

Conformity Assessment Approaches and Best Practices NIST Public Workshop

Session 4:

Conformity Assessment Case Study *Personal Protective Technologies*

Maryann D'Alessandro, Ph.D.

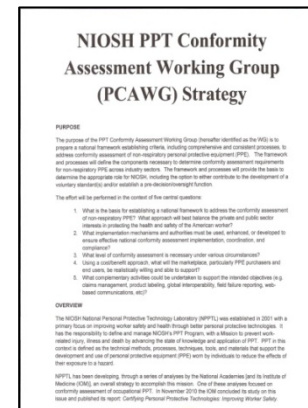
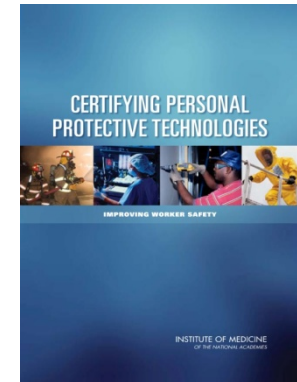
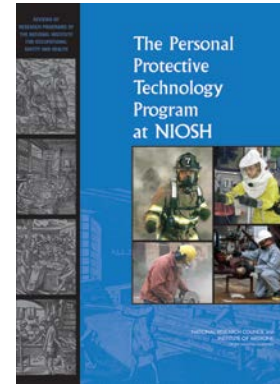
**Director, National Personal Protective
Technology Laboratory**

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April 12, 2012

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



NIOSH PPT Program Mission

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**

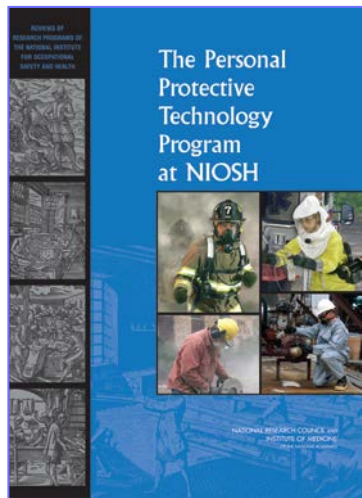
- Engineering Evaluation
- Respirator Testing
- QA Plan Evaluation

- **Post Approval Activities**

- Manufacturing Site Audits
- Respirator Product Audits
- Respirator Evaluations



NIOSH Conformity Assessment Foundational Background



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

Introduction

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The Mission of the PPT Cross Sector Program within NIOSH is to prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies (PPT).

Proper use of personal protective equipment (PPE) and technology substantially reduce injuries, illnesses, and fatalities among our nation's workers. An estimated 20 million workers use PPE on a regular basis to protect them from job hazards. PPE prevents workers from death and disabling injuries and illnesses resulting from exposures to hazardous airborne particles, harmful chemicals, and excessive noise, heat, physical trauma, and fires. Improvements in personal protective technology are realized through better standards and regulations and subsequent availability of PPE complying with the new standards and regulations, worker

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NIOSH Docket Number 237

PPT Conformity Assessment

NIOSH, NPPTL assessed the availability of the PPT (Personal Protective Technology) Conformity Assessment Docket, NIOSH Docket 237, and solicited input from interested parties. The docket was established to provide interested parties the opportunity to provide input to the NIOSH, NPPTL strategy to address the recommendations issued in November 2009 by the Institute of Medicine (IOM) in its report *Certifying Personal Protective Technologies: Improving Worker Safety*. The report focuses on the need for a consistent risk-based approach to PPT conformity assessment. This docket was available until July 1, 2010. All comments will be assessed as part of the effort to address the IOM recommendations.

Background Information

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NIOSH PPT Conformity Assessment Working Group (PCAWG) Strategy

PURPOSE

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2. What implementation mechanisms and authorities must be used, enhanced, or developed to ensure effective national conformity assessment implementation, coordination, and compliance?
3. What level of conformity assessment is necessary under various circumstances?
4. Using a cost/benefit approach, what will the marketplace, particularly PPE purchasers and end users, be materially willing and able to support?
5. What complementary activities could be undertaken to support the intended objectives (e.g. claims management, product labeling, global interoperability, field failure reporting, web-based communications, etc)?

OVERVIEW

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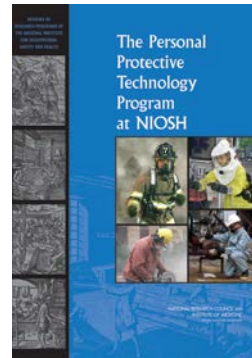
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NA Report Observations

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

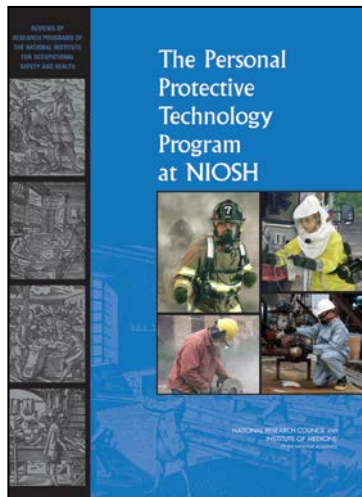
“There is no analogous federal process for ensuring the **certification** of the efficacy of nonrespiratory PPT.”



