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From: Holler, James S. (Jim) (ATSDR/DTEM/PRMSB)
Sent: Monday, March 14, 2011 6:53 AM
To: NIOSH Docket Office (CDC)
Cc: Niemeier, Richard W. (CDC/NIOSH/EID)
Subject: Review CIB on IDLH derivation - Docket No NIOSH-156
Attachments: Holler_NIOSH MEMO.doc

Attached is my review of the CIB on IDLH derivation.

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Atlanta, GA 30333

Memorandum

Date March 14, 2011

From James Holler, DTEM, ATSDR

Subject Review of Current Intelligence Bulletin – IDLH Values (Reference docket NIOSH-156)

To NIOSH Docket Office

This reviewer is encouraged by this effort to upgrade the reference values using a state-of-the-art to risk assessment. The IDHL database is often used as a reality check as other reference values are derived and this enhancement and update will increase the value of the IDLH program. The documentation of the derived values will be used to risk assessors and risk managers in both occupational and other settings.

1. Should additional information or guidance relating to the derivation of IDLH values be included within the document? If so, what?

The IDLH might benefit from published procedures for other reference value programs. The Provisional Advisory Levels are at the shortest exposure duration a 24 hour period. However, the description of the procedure provides useful suggestions on evaluating studies, selection of the critical effect and point of departure and uncertainty factor application. (R A Young et.al. Overview of the Standing Operating Procedure (SOP) for the development of Provisional Advisory Levels (PALs) *InhalationToxicology*, 2009, 21(S3):1-11.

On page 36 there is brief mention of the benchmark approach. The use of this technique is becoming more widespread in risk assessment activities. In fact we have recently been criticized in a recent project for adopting the LOAEL/NOAEL approach rather than the benchmark approach, in spite of the fact that the data fit was poor in the benchmark dose approach. I think you should enhance the portion of the activity, and provide additional criteria for this application. Not every data set is suitable for the benchmark dose approach. Establishing standards or criteria for data quality to begin with eliminates disagreement when a derivation is underway. The other factor which needs identification up front is the criteria from the benchmark for the identified data point, BM_{10}, BM_{05}, etc.

The ATSDR approach to literature acceptability, based on our enabling legislation, is to require peer review of all information used in our risk assessment. We accept that all published literature has undergone adequate peer review in the publication process. Unpublished studies are subjected to a separate peer before they are considered valid information. I believe you need to identify specific criteria for the use of "other key unpublished literature" described on page 31. For example, will you use meeting abstracts or study abstracts if such information is the only studies for a substance.

2. Do the data cited within the draft CIB support the objectives of the document?

The information provided in the draft supports the objectives of the document.

3. Does the new protocol outlined in the draft CIB support the development of health protective IDLH values in light of the current understanding of the toxicological data and application of the principles of risk assessment?

Initiating a major rewrite of such a program can be quite an undertaking. The approach described in the protocol is very collegial and emphasizes the use of the weight of evident approach. This is certainly the desired approach, but it can be sorely tested when different groups with divergent economic interests provide their "expert judgment". I recommend that this document be followed with a more specific Standard Operating Procedure which can address some of the specific operational issues.

/s/ James Holler, Ph.D

cc

Richard W. Niemeier