

**Miller, Diane M. (CDC/NIOSH/EID)**

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**From:** Richardson, Irene L Ms CIV USA MEDCOM PHC [Irene.Richardson@us.army.mil]  
**Sent:** Monday, March 14, 2011 11:11 AM  
**To:** NIOSH Docket Office (CDC)  
**Subject:** 156 - Current Intelligence Bulletin (CIB): Derivation of Immediately Dangerous to Life and Health (IDLH) Values - Comments (UNCLASSIFIED)  
**Attachments:** AIPH Comments for NIOSH IDLH CIB - 11 Mar 11.pdf

**Classification:** UNCLASSIFIED

**Caveats:** NONE

The Army Institute of Public Health, US Army Public Health Command, is pleased to submit the attached comments for Docket number NIOSH-156: CIB on the Derivation of IDLH Values. Please address questions to the undersigned.

Regards, -Irene

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DEPARTMENT OF THE ARMY  
US ARMY INSTITUTE OF PUBLIC HEALTH  
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Office of the Director

11 March 2011

Ms. Diane Miller  
Docket Office Manager  
National Institute for Occupational Safety and Health  
4676 Columbia Parkway  
Cincinnati, Ohio 45226

Dear Ms. Miller:

The Army Institute of Public Health has reviewed and is submitting the enclosed comments for your consideration in response to Docket Number NIOSH-156, Current Intelligence Bulletin: Derivation of Immediately Dangerous to Life or Health (IDLH) Values.

The mission of the Army Institute of Public Health is to promote health and prevent disease, injury, and disability of Soldiers and military retirees, their Families, and Department of the Army civilian employees as well as assure the effective execution of full spectrum veterinary services for Army and Department of Defense Veterinary missions. To that end, we are very interested in the development of your new protocol, its future use in revising and/or creating new IDLH values, and the potential impact on key Army programs such as the Army Respiratory Protection Program.

Our point of contact for this action is Ms. Irene Richardson, Industrial Hygienist, Occupational Health Sciences Portfolio, at (410) 436-3118, or via electronic mail at Irene.Richardson@us.army.mil.

Sincerely,

A handwritten signature in black ink, appearing to read "John J. Resta".

John J. Resta  
Director  
Army Institute of Public Health

Enclosure

Docket Number NIOSH-156, NIOSH Current Intelligence Bulletin: Derivation of Immediately Dangerous to Life or Health Values  
 Comments from: US Army Public Health Command, Army Institute of Public Health, Aberdeen Proving Ground, MD 21010-5403

COMMENTS	PAGE	PARA	LINE	COMMENT	RATIONALE
Christopher Carroll, CIH 410-436-5465 Chris.carroll@ us.army.mil				GENERAL COMMENT: In deriving an IDLH, should impacts on the immune system be considered? For instance, some substances may suppress the immune system for an extended time after the exposure has been removed. Such immune suppression might increase vulnerabilities to etiologic agents that could have more serious consequences than would have normally occurred.	
Christopher Carroll, CIH 410-436-5465 Chris.carroll@ us.army.mil				GENERAL COMMENT: Due to biological rhythms, physiological responses to chemical exposures may vary according to the time of day and the shift that one is working. In deriving the IDLHs, should the documentation consider this?	
Christopher Carroll, CIH 410-436-5465 Chris.carroll@ us.army.mil				GENERAL COMMENT: The CIB should indicate that certain prescribed and over-the-counter medications can have interactive effects with some chemical exposures and that the derived IDLHs do not consider this.	
Christopher Carroll, CIH 410-436-5465 Chris.carroll@ us.army.mil				GENERAL COMMENT: Some exposure situations will include mixtures of chemical substances that might have combined effects (additive, synergistic, potentiating). Since the IDLHs are derived based upon exposure to one substance at a time, how should mixtures be handled? For instance, where the primary basis for the derivation of an IDLH in the documentation was the same as for another chemical within the mixture, should an additive effects formula be applied, e.g., that is if the sum of $(C1/T1 + C2/T2 + \dots Cn/Tn)$ exceeds unity, the IDLH limit of the mixture should be considered as being exceeded (where C1 indicates the observed atmospheric concentration and T1 is the corresponding IDLH)?	
Christopher Carroll, CIH 410-436-5465 Chris.carroll@ us.army.mil				GENERAL COMMENT: The CIB does not indicate what average and peak breathing rates the IDLHs will be based on. There can be a range of breathing rates expected in different IDLH scenarios, such as in different normal/routine work scenarios and in emergency response situations.	
Christopher Carroll, CIH 410-436-5465 Chris.carroll@ us.army.mil				GENERAL COMMENT: Where an IDLH is derived based upon an aerosol (solid or liquid dispersoid in air), will the documentation include a recommendation as to what size fraction the limit is based upon, i.e., inhalable, thoracic, respirable, etc.?	