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

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4. Using a cost/benefit approach, what will the marketplace, particularly PPE purchasers and end users, be most likely willing and able to support?
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Engaging the IOM to Assess Nonrespiratory PPT Certification

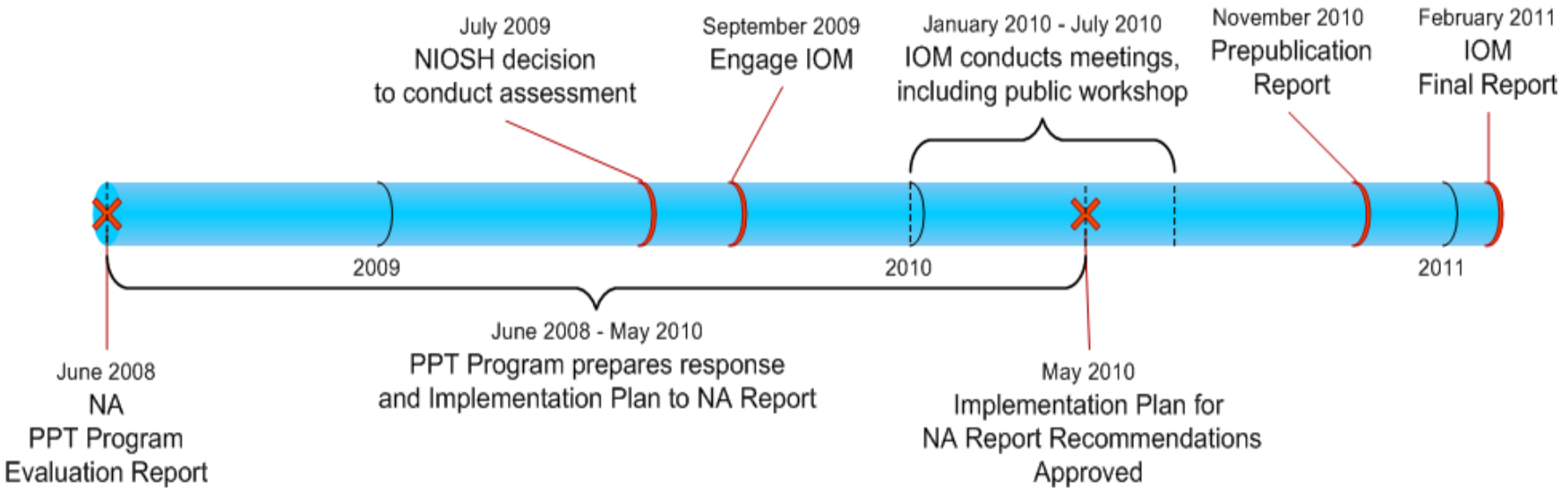
Implementation Plan in Response to the Evaluation by the National Academies of the Personal Protective Technology Program at NIOSH

Introduction

In fiscal year (FY) 2008, the U.S. Congress allocated funds to develop research and technology for personal protective equipment (PPE) to protect the health and safety of workers in response to the 2002 report of the National Academies of Sciences, Engineering, and Medicine (NAEAM) on the status of research and development in PPE, such as respirators, fall protection, and eye and face protection. Congress also authorized the implementation of an independent research program. In 2003, NIOSH established the independently funded research program, the Personal Protective Technology (PPT) Program. The establishment of NPTI helped to increase the visibility of PPT activities within NIOSH. This initiative was further advanced when the PPT User Survey Program was formally established in 2007. The PPT User Survey Program is the vehicle to collect user needs and implement the Strategic Plan Program and the Research and Development Program.

The Mission of the PPT User Survey Program within NIOSH is to assess work-related issues, risks, and needs, to enhance the role of knowledge and application of personal protective technology (PPT).

Progress on personal protective equipment (PPE) and technology advancement includes research, research, and facilities among our nation's workers. The National Institute for Occupational Safety and Health (NIOSH) is a leader in this effort. PPE protects workers from death and disability. Research and development in PPE is essential to the health and safety of our nation's workers. The PPT User Survey Program is the vehicle to collect user needs and implement the Strategic Plan Program and the Research and Development Program.



