Session 4:

Conformity Assessment Case Study
Personal Protective Technologies

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Presentation Overview

- NIOSH’s PPT Program and Its Background in Conformity Assessment
- IOM CA Report Recommendations
- NIOSH Strategy to Address Recommendations
- Status of Implementing the Strategy
An estimated 20 million workers use personal protective equipment on a regular basis to protect themselves from job hazards.

The MISSION of the PPT program is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies (PPT).
NIOSH Respirator Conformity Assessment Activities

- Respirator Approval Activities
  - Engineering Evaluation
  - Respirator Testing
  - QA Plan Evaluation

- Post Approval Activities
  - Manufacturing Site Audits
  - Respirator Product Audits
  - Respirator Evaluations
NIOSH Conformity Assessment

Foundational Background

June 2008
NA
PPT Program Evaluation Report: Five Recommendations

May 2010
PPT Program’s Action Plan to Implement Recommendations

February 2011
IOM’s Analysis of NA Report Recommendation 1: Comprehensive CA Program

May 2011
NIOSH Docket # 237 Public Comment on IOM CA Report

October 2011
NIOSH PPT Conformity Assessment Working Group Established
NA Report Observations

“NIOSH certification of respirators has had a significant positive impact on the quality of respirators available in the workplace.”

“There is no analogous federal process for ensuring the certification of the efficacy of nonrespiratory PPT.”

NA Report Recommendation 1

- Oversee all PPT certification in order to ensure a minimum uniform standard of protection and wearability. The National Program should collaborate with other relevant government agencies, private-sector organizations, and not-for-profit organizations to conduct an assessment of the certification mechanisms needed to ensure the efficacy of all types of PPT (emphasis added); and
Engaging the IOM to Assess Nonrespiratory PPT Certification

- June 2008 - May 2010
  - PPT Program prepares response and Implementation Plan to NA Report

- July 2009
  - NIOSH decision to conduct assessment

- September 2009
  - Engage IOM

- January 2010 - July 2010
  - IOM conducts meetings, including public workshop

- November 2010
  - Prepublication Report

- February 2011
  - IOM Final Report

- May 2010
  - Implementation Plan for NA Report Recommendations Approved
Charge to the IOM Committee

- Assess the [conformity assessment] mechanisms needed to ensure the efficacy of nonrespiratory personal protective technologies (PPT)
- Examine various approaches to various [conformity assessment elements] (e.g., federal laboratory certification, third-party certification, federal certification of nongovernmental laboratories)
- Provide recommendations on [conformity assessment for] non-respiratory PPT
The Personal Protective Technology Program at NIOSH

Implementation Plan in Response to the Evaluation by the National Academies of the Personal Protective Technology Program at NIOSH

CERTIFYING PERSONAL PROTECTIVE TECHNOLOGIES

NIOSH Docket Number 237
PPT Conformity Assessment

NIOSH PPT Conformity Assessment Working Group (PCAWG) Strategy

June 2008
NA
PPT Program Evaluation Report: Five Recommendations

May 2010
PPT Program’s Action Plan to Implement Recommendations

February 2011
IOM’s Analysis of NA Report Recommendation 1: Comprehensive CA Program

May 2011
NIOSH Docket # 237 Public Comment on IOM CA Report

October 2011
NIOSH PPT Conformity Assessment Working Group Established
Recommendation 1 - Develop and Implement Risk-Based [Conformity Assessment Processes] for Nonrespiratory PPT

Recommendation 2 - Enhance Research, Standards Development, and Communication

Recommendation 3 - Establish a PPT and Occupational Safety and Health Surveillance System
IOM Report
Conformity Assessment
Tiered Approach

- **Low risk**
  - Manufacturer attestation to the standard

- **Medium risk**
  - Third-party testing and certification by accredited entities

- **High risk**
  - Third-party testing and certification by accredited entities
  - Government involvement to provide oversight and to assist in enforcement
NIOSH Conformity Assessment
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NIOSH Conformity Assessment
Foundational Background

Responses to NIOSH Docket # 237

• 3M Corporation
• International Safety Equipment Association (ISEA)
• International Association of Firefighters (IAFF)
• Kimberly-Clark Corporation
• International Personal Protection, Inc. (Stull & Stull)
• Oil and Gas Industry Representative (Reznicek)
NIOSH Conformity Assessment
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The Status of Conformity Assessment of PPE in the US

- Few formal requirements exist in the US that PPE be independently tested and certified
  - Respirators require NIOSH testing and approval
  - Third-party certification is required in fire and emergency service standards from NFPA
  - Other workplace PPE such as safety glasses, hard hats and fall protection may be tested by manufacturer to show conformance to a consensus standard
The Status of Conformity Assessment of PPT in the US

- Manufacturers develop products to meet consensus standards
  - Checks and balances in place through litigation
- Current legal processes do not penalize for false claims
- ISEA Draft Conformity Assessment Standard under development
- Consensus standard organizations sometimes incorporate CA in support of performance standards
Guiding Principles for the NIOSH Strategy

• **First: Collaborate.**
  
  “The National Program should collaborate with other relevant government agencies, private-sector organizations, and not-for-profit organizations to conduct [the] assessment…” (NA Report)

• **Second: Do no harm.**
  
  “The committee recognizes that many conformity assessment processes already in place can fit this framework.” (IOM Report)

• **Third, Don’t re-invent the wheel.**
  
  “A single reputable source of information on all certified PPT is needed...[that] could link to lists of certified equipment from accredited third-party organizations.” (IOM Report)
What is our Challenge?

