. All information

received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226.

FOR FURTHER INFORMATION CONTACT: G. Scott Dotson, NIOSH, Robert A. Taft Laboratories, MS C-32, 1090 Tusculum Avenue, Cincinnati, OH 45226. (513)533-8540 (not a toll free number).

SUPPLEMENTARY INFORMATION:

The draft documents are based on the process outlined in the NIOSH Current Intelligence Bulletin 66 - Derivation of Immediately Dangerous to Life or Health (IDLH) Values

<http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf>.

To facilitate the review of these documents, NIOSH requests that the following questions be taken into consideration:

1. Does this document clearly outline the health hazards associated with acute (or short-term) exposures to the chemical? If not, what specific information is missing from the document?

2. Are the rationale and logic behind the derivation of an IDLH value for a specific chemical clearly explained? If not, what specific information is needed to clarify the basis of the IDLH value?

3. Are the conclusions supported by the data?

4. Are the tables clear and appropriate?

5. Is the document organized appropriately? If not, what improvements are needed?

6. Are you aware of any scientific data reported in governmental publications, databases, peer-reviewed journals, or other sources that should be included within this document?

NIOSH seeks comments on 14 draft IDLH values and IDLH Value Profiles. The draft IDLH Value Profiles were developed to provide the scientific rationale behind derivation of IDLH values for the following chemicals:

Document # Chemical(s)

A-01 Acrylonitrile (CAS# 107-13-1)

A-02	Benzonitrile	(CAS# 100-47-0)
A-03	Methyl isocyanate	(CAS# 624-83-9)
A-04	HCFC-141B	(CAS# 1717-00-6)
A-05	Chloroacetyl chloride	(CAS# 79-04-9)
A-06	Chlorine pentafluoride	(CAS# 13637-63-3)
	Bromine pentafluoride	(CAS# 7789-30-2)
A-07	Iron pentacarbonyl	(CAS# 13463-40-6)
A-08	1,3-Butadiene	(CAS# 106-99-0)
A-09	Diketene	(CAS# 674-82-8)
A-10	Furan	(CAS# 110-00-9)
A-11	Hexafluoroacetone	(CAS# 684-16-2)
A-12	n-Butyl acrylate	(CAS# 141-32-2)
A-13	Peracetic acid	(CAS# 79-21-0)
A-14	Butane	(CAS# 106-97-8)

Each IDLH Value Profile provides a detailed summary of the health hazards of acute exposures to high airborne concentrations and the rationale for the proposed IDLH value with the chemical(s) of interest.

In 2013, NIOSH published Current Intelligence Bulletin (CIB) 66 - Derivation of Immediately Dangerous to Life or Health (IDLH) Values [NIOSH 2014-100;

<http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf>].

The draft documents available for public review use the methodology in this document. Since the establishment of the IDLH values in the 1970s, NIOSH has continued to review available scientific data to improve the protocol used to derive acute exposure guidelines, in addition to the chemical-specific IDLH values. The information presented in this CIB represents the most recent update of the scientific rationale and the methodology (hereby referred to as the IDLH methodology) used to derive IDLH values. The primary objectives of this document are to:

1. Provide a brief history of the development of IDLH values
2. Update the scientific basis and risk assessment methodology used to derive IDLH values from quality data
3. Provide transparency behind the rationale and derivation process for IDLH values
4. Demonstrate how scientifically credible IDLH values can be derived from available data resources

The IDLH methodology outlined in this CIB reflects the modern principles and understanding in the fields of risk assessment, toxicology, and occupational health and provides the scientific rationale for the derivation of IDLH values based on contemporary risk assessment practices. According to this protocol, IDLH values are based on health effects considerations determined through a critical assessment of the toxicology and human health effects data. This approach ensures that the IDLH values reflect an airborne concentration of a substance that represents a high-risk situation that may endanger workers' lives or health. Relevant airborne concentrations are typically addressed through the characterization of inhalation exposures; however, airborne chemicals can also contribute to toxicity through other exposure routes, such as the skin and eyes. In this document, airborne concentrations are referred to as acute inhalation limits or guidelines to adhere to commonly used nomenclature.

The emphasis on health effects is consistent with both the traditional use of IDLH values as a component of the respirator selection logic and the growing applications of IDLH values in Risk Management Plan (RMPs) for non-routine

work practices governing operations in high-risk environments (e.g., confined spaces) and the development of Emergency Preparedness Plans (EPPs). Incorporated in the IDLH methodology are the standing guidelines and procedures used for the development of community-based acute exposure limits called Acute Exposure Guideline Levels (AEGLs). The inclusion of the AEGL methodology has helped ensure that the health-based IDLH values derived with use of the guidance provided in this document are based on validated scientific rationale.

The IDLH methodology is based on a weight-of-evidence approach that applies scientific judgment for critical evaluation of the quality and consistency of scientific data and in extrapolation from the available data to the IDLH value. The weight-of-evidence approach refers to critical examination of all available data from diverse lines of evidence and the derivation of a scientific interpretation on the basis of the collective body of data, including its relevance, quality, and reported results. This is in contrast to a purely hierarchical or strength-of-evidence approach, which relies on rigid decision criteria for selecting a critical adverse effect, a point of departure (POD), or the point on the dose-response curve

from which dose extrapolation is initiated and for applying default uncertainty factors (UFs) to derive the IDLH value. Conceptually, the derivation process for IDLH values is similar to that used in other risk assessment applications, including these steps:

1. Hazard characterization
2. Identification of critical adverse effects
3. Identification of a POD
4. Application of appropriate UFs, based on the study and
POD

Dated: April 24, 2015.

John Howard,
Director,
National Institute for Occupational Safety and Health,
Centers for Disease Control and Prevention.

[FR Doc. 2015-10295 Filed: 4/30/2015 08:45 am; Publication

Date: 5/1/2015]