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**

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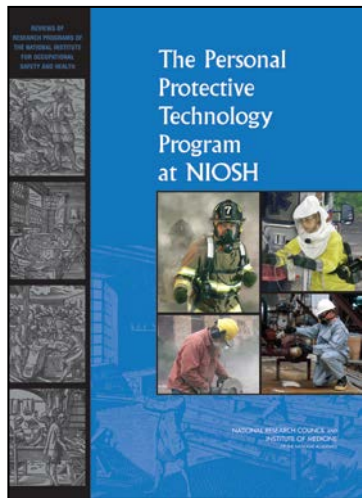
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In April 2007 (PPT 2007), the U.S. Congress directed NIOSH to develop research and information to help protect the health and safety of American workers who use PPT, such as respirators, fall protection, and other safety equipment. Congress also directed NIOSH to conduct a study on the effectiveness of PPT. In 2007, NIOSH established the implementation plan for the PPT 2007 study. The study was completed and published in 2008. The study was titled "Personal Protective Technology: A Study of the Effectiveness of PPT in the Workplace." The study was published in the journal "Safety Science" in 2008.

The Mission of the PPT Close Sector Program within NIOSH is to assess work-related risks, identify and control the risks of injury and illness, and to improve the safety and health of workers by providing the best available research and information on PPT.

Proper use of personal protective equipment (PPE) and technologies (referred to as PPT) can reduce the risk of injury and illness among workers. The National Institute for Occupational Safety and Health (NIOSH) is committed to ensuring that workers have the information they need to use PPT in a way that is most effective. PPT products include fall protection, fall arrest, fall restraint, and fall prevention systems, as well as other safety equipment. PPT products are used in a wide range of industries and occupations. PPT products are used to protect workers from falls, electrical shock, and other hazards. PPT products are used to protect workers from injury and illness. PPT products are used to protect workers from death and disability. PPT products are used to protect workers from serious and permanent injury and illness. PPT products are used to protect workers from death and disability. PPT products are used to protect workers from serious and permanent injury and illness. PPT products are used to protect workers from death and disability.

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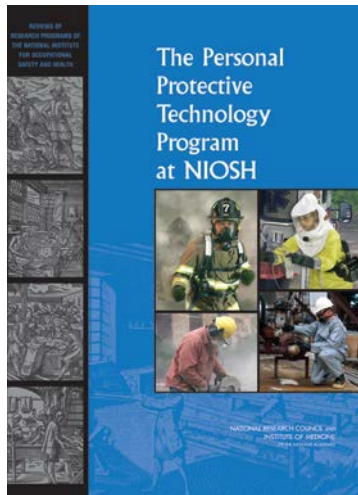
- **Recommendation 1 - Develop and Implement Risk-Based [Conformity Assessment Processes] for Nonrespiratory PPT**
- Recommendation 2 - Enhance Research, Standards Development, and Communication
- Recommendation 3 - Establish a PPT and Occupational Safety and Health Surveillance System

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

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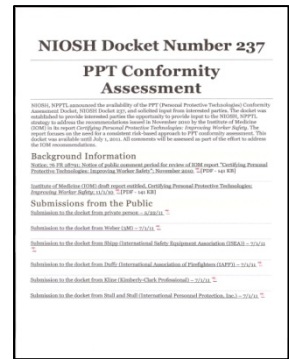
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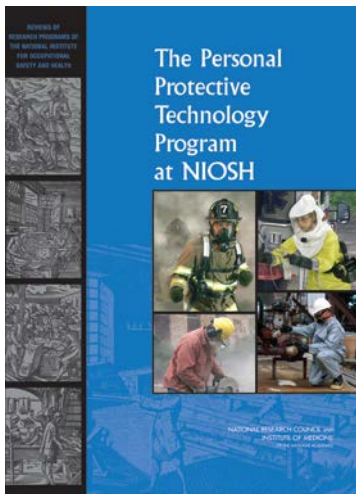
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- 3M Corporation
- International Safety Equipment Association (ISEA)
- International Association of Firefighters (IAFF)
- Kimberly-Clark Corporation
- International Personal Protection, Inc. (Stull & Stull)
- Oil and Gas Industry Representative (Reznicek)

NIOSH Conformity Assessment Foundational Background



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

Introduction

In fiscal year (FY) 2001, the U.S. Congress allocated funds to develop standards and technologies for protecting the health and safety of America's workers who rely on PPE, such as respirators, clothing, gloves, hard hats, eye and hearing protection devices with an emphasis on emergency responders. Creation of NPPTL in 2001 consolidated the congressionally mandated respirator approval program, with respiratory protection research and standard-development activities. The establishment of NPPTL began an initiative to align all PPT activities within NIOSH. This initiative was expanded and further developed when the PPT Cross Sector Program was formally established in 2005. The PPT Cross Sector Program is also relevant to all industry sectors and encompasses the Hearing Loss Program and the Traumatic Injury Program.

The Mission of the PPT Cross Sector Program within NIOSH is to prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technology (PPT).

