

Developing the Nonrespiratory Personal Protective Equipment Conformity Assessment Framework for the Nation

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Abstract

There is no nationally recognized central authority for certifying or overseeing the certification of non-respiratory personal protective technologies (PPT). The National Academies (NA) in its 2008 review of the NIOSH PPT Program defines this as one of the most significant weaknesses of the national efforts concerning worker health and safety protection. One of the report's primary recommendations specifically addressed this situation. It recommended that NIOSH oversee all PPT certification in order to ensure a minimum uniform standard of protection and wearability. [1]

The expansion of NIOSH's responsibilities to overseeing certification activities of non-respiratory PPT through development of a conformity assessment consensus standard and/or an audit/oversight function are feasible options to provide safer and healthier workplaces across the nation.

Background

The 2008 NA report recognized that NIOSH's historical role in providing certification of respirators (Figure 1) has had a significant positive impact on the quality of respirators available in the workplace with consequent reductions in deaths and serious injuries.

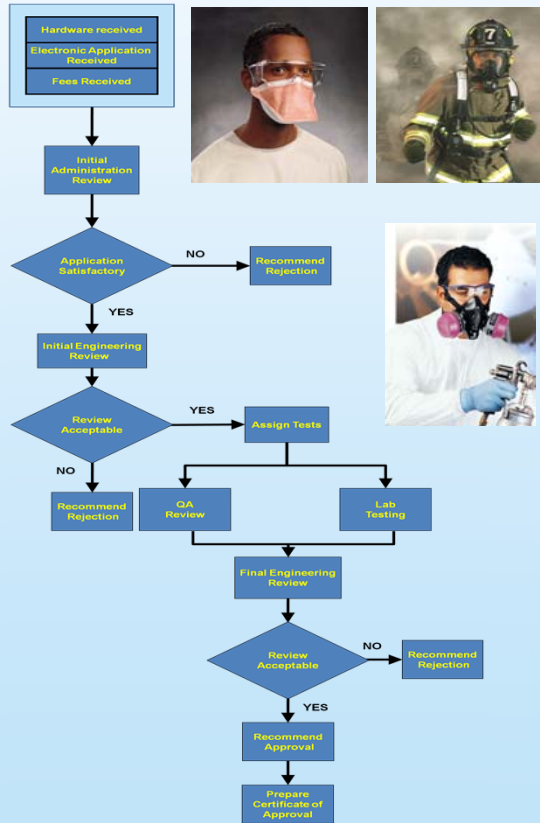


Figure 1. Overview of NIOSH respirator certification process

Conformity Assessment (CA) is the "demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled" ISO/IEC 17000 [2]

The level of independence necessary in a CA process may be determined by examining perceived risk (Figure 2)

Types of Conformity Assessment [3]

- SDoC ISO/IEC 17050
- Testing ISO/IEC 17025
- Inspection ISO/IEC 17020
- Certification ISO/IEC Guide 65
- Registration ISO/IEC 17021
- Accreditation ISO/IEC 17011

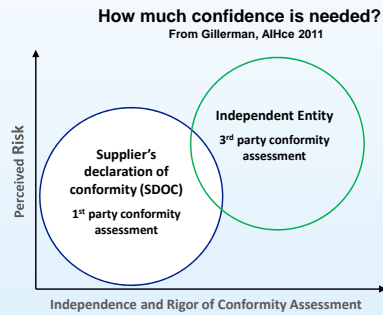


Figure 2. Perceived risk versus risk [4]

Who declares conformity?

- First party – seller or manufacturer (SDOC)
- Second party – purchaser or user
- Third party – independent entity

Methods

- NIOSH developed a strategy and timeline to assess certification mechanisms (Figure 3)
- NIOSH Engaged the Institute of Medicine (IOM) to better define the implications of the 2008 recommendation to assess various certification mechanisms [5]
- NIOSH opened a docket to solicit comments on the CA strategy [6]

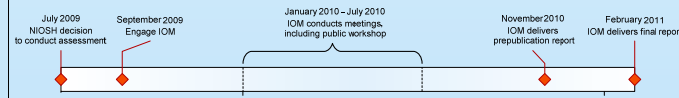


Figure 3. Timeline for conducting assessment of various certification mechanisms and their potential applicability to non-respiratory PPT

Stakeholders

All workers who wear personal protective equipment (PPE)



Partners

Results

- IOM Certifying PPT Report (November 2010) Provided three Recommendations[5]
 - Develop and Implement Risk-Based Conformity Assessment Processes for Non-Respirator PPT
 - Enhance Research, Standards Development, and Communication
 - Establish a PPT and Occupational Safety and Health Surveillance System
- NIOSH developed core conformity assessment questions to be addressed
 - What approach will best balance the private and public sector interests in protecting the health and safety of the American Worker?
 - What implementation mechanisms and authorities must be used, enhanced, or developed to ensure effective national CA implementation, coordination, and compliance?
 - Using a cost/benefit approach, what will the marketplace, particularly PPE purchasers and end users, be realistically willing and able to support?
 - What level of CA is necessary under various circumstances?

Next steps

- NIOSH will develop a CA framework with input from partners (Figure 4)
- Framework will serve as the basis for CA standard and/or NIOSH audit/oversight approach

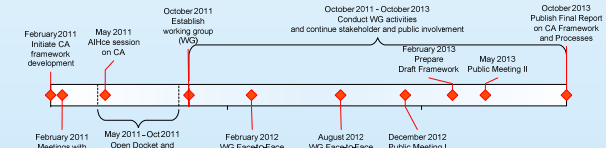


Figure 4. Timeline for developing the PPT conformity assessment framework

References

- [1] Institute of Medicine and National Research Council, *The Personal Protective Technology Program at NIOSH. Committee to Review the NIOSH Personal Protective Technology Program. Rpt. No. 5, Reviews of Research Programs of the National Institute for Occupational Safety and Health*, ed. Committee to Review the NIOSH Personal Protective Technology Program, 2008, Washington, DC: The National Academies Press. Available from: http://www.nap.edu/catalog.php?record_id=12203
- [2] ISO/IEC 17000
- [3] National Conformity Assessment Principles for the United States, www.ansi.org/ncap
- [4] Gordon Gillerman's presentation from AIHce 2011 (Emerging Issues session)
- [5] IOM (Institute of Medicine). *Certifying Personal Protective Technologies: Improving Worker Safety*, ed. Committee on the Certification of Personal Protective Technologies, Howard J. Cohen and Catharyn T. Liverman. 2011, Washington, DC: The National Academies Press. 190. Available from: http://www.nap.edu/catalog.php?record_id=12962
- [6] NIOSH docket 237 (PPT Conformity Assessment). Available from: <http://www.cdc.gov/niosh/docket/review/docket237/default.html>

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