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COMMENTER	PAGE	PARA	LINE	COMMENT	RATIONALE
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	iii, v-vi	Fwd and Exec Sum	multi	<p>GENERAL COMMENT: Concur strongly with summary of purpose, rationale, and general approach as described in Forward and Exec Sum ( especially in para below from Forward and then on page vi); HOWEVER, there are aspects later in document (per following comments) that do not appear to be in sync with this 'big picture' - Please consider the following:</p> <p>" The primary objective of this Current Intelligence Bulletin (CIB) is to present a protocol, based on the modern principles of risk assessment and toxicology, for the derivation of IDLH values that characterize the health risks of occupational exposures to high concentrations of airborne contaminants. The new protocol for deriving IDLH values incorporates the methodology established by the National Advisory Committee (NAC) on Acute Exposure Guideline Levels for Hazardous Substances - consisting of members from the U.S. Environmental Protection Agency (EPA), the Department of Defense (DOD), the Department of Energy (DOE), the Department of Transportation, other federal and state governments, the chemical industry, academia, and other organizations from the private sector - during the derivation of community-based acute exposure limits called Acute Exposure Guideline Levels (AEGs). The inclusion of the AEG methodology has helped ensure that the IDLH values derived using the guidance provided within this document are based on validated scientific rationale. The intent of this document is not only to update the protocol used by NIOSH to develop health based IDLH values, but to also increase the transparency behind their derivation. We hope that the increased transparency will provide occupational health professionals additional information that can be applied to improve the characterization of the hazards of high concentrations of airborne contaminants and result in a more informed decision process for the selection of respirators, establishment of Risk Management Plans for non-routine work practices and Emergency Preparedness Plans capable of better protecting workers."</p>	<p>Need to ensure consistency and especially reasonableness of end products of the process (e.g. the IDLH values) as criteria for respirator logic and other "High risk" environments. The concept to be 'transparent' and use AEG methods are good - but need to be careful to avoid letting a too standardized process result in values that don't make sense. For example: in Appendix A is a perfect example of what can go wrong - e.g. the IDLH value for vinyl acetate (100 ppm) which is much less than even 1/2 of the 30-minute AEG-2 value (safe for general public) and is actually even less than the 4-hour AEG-2. This is inconsistent with statements on page 15 of the document that describe how "recent AEG-2 and AEG-3 values can provide a rough gauge for identifying a potential range for the IDLH value." As our organization has employees who have been involved with AEG development, it is essential that this process and developers of IDLH values specifically consider the AEG values, especially their basis. As this document acknowledges, AEGs are extremely well evaluated and documented. However, the basis (or interpretation) of chemical-specific AEG data tends to be especially 'conservative' (protective) and as a result the actual AEG-2 definition is not really the same 'escape impairing criteria' that the occupational community would use for respirator logic. So to have an IDLH value even below the 30-minute AEG-2, without a 'transparent' discussion of a reason for the inconsistency, is: a) technically not in line with the stated purpose of this document; b) inconsistent with the concepts on Page 15 of this document; and c) not adequately transparent.</p>

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COMMENTER	PAGE	PARA	LINE	COMMENT	RATIONALE
Dr. Laurie Roszell 410-436-8774 Laurie.roszell@us.army.mil	v		17-21	Suggest rewriting "the intended purpose of establishing an IDLH value is (1) to ensure that the worker can escape from a given contaminated environment in the event of failure of the respiratory protection equipment and (2) is considered a maximum level above which only a highly reliable breathing apparatus providing maximum worker protection is permitted." As "the intended purpose of establishing an IDLH value is (1) to ensure that the worker can escape from a given contaminated environment in the event of failure of the respiratory protection equipment and (2) is considered to provide a maximum level above which only a highly reliable breathing apparatus providing maximum worker protection is permitted."	Grammar
Christopher Carroll, CIH 410-436-5465 Chris.carroll@us.army.mil	viii		15-16	Delete ", which represents a life-threatening condition."	Though an environment with an oxygen concentration < 19.5% may be considered oxygen deficient, it does not represent a life-threatening condition until at much lower concentrations. Other organizations (ANSI, OSHA) have suggested much lower oxygen concentration (at STP) and equivalent oxygen partial pressure values as IDLH. Additionally, oxygen partial pressure is a better means of expressing oxygen deficient environments, since this is more physiologically relevant and because the partial pressure is reduced with altitude though the concentration of oxygen remains the same with altitude.
Dr. Laurie Roszell 410-436-8774 Laurie.roszell@us.army.mil	xv		10	PALs are described as being developed by DHS. This is incorrect, PALs are developed by EPA. They are correctly defined as being developed by EPA on page xxvi, lines 19-23.	Correctness