Proper use of personal protective equipment (PPE) and technologies substantially reduce injuries, illnesses, and fatalities among our nation's workers. An estimated 20 million workers use PPE as a regular part of their work lives. PPT prevents workers from death and disabling injuries and illnesses resulting from exposures to hazardous airborne particles, harmful chemicals, and excessive noise, falls, physical trauma, and fire. Improvements in personal protective technology are realized through better standards and regulations and subsequent availability of PPE complying with the new standards and regulations, worker

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

CERTIFYING PERSONAL PROTECTIVE TECHNOLOGIES

IMPROVING WORKER SAFETY

NIOSH Docket Number 237

PPT Conformity Assessment

NIOSH, NPPTL assessed the availability of the PPT (Personal Protective Technology) Conformity Assessment Docket, NIOSH Docket 237, and solicited input from interested parties. The docket was established to provide interested parties the opportunity to provide input to the NIOSH, NPPTL strategy to address the recommendations issued in November 2005 by the Institute of Medicine (IOM) in its report *Certifying Personal Protective Technologies: Improving Worker Safety*. The report focuses on the need for a consistent risk-based approach to PPT conformity assessment. This docket was available until July 4, 2011. All comments will be assessed as part of the effort to address the IOM recommendations.

Background Information

NIOSH, as the alpha, holder of public comment period for review of IOM report, *Certifying Personal Protective Technologies: Improving Worker Safety*, 11/13/05. (PPT - 141 KB)

Institute of Medicine (IOM) draft report entitled, *Certifying Personal Protective Technologies: Improving Worker Safety*, 11/13/05. (PPT - 141 KB)

Submissions from the Public

Submission to the docket from private person - 5/22/11

Submission to the docket from Weber (LMI) - 7/1/11

Submission to the docket from Shiping (International Safety Equipment Association (ISEA)) - 7/1/11

Submission to the docket from Duffy (International Association of Firefighters (IAFF)) - 7/1/11

Submission to the docket from Kline (Kishner-Clark Professional) - 7/1/11

Submission to the docket from Bull and Bull (International Personnel Protection, Inc.) - 7/1/11

NIOSH PPT Conformity Assessment Working Group (PCAWG) Strategy

PURPOSE

The purpose of the PPT Conformity Assessment Working Group (hereafter identified as the WAG) is to prepare a national framework establishing criteria, including comprehensive and consistent processes, to address conformity assessment of non-respiratory personal protective equipment (PPE). The framework and processes will define the components necessary to determine conformity assessment requirements for non-respiratory PPE across industry sectors. The framework and processes will provide the basis to determine the appropriate role for NIOSH, including the option to either contribute to the development of a voluntary electronic and/or establish a pre-decision/oversight function.

The effort will be performed in the context of five central questions:

1. What is the basis for establishing a national framework to address the conformity assessment of non-respiratory PPE? What approach will best balance the private and public sector interests in protecting the health and safety of the American worker?
2. What implementation mechanisms and authorities must be used, enhanced, or developed to ensure effective national conformity assessment implementation, coordination, and compliance?
3. What level of conformity assessment is necessary under various circumstances?
4. Using a cost/benefit approach, what will the marketplace, particularly PPE purchasers and end users, be naturally willing and able to support?
5. What complementary activities could be undertaken to support the intended objectives (e.g. claims management, product labeling, global interoperability, field failure reporting, web-based communications, etc)?

OVERVIEW

The NIOSH National Personal Protective Technology Laboratory (NPPTL) was established in 2001 with a primary focus on improving worker safety and health through safer personal protective technologies. It has the responsibility to define and manage NIOSH's PPT Program, with a Mission to prevent work-related injury, illness and death by advancing the state of knowledge and application of PPT. In this context as defined by the technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment (PPE) worn by individuals to reduce the effects of their exposure to a hazard.

NPPTL has been developing, through a series of analyses by the National Academies [and its Institute of Medicine (IOM)] an overall strategy to accomplish this mission. One of these analyses focused on conformity assessment of occupational PPE. In November 2010 the IOM concluded its study on this issue and published its report, *Certifying Personal Protective Technologies: Improving Worker Safety*.

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

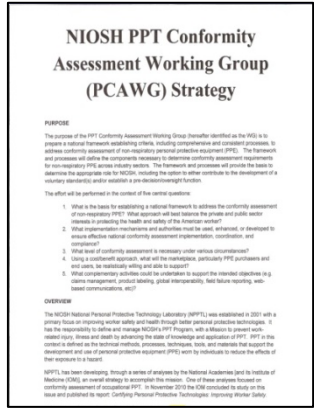
May 2011

NIOSH Docket # 237 Public Comment on IOM CA Report

October 2011

NIOSH PPT Conformity Assessment Working Group Established

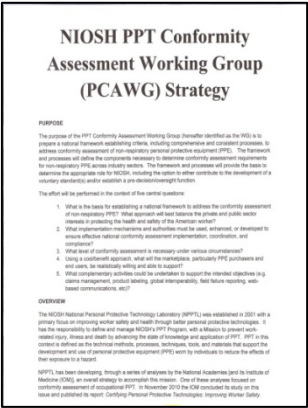
The Status of Conformity Assessment of PPE in the US