Develop consensus regarding what types of assurance are needed to demonstrate that particular PPE products meet standards to which they are marked.

• What is the basis for establishing a national framework to address the conformity assessment of nonrespiratory PPE?
• What are the appropriate implementation mechanisms and needed authorities?
• What level of conformity assessment is necessary under various circumstances?
• What will the PPE manufacturer and user communities be realistically willing and able to support?
Working Group Schedule

February 2011
Initiate CA framework development

May 2011
AIHce session on CA

October 2011
Establish working group (WG)

February 2012
WG Face-to-Face Meeting

August 2012
WG Face-to-Face Meeting

December 2012
Public Meeting I

October 2011 - October 2013
Conduct WG activities and continue stakeholder and public involvement

February 2013
Prepare Draft Framework

May 2013
Public Meeting II

October 2013
Publish Final Report on CA Framework and Processes

February 2011
Meetings with ISEA & NIST

May 2011 - Oct 2011
Open Docket and analyze comments
Working Group Approach

Develop a framework for a national strategy for nonrespiratory PPT conformity assessment
Terminology:  
Key Activities

- Identify applicable terms needed to establish consistent language

- Definitions
  - List of important terms
  - List of terms which may be referenced
  - Terms selected for deletion
Terminology: Important Terms

- Accreditation
- Accreditation body
- Approval
- Attestation
- Certificates or marks of conformity
- Certification
- Conformance
- Conformity assessment
- Conformity assessment body
- Declaration
- Environmental conditions
- Failure
- First party
- Hazard
- Hazard identification
- Incorrect use
- Inspection
- Non-conformance
- Probability
- Regulations
- Revocation
- Risk
- Risk assessment
- Risk Evaluation
- Risk Management
- Risk Reduction
- Second Party
- Severity
- Supplier’s Declaration
- Surveillance
- Third Party
- Type Test
- Unilateral Arrangement

Do these terms capture those needed for the WG products?
Products and Standards: Key Activities

- Inventory product and performance standards
- Identify classes of PPE to which specific standards and requirements apply
- Assess national and international conformity assessment processes
- Identify existing third party certifiers of PPE, their current accreditation, and standards to which they test products
- Document and identify PPE integration and interface issues

Outputs will feed into the development of the conformity assessment model(s).
Surveillance Data: Key Activities

• Over 30 data sources assessed and documented to define data gathering needs
• Case studies and sources of incidents evaluated
• Need for improved approaches identified
  • Assessing PPE failures and inadequacies
  • Reporting incidents of PPE failure
  • Reporting fraudulent or counterfeit PPE in the marketplace

Are there any other databases or sources of information which may provide information on PPE conformity?
Medwatch Adverse Event and Reporting System

- Voluntary
- Media
  - Electronic
  - Paper (mail or fax)
  - Phone
- 40,000 incidents/year
- Resources
  - 1.5 personnel
  - $300K/year dedicated to data entry
Compliance and Enforcement: Key Activities

• Assess and document existing national compliance programs
• Enumerate needs, gaps, and deficiencies in these programs
  • Conformity assessment requirements
  • Enforcement authority guidelines for classes of PPE
• Benchmark international conformity assessment programs
Candidate Countries to Benchmark

- Asia
  - Japan

- Australia

- Europe
  - England
  - Germany
  - Sweden

- North America
  - Canada - Ontario
  - Canada – Quebec
  - Mexico

- South America
  - Brazil

• Are these the right countries?

• Which other countries should be considered?
Benchmarking Approach: Survey

- Key Issues
  - Are CA standards voluntary or required by law, regulation, or other authority?
  - What quantitative surveillance data were used in structuring the PPE CA system?
  - How were the categories of risk determined?
  - What are the major issues concerning compliance and enforcement?
  - What successes/benefits have you realized from the program?
Levels of Risk: Key Activities

• Develop appropriate levels of risk model
• Define appropriate use of existing data in the absence of complete surveillance data
• Explore and develop operations research methodologies (expert decision models) to assign risk levels
• Develop a risk assessment process
Working Group Schedule

- **February 2011**: Initiate CA framework development
- **May 2011**: A1Hce session on CA
- **October 2011**: Establish working group (WG)
- **2012**: February 2012 WG Face-to-Face Meeting
- **August 2012**: WG Face-to-Face Meeting
- **December 2012**: Public Meeting I
- **February 2013**: Prepare Draft Framework
- **May 2013**: Public Meeting II
- **October 2011 - October 2013**: Conduct WG activities and continue stakeholder and public involvement
- **October 2013**: Publish Final Report on CA Framework and Processes

**Key Dates:**
- February 2011: Meetings with ISEA & NIST
- May 2011 - Oct 2011: Open Docket and analyze comments
Quality Partnerships Enhance Worker Safety & Health

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Thank you!