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Christopher Carroll, CIH 410-436-5465 Chris.carroll@us.army.mil	xxviii		25-29	The TLV definition is not completely inaccurate, indicating that it is just an average concentration for an 8-hour workday and 40-hour workweek. Replace the TLV definition with the following from the ACGIH TLV Booklet: "Threshold Limit Values (TLVs®) refer to airborne concentrations of chemical substances and represent conditions under which it is believed that <i>nearly all</i> workers may be repeatedly exposed, day after day, over a working life-time, without adverse health effects." Add the other three TLV related definitions (i.e., TLV-TWA, TLV-STEL, & TLV-C) and define them exactly as in the most current ACGIH TLV booklet.	Correctness.  Also, three categories of TLVs are specified: time-weighted average (TLV-TWA); short-term exposure limit (TLV-STEL); and a ceiling (TLV-C). Those who use the TLVs <b>MUST</b> consult the latest <i>Documentation of TLVs</i> to ensure they understand the basis for the specific TLV and the information used in its development.
Dr. Laurie Roszell 410-436-8774 Laurie.roszell@us.army.mil	13		1	Table 2.1 – Modify purpose of AEGIs and ERPGs to read "Acute exposure guidelines for protection of the general public during emergency or unusual releases. Values are for single, <u>not repeated exposures.</u> "	Clarity
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	15	2.1	13	CRITICAL COMMENT: Add following new sentence after "...population of working adults."  "In addition, the selection of the critical effect (health endpoint) and interpretation of the severity of the health impact to the population of interest (in this case a worker population in a high risk environment) may be different that that used for the AEG-2."	While overall this paragraph relating the AEG-2 concept to IDLH is conceptually okay, it is critical to clarify that even if the concept of an AEG-2 seems to parallel that of the IDLH - e.g. in addition to the 'population susceptibility' differences, the types and severity of effects used for development of the two (for example degree of irritation) in many cases should <i>not</i> be the same - the actual chemical specific AEG-2 levels do not represent such a degree of severity that a respirator (such as supplied air) is needed.
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	32	3.4	5-9	CRITICAL COMMENT: Add new bullet  • "Existing 30-minute exposure guidelines (AEGs 1-3) and their basis (critical effect levels used)"	Per general comment and as in the example given in Appendix A, the process should include an upfront review of any established 30-minute AEG values since this document already cites the AEG methodology as the primary basis for the approach to be used and cites the AEG 2-3 range as a gauge for where IDLH values should fall. Start with a look at the AEG values and what critical effects (and studies) were selected, then determine if these are appropriate or not for an IDLH value and document decisions. This relationship will be a common question to address.

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Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	35	3.4.2.1.1	8-15	This is confusing as written and should be rewritten to include showing exactly what the final IDLH value would be as opposed to a range. The IDLH value should not be less than a Human No Observed Adverse Effect Level (NOAEL) for mild effects (in this case 20 ppm).	First, 20 ppm is a NOAEL for MILD effects and not considered escape impairing - thus an IDLH below that value doesn't make sense. Line #7 specifically states 30 ppm is "escape impairing". The statement in line 8 that the range for an IDLH should be between 20 to 30 then seems reasonable. However, the last sentence (lines 14-15) indicates the IDLH is between 10-20 ppm. Also, this evaluation should be in context with other values (e.g. AEGs) that could provide needed perspective.
Rebecca Adams 410-436-5213 Rebecca.a.adams@us.army.mil	35	3.4.2.1.1	14-15	Further clarification is needed on the decision to recommend the IDLH value of 10-20 ppm in this example.	In line 6 it is stated that only mild responses were seen at 20 ppm in humans at 30 minutes. As described this is ideal data for deriving IDLH values. However it is later stated that the appropriate IDLH value is somewhere between 10-20ppm. Further justification for not using the data supported value of 20 ppm would clarify this example.
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	38-41	3.4.2.1.3 to 3.4.2.1.4		Provide Table(s) summarizing the described categories of "escape impairing effects" as well as "severe and irreversible effects" and provide at least one chemical-specific example of how actual data would be interpreted to determine a "Point of Departure (POD)" from such endpoint data (e.g.: provide an example of when developmental toxicity would be a basis for a IDLH).	As presented, the discussion is not in adequate detail to demonstrate how the effects would actually be used to represent a level that is relevant for respirator selection purposes of a healthy worker population - e.g.: give an example of when developmental toxicity would be a basis for an IDLH or cardiac sensitization.
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	41	3.4.2.1.4	26	Delete "(usually by a factor of 3)"	This suggestion of a specific UF value encourages its use. The decision as to what value (1-10) is appropriate or necessary should be based on each chemical specific evaluation.
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	45	3.4.2.2.2	16	CRITICAL COMMENT: Add the following sentence at the end of the paragraph:  "Because AEGs are derived specifically from short term exposure data to include (when possible) 30 minute data for 30 minute AEGs, studies used in derivation of published AEG values will be evaluated."	Per general comments and as in the example in Appendix A, the process should include an upfront review of any established 30-minute AEG values since this document already cites the AEG methodology as the primary basis for the approach to be used