- Few formal requirements exist in the US that PPT 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

NIOSH PPT Conformity Assessment Working Group (PCAWG) Strategy

PURPOSE
The purpose of the PPT Conformity Assessment Working Group (hereafter identified as the WG) is to prepare a national framework establishing criteria, including comprehensive and consistent processes, to address conformity assessment of non-respiratory personal protective equipment (PPE). The framework and processes will define the components necessary to determine conformity assessment requirements for non-respiratory PPE across various sectors. The framework and processes will address the issues to determine the appropriate role for NIOSH, including the factors to which contribute to the development of a voluntary, non-licensing, market-oriented, self-enforcement system.

The effort will be performed in the context of the central questions:

1. What is the basis for establishing a national framework to address the conformity assessment of non-respiratory PPE? What approach will best balance the private and public sector interests in protecting the health and safety of the American workforce?
2. What organizational mechanisms and authorities need to exist, enhanced, or developed to allow effective national conformity assessment requirements, coordination, and implementation?
3. What level of conformity assessment is necessary under various circumstances?
4. Using a consistent approach, what will be the marketplace, particularly PPE purchasers and end users, be responsible for testing and certification?
5. What complementary activities could be undertaken to support the intended objectives (e.g. capacity management, model testing, global harmonization, best practice reporting, web-based communications, etc)?

OVERVIEW
The NIOSH National Personal Protective Technology Laboratory (NPPTL) was established in 2001 with a primary focus on improving worker safety and health through better personal protective technologies. It has the responsibility to define and manage NIOSH's PPT Programs, with a focus to protect workers' health and safety by advancing the state of knowledge and application of PPT. PPT in this context is defined as the technical methods, techniques, tools, and materials that support the development and use of personal protective equipment (PPE) worn by individuals to reduce the effects of their exposure to hazard.

NPPTL has been developing, through a series of analyses by the National Academies (and its Institute of Medicine (IOM)), an overall strategy to accomplish this mission. One of these analyses focused on conformity assessment of occupational PPE. In November 2010 the IOM conducted its study on this topic and submitted its report, "Confidence Personal Protective Technology: Harmonizing Worker Safety."

- **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)

PCAWG Members and Consultants



The miracles of science™

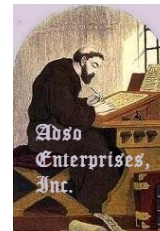


Raytheon

JSJ and Associates

3M

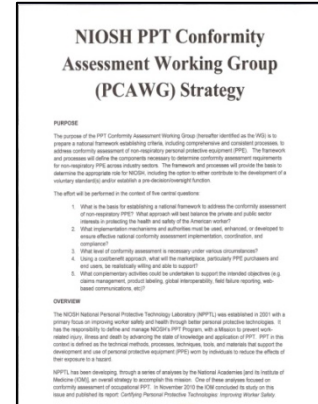
International Personal Protection, Inc.



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

NIOSH PPT Conformity Assessment Working Group (PCAWG) Strategy

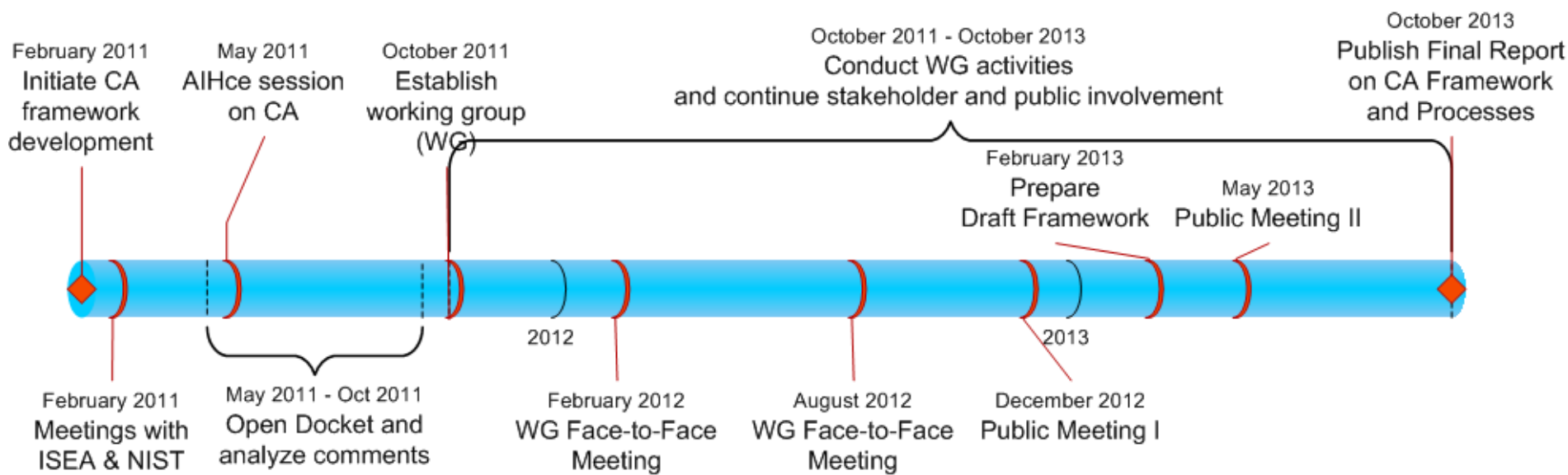
PURPOSE
 The purpose of the PPT Conformity Assessment Working Group (hereafter identified as the WG) is to prepare a national framework establishing criteria, including comprehensive and consistent processes, to address conformity assessment of non-respiratory personal protective equipment (PPE). The framework and processes will define the components necessary to determine conformity assessment requirements for non-respiratory PPE across multiple sectors. The framework and processes will provide the basis to determine the appropriate role for NIOSH, including the ability to either contribute to the development of a voluntary, nationally-accepted standard or a development/implementation.

