



BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Docket Number CDC-2017-0017, NIOSH 153-D

Proposed Revised Definitions for the Levels of Evidence for NIOSH

Skin Notation Profiles; Request for Comment

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 comments.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) proposes to clarify the definitions for 'sufficient', 'limited', and 'insufficient' levels of evidence for the designation of NIOSH skin notations. In NIOSH Current Intelligence Bulletin (CIB) 61 - A *Strategy for Assigning New NIOSH Skin Notations*, Appendix E.2, Evaluation of data, pp. 41-42 [<http://www.cdc.gov/niosh/docs/2009-147/pdfs/2009-147.pdf>] these levels of evidence are defined as the following:

"Data sets classified as sufficient are those that include human and/or animal toxicity studies conducted according to standardized protocols and that provide in-depth descriptions of the exposure conditions and study findings. Data sets classified as limited via the qualitative ranking scheme contain either human and/or animal studies conducted by non-standardized protocols or contain incomplete descriptions of the exposure conditions and study findings. Data sets classified as insufficient include studies that primarily either did not apply standard protocols or did not provide an in-depth description of the exposure conditions or study findings. Data sets that receive the insufficient ranking will not be used as the basis for the NIOSH skin notation."

NIOSH proposes to clarify the definitions for the sufficient, limited, and insufficient levels of evidence to the following:

"Data sets classified as sufficient are those that include human and/or animal studies conducted using standardized protocols and that provide complete descriptions of the exposure conditions and study findings. Data sets classified as limited are those that include human and/or animal studies conducted using non-standardized protocols or that provide incomplete descriptions of the exposure conditions or study findings. Data sets classified as insufficient are those that include human and/or animal studies conducted using non-standardized protocols and that provide incomplete descriptions

of the exposure conditions and study findings. Data sets that receive the insufficient ranking will not be used as the basis for the NIOSH skin notation.”

Evaluation of dose-related effects in studies with limited or insufficient evidence, mechanistic data, and analogous chemical properties may be factored into the classification scheme for determining the level of evidence for identified studies. Data sets that provide insufficient evidence will not be used as the basis for the NIOSH skin notation but, in some cases, may provide information to support or contradict evidence for the skin notation.

For data sets with conflicting findings, an overall determination based on the body of evidence will be developed by evaluating data adequacy, reliability and relevance, and assessing each study’s quality of evidence. The studies with the best quality and validity to support the notation are identified and cited in the individual Skin Notation Profile documents.

NIOSH seeks comments on proposed changes as described above.

DATES: Comments must be submitted on or before [INSERT DATE 30 DAYS FROM PUBLICATION].

ADDRESSES: You may submit comments, identified by CDC-2017-0017 and docket number NIOSH 153-D, by any of the 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, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2017-0017; NIOSH 153-D]. All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to www.regulations.gov. For access to the original docket [NIOSH-153] to view background documents or comments received, go to <https://www.cdc.gov/niosh/docket/archive/docket153.html>. All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT: Naomi Hudson or G. Scott Dotson, NIOSH, Education and Information Division, Robert A. Taft Laboratories, 1190 Tusculum Ave, MS C-32, Cincinnati, OH 45226, email: iuz8@cdc.gov or fya8@cdc.gov.

SUPPLEMENTARY INFORMATION: In 2009, NIOSH published Current Intelligence Bulletin 61 - *A Strategy for assigning New NIOSH Skin Notations* [NIOSH 2009-147; <http://www.cdc.gov/niosh/docs/2009-147/pdfs/2009-147.pdf>]. The CIB presents a strategic framework that is a form of hazard identification that ensures that the assigned skin notations reflect the contemporary state of scientific knowledge, provides transparency behind the assignment process, communicates the hazards of chemical exposures of the skin, and meets the needs of health professionals, employers, and others interested in protecting workers from chemical contact with the skin. Published Skin Notation Profile documents are available at https://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html.

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[FR Doc. 2017-04628 Filed: 3/8/2017 8:45 am; Publication Date: 3/9/2017]