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Christopher Carroll, CIH 410-436-5465 Chris.carroll@us.army.mil	52		1-15	In estimating systemic dose equivalency for extrapolations from oral or i.p. studies to an IDLH, an argument is made that one should assume 10 m <sup>3</sup> of air inhaled rather than 1.5 m <sup>3</sup> (50 L/min for 30 minutes). It seems, however, that 1.5 m <sup>3</sup> is more realistic and therefore more appropriate.	
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	64	4.2	7-11	Change the word "most" to "many" as follows: "However, in most many cases the available POD values need to be further adjusted to develop an IDLH value that protects workers from potential lethal, severe or irreversible, or escape-impairing health effects." <b>CRITICAL COMMENT:</b> Change wording as follows – do NOT pre-determine a single one-size-fits-all "preferred UF": "Thus, a range of preferred UFs is shown for each of the typical types of effect levels that are available as a POD. However, the actual UF applied is determined based on the weight-of-evidence evaluation for each chemical that allows for modifying the preferred selecting a UF from the overall typical range based on additional considerations unique to the dataset."	"Most" sets up a pre-determined standard - "many" allows more flexibility for what should be a chemical-specific determination.  The typical range is a range for a reason. Leave the determination to the chemical specific evaluation.
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	66	4.2	7-11		
Veronique Hauschild, MPH 410-436-1010 v.hauschild@us.army.mil	67	4.2	Table	<b>CRITICAL COMMENT:</b> DELETE "Preferred Uncertainty Factor" column entirely	The typical uncertainty factor range is a range for a reason. Let the uncertainty factor determination be specific to each individual chemical evaluation.
Christopher Carroll, CIH 410-436-5465 Chris.carroll@us.army.mil	68		4	It says, "Since IDLH values are used in worker-health applications, the range of variability that needs to be covered in applying the UF is expected to be less than for the development of exposure values/limits meant to protect sensitive members of the general public." Shouldn't "worker-health" be "healthy-worker", instead?	

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<p>Christopher Carroll, CIH            410-436-5465            Chris.carroll@us.army.mil</p>	79			<p>Appendix A only provides one example of the derivation of an IDLH value, and this is for a substance that does not currently have an IDLH. Ideally, this CIB should also examine all of the existing substances with IDLHs and apply this new approach to derive new proposed IDLHs so that one may better understand the impact newly derived and proposed IDLHs may have on their existing respiratory protection programs. At a minimum, more and varied examples should be added and include substances with existing IDLHs.</p>	<p>It is not immediately evident to what degree this new methodology may change existing IDLHs. This creates a great deal of uncertainty, given changes in current IDLHs could result in significant changes in respiratory protection programs (e.g., atmosphere-supplying respirators required where they were not previously required) and therefore have an enormous impact (financial, etc.) on those that would be affected by such changes.</p>
<p>Veronique Hauschild, MPH            410-436-1010            v.hauschild@us.army.mil</p>	79-81	App. A	multi	<p>CRITICAL COMMENT:            Modify/change this example to ensure a more complete example is shown and is consistent with other elements of this document (purpose/application of IDLH, &gt; AEGl-2, completeness and transparency). For example - lines 6-11 on page 81 'mention' sub lethal data - Need to expand description and provide data. Also, include a discussion of AEGl-2 values and critical effects and rationale. If it is determined that an IDLH must be LOWER than an AEGl-2, then substantial justification/rationale MUST be provided (this does not pass a basic common sense test).</p>	<p>The IDLH value for vinyl acetate (100 ppm) is much less than even 1/2 of the 30-minute AEGl-2 value ( safe for general public) and is actually even less than the 4-hour AEGl-2 value. This is inconsistent with statements on page 15 of documents that state: "recent AEGl-2 and AEGl-3 values can provide a rough gauge for identifying a range for the IDLH value." As our organization has members who have been involved with the AEGl development process, it is essential that this process and specifically developers of IDLH values consider the AEGl values...especially their basis. A comparison between the AEGl 2-3 values and future IDLH values are inevitable so the explanation of relationships should be part of IDLH development.</p>