# Certifying Personal Protective Technologies: Improving Worker Safety

ISBN
978-0-309-15855-8

166 pages
6 x 9
PAPERBACK (2010)

Howard J. Cohen and Catharyn T. Liverman, Editors; Committee on the Certification of Personal Protective Technologies; Institute of Medicine

# CERTIFYING PERSONAL PROTECTIVE TECHNOLOGIES

## IMPROVING WORKER SAFETY

Committee on the Certification
of Personal Protective Technologies

Board on Health Sciences Policy

Howard J. Cohen and Catharyn T. Liverman, *Editors*

INSTITUTE OF MEDICINE
*OF THE NATIONAL ACADEMIES*

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
**www.nap.edu**

**THE NATIONAL ACADEMIES PRESS • 500 Fifth Street, N.W. • Washington, DC 20001**

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This study was requested by the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention and supported by Award No. 200-2005-10881, T.O. #9, between the National Academy of Sciences and the Centers for Disease Control and Prevention. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

International Standard Book Number-13: 978-0-309-15855-8
International Standard Book Number-10: 0-309-15855-9

Additional copies of this report are available from The National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu.

For more information about the Institute of Medicine, visit the IOM home page at: **www.iom.edu.**



Printed in the United States of America

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

Cover credit: Photo of firefighters reprinted with permission from MSA – The Safety Company.

Suggested Citation: IOM (Institute of Medicine). 2011. *Certifying personal protective technologies: Improving worker safety.* Washington, DC: The National Academies Press.

*"Knowing is not enough; we must apply.*
*Willing is not enough; we must do."*
—Goethe



INSTITUTE OF MEDICINE
*OF THE NATIONAL ACADEMIES*

**Advising the Nation. Improving Health.**

THE NATIONAL ACADEMIES

*Advisers to the Nation on Science, Engineering, and Medicine*

The **National Academy of Sciences** is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Ralph J. Cicerone is president of the National Academy of Sciences.

The **National Academy of Engineering** was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Charles M. Vest is president of the National Academy of Engineering.

The **Institute of Medicine** was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Harvey V. Fineberg is president of the Institute of Medicine.

The **National Research Council** was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Ralph J. Cicerone and Dr. Charles M. Vest are chair and vice chair, respectively, of the National Research Council.

**www.national-academies.org**

## COMMITTEE ON THE CERTIFICATION OF PERSONAL PROTECTIVE TECHNOLOGIES

**HOWARD J. COHEN** (*Chair*), Professor of Occupational Safety and Health, Emeritus, University of New Haven
**ROGER L. BARKER,** Professor, North Carolina State University
**JANICE COMER BRADLEY,** Executive Vice President, Waste Equipment Technology Association, Washington, DC
**BARBARA J. BURGEL,** Clinical Professor of Occupational and Environmental Health Nursing, University of California, San Francisco
**MICHAEL EASTERBROOK,** Professor of Ophthalmology, University of Toronto
**CHRISTINA EGAN,** Director, Biodefense Laboratory, Wadsworth Center, New York State Department of Health, Albany
**ALEXANDER ISAKOV,** Executive Director, Office of Critical Event Preparedness and Response, Emory University, Atlanta, Georgia
**SUNDARESAN JAYARAMAN,** Professor, Georgia Institute of Technology, Atlanta
**JAMES S. JOHNSON,** Consultant, JSJ and Associates, Pleasanton, California
**MELISSA A. MCDIARMID,** Director, Occupational Health Program, University of Maryland
**JAMES W. PLATNER,** Associate Director, CPWR–Center for Construction Research and Training, Silver Spring, Maryland
**ANUGRAH SHAW,** Professor, University of Maryland–Eastern Shore
**TANYA WANCHEK,** Health Economist, Center for Economic and Policy Studies, University of Virginia, Charlottesville
**SAMUEL E. WEHR,** Consultant in Survival and Flotation Technology, Standards and Regulations Manager, Mustang Survival Corporation, Woodbridge, Virginia

*Study Staff*

**CATHARYN T. LIVERMAN,** Study Director
**ANDREW M. POPE,** Board on Health Sciences Policy Director
**SARAH L. HANSON,** Associate Program Officer (through July 2010)
**JUDITH L. ESTEP,** Program Associate

# Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

**Jacqueline Agnew,** Johns Hopkins University Bloomberg School of Public Health
**Paