

Dated: May 11, 2011.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-237]

Strategy To Address Recommendations Issued by the Institute of Medicine in November 2010 Report; Comment Request

AGENCY: The 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: Notice of public comment period.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory (NPPTL), requests input on the NIOSH, NPPTL strategy to address the recommendations issued by the Institute of Medicine (IOM) in the November 2010 report *Certifying Personal Protective Technologies: Improving Worker Safety*. The report focuses on the need for a consistent and risk-based approach to Personal Protective Technology (PPT) conformity assessment.

PUBLIC COMMENT PERIOD: Written or electronic comments must be received on or before July 1, 2011.

ADDRESSES: You may submit comments, identified by docket number NIOSH-237, by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226

- *Facsimile:* (513) 533-8285
- *E-mail:* nioshdocket@cdc.gov

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226. All comments received will be available on the NIOSH Docket Web page at <http://www.cdc.gov/niosh/docket>, and in writing by request. NIOSH includes all comments received without change in the docket and the electronic docket, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: John Sporrer, NIOSH, NPPTL, Post Office Box 18070, Building 20, Pittsburgh, PA 15236; E-mail ppeconcerns@cdc.gov, telephone (412) 386-6435.

SUPPLEMENTARY INFORMATION: In the November 2010 report the Institute of Medicine (IOM) made three recommendations for advancing conformity assessment for Personal Protective Technologies (PPT) in the nation. These recommendations are:

(1) Develop and Implement Risk-Based Conformity Assessment Processes for Non-Respirator PPT; (2) Enhance Research, Standards Development, and Communication; and (3) Establish a PPT and Occupational Safety and Health Surveillance System.

The report may be accessed, for free, at: http://www.nap.edu/catalog.php?record_id=12962.

Conformity Assessment Components

NIOSH, NPPTL envisions that PPT conformity assessment can involve the following components: standards, testing, inspection, certification, registration, accreditation, supplier's declaration of conformity (SDoC), communication, post-market testing and evaluation, and health surveillance. NIOSH, NPPTL is already responsible for certifying respirators for use in the United States. The management responsibilities of PPT Program conformity assessment undertaken by NIOSH, NPPTL include developing the strategy to implement the IOM recommendations.

Near Term Strategy

NIOSH, NPPTL intends to implement a multi-year strategy to address Recommendation 1 of the IOM report to develop and implement risk-based conformity assessment processes for non-respirator PPT.

The impacts of non-compliance (consequences of failure to provide the expected protection) are best described in terms of their potential risk to the user and the independence and rigor of conformity assessment. This relationship is described in Gordon Gillerman's *Making the Confidence Connection* published in ASTM Standardization News (2004), which can be viewed at http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html.

Timeline To Address Recommendation 1

The timeline to address Recommendation 1 includes, but is not limited to the following activities conducted over a two year time period:

1. defining the standards to be included in the process;
2. identifying the PPE on the market which complies with current standards;
3. finalizing the conformity assessment terminology to be used in the effort;
4. defining low, medium, and high levels of risk;
5. assessing available sources (e.g. surveillance data) to document the risks of the PPE not working properly and the risks of noncompliance;
6. defining the level of conformity assessment, including configuration management, required for each level of risk; and
7. defining the types of PPE to be included in the framework to include those required by regulation, those desired by the user, and those that respond to specific health and safety needs in the marketplace.

NIOSH, NPPTL will develop a draft risk-based strategy and solicit public comment on the strategy. NIOSH, NPPTL will conduct face-to-face and virtual public meetings to discuss the PPT conformity assessment strategy during the strategy development process. The proposed strategy will be published and is expected to serve as a reference for standards development organizations.

Stakeholder input to the NIOSH, NPPTL strategy to address the recommendations provided in the IOM report may be submitted to NIOSH Docket 237 until July 1, 2011.

Dated: May 11, 2011.

John Howard,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10292]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send