The effort will be performed in the context of the central question:

1. What is the basis for establishing a national framework to address the conformity assessment of non-respiratory PPE? What approach will best balance the private and public sector interests in protecting the health and safety of the American worker?
2. What regulatory mechanisms and enforcement tools (i.e., rule, enforce, or standard) to address effective national conformity assessment requirements, coordination, and implementation?
3. What level of conformity assessment is necessary under various circumstances?
4. Using a consistent approach, what will the marketplace, particularly PPE producers and users, be reasonably willing and able to support?
5. What complementary activities could be undertaken to support the intended objectives (e.g. open transparency, avoid redundancy, global harmonization, best practice reporting, web-based communications, etc)?

OBJECTIVE
 The NIOSH National Personal Protective Technology Laboratory (NPPTL) was established in 2001 with a primary focus on improving worker safety and health through better personal protective technologies. It has the responsibility to define and manage NIOSH's PPT Programs, with a focus to prevent work-related injury, illness and death by advancing the state of knowledge and application of PPT. PPT in this context is defined as the technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment (PPE) worn by individuals to reduce the effects of their exposure to hazard.

NPPTL has been developing through a series of analyses for the National Academies (and its Institute of Medicine (IOM)) an overall strategy to accomplish this mission. One of these analyses focused on conformity assessment of occupational PPE. In November 2010 the IOM conducted a study on the topic and submitted its report, "Confined Personal Protective Technology: Honoring Worker Safety."



Working Group Approach

Develop a framework for a national strategy for nonrespiratory PPT conformity assessment

NIOSH PPT Conformity Assessment Working Group (PCAWG) Strategy

PURPOSE

The purpose of the PPT Conformity Assessment Working Group (hereinafter identified as the WG) is to prepare a national framework establishing criteria, including comprehensive and consistent processes, to address conformity assessment of nonrespiratory personal protective equipment (PPE). The framework and processes will define the components necessary to determine conformity assessment requirements for nonrespiratory PPE across multiple sectors. The framework and processes will provide the basis to determine the appropriate role for NIOSH, including the degree to which NIOSH will contribute to the development of a voluntary, nationally accepted, or a development/regulated function.

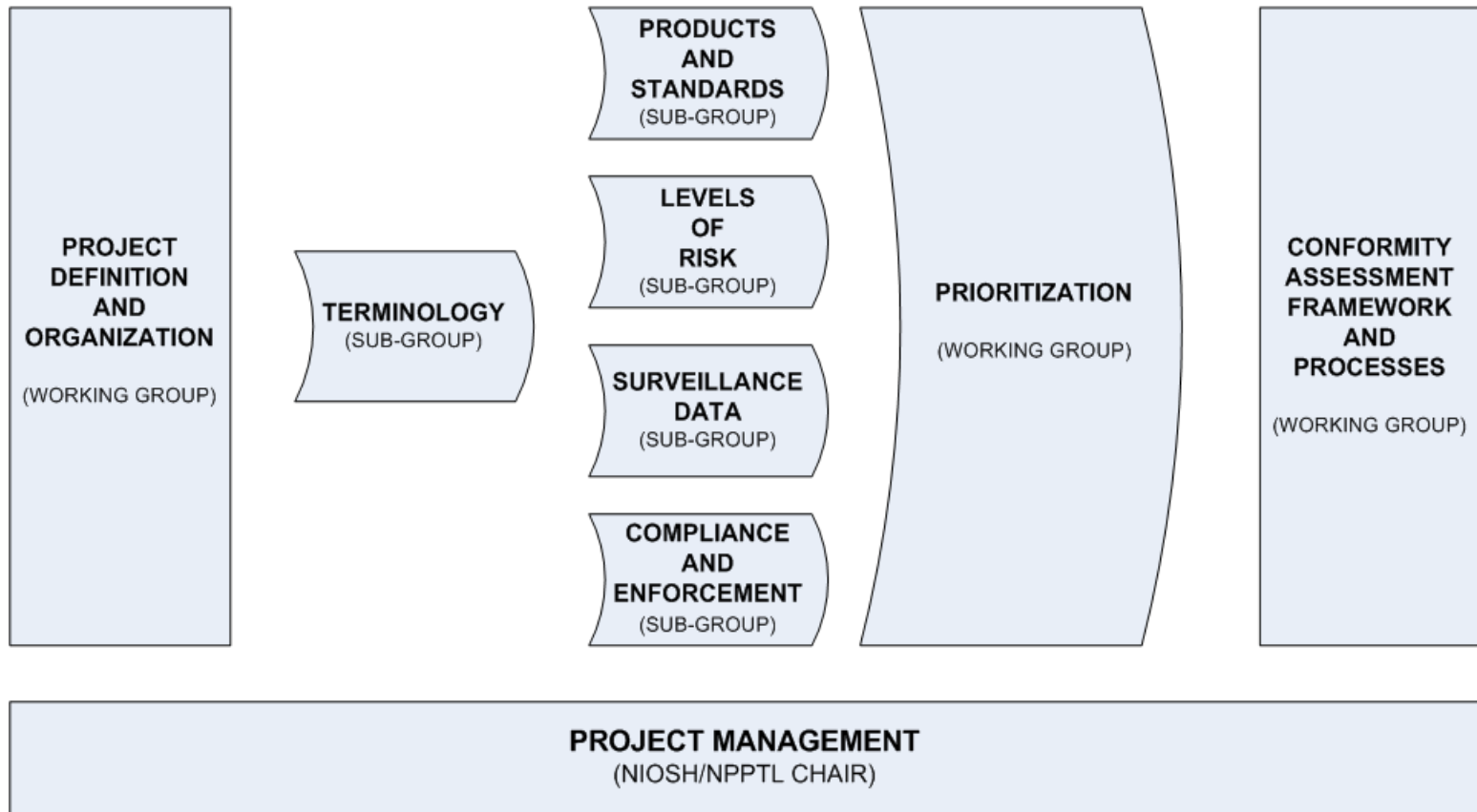
The effort will be performed in the context of the central questions:

1. What is the basis for establishing a national framework to address the conformity assessment of nonrespiratory PPE? What approach will best balance the public and private sector interests in protecting the health and safety of the American worker?
2. What regulatory mechanisms and authorities need to be used, enhanced, or developed to address effective national conformity assessment requirements, coordination, and enforcement?
3. What level of conformity assessment is necessary under various circumstances?
4. Using a consistent approach, what will the requirements, particularly PPE purchases and use cases, be nationally willing and able to support?
5. What complementary activities could be undertaken to support the intended objectives (e.g. capacity management, product labeling, global harmonization, best practice reporting, web-based communications, etc)?

OVERVIEW

The NIOSH National Personal Protective Technology Laboratory (NPPTL) was established in 2001 with a primary focus on improving worker safety and health through better personal protective technologies. It has the responsibility to define and manage NIOSH's PPT Programs, with a focus to protect workers' safety and health by advancing the state of knowledge and application of PPT. It is also tasked to define and implement methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment (PPE) worn by individuals to reduce the effects of their exposure to hazard.

NPPTL has been developing, through a series of analyses by the National Academies (and its Institute of Medicine (IOM)), an overall strategy to understand the issues. One of these analyses focused on conformity assessment of occupational PPE. In November 2010 the IOM conducted a study on the issue and submitted its report, "Conforming Personal Protective Technology: Honoring Worker Safety."



Terminology: Key Activities

TERMINOLOGY
(SUB-GROUP)

- **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

TERMINOLOGY
(SUB-GROUP)

- 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

PRODUCTS
AND
STANDARDS
(SUB-GROUP)

- **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).

25

Surveillance Data: Key Activities

**SURVEILLANCE
DATA**
(SUB-GROUP)

- **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

**SURVEILLANCE
DATA
(SUB-GROUP)**

- **Voluntary**
- **Media**
 - Electronic
 - Paper (mail or fax)
 - Phone
- **40,000 incidents/year**
- **Resources**
 - 1.5 personnel
 - \$300K/year dedicated to data entry

The screenshot shows the 'Safety Reporting Portal' website. At the top, there is a navigation bar with links: 'ABOUT THE PORTAL', 'SAFETY REPORT DIRECTORY', 'FAQS', 'RELATED LINKS', and 'CONTACT US'. The main content area is divided into several sections:

- The Safety Reporting Portal:** A introductory paragraph explaining that the portal streamlines reporting to the FDA and NIH, and a paragraph stating that users make a vital contribution to the safety of America's products.
- Begin Reporting Here:** A central section with three columns:
 - 1. Login:** Includes fields for 'EMAIL' and 'PASSWORD', a 'Log In' button, and a link for 'Forgot your password?'. There is also a 'Remember me' checkbox.
 - 2. Report As Guest:** A section for users not ready to create an account, with a 'Report as Guest' button.
 - Account Benefits:** Lists benefits such as 'Save a draft', 'Easier follow up', 'View submissions', and 'Faster data entry', with a 'Create Account' button.
- Who Should Submit a Safety Report?:** A section listing professional roles (Food Manufacturers, Researchers, Drug Manufacturers) and other individuals (concerned citizens, health professionals) who may submit reports.
- Reports You Can Submit Through this Portal:** A section listing FDA safety issues (Human/animal reportable foods, Animal drugs, Pet foods) and NIH safety issues (NIH gene-transfer research), with a link to 'find out where to submit your report.'

Compliance and Enforcement: Key Activities

COMPLIANCE
AND
ENFORCEMENT
(SUB-GROUP)

- **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 ?*

- **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

LEVELS
OF
RISK
(SUB-GROUP)

- **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

NIOSH PPT Conformity Assessment Working Group (PCAWG) Strategy

PURPOSE

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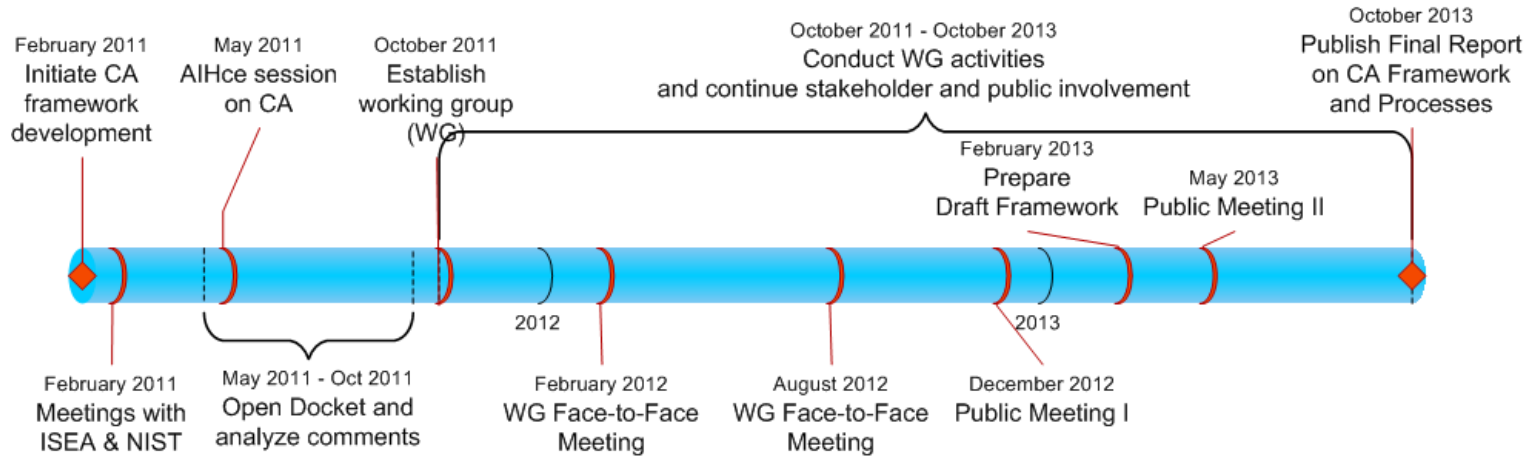
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3. What level of conformity assessment is necessary under various circumstances?
4. Using a consistent approach, what will be the marketplace, particularly PPE purchasers and end users, be responsible for setting and enforcing?
5. What complementary activities could be undertaken to support the intended objectives (e.g. open management, model sharing, global harmonization, best practice reporting, web-based communications, etc)?

OBJECTIVE

The NIOSH National Personal Protective Technology Laboratory (NPPTL) was established in 2001 with a primary focus on improving worker safety and health through better personal protective technologies. It has the responsibility to define and manage NIOSH's PPT Programs, with a focus to prevent work-related injury, illness and death by advancing the state of knowledge and application of PPT. PPT in this context is defined as the technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment (PPE) worn by individuals to reduce the effects of their exposure to hazard.

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Disclaimer:

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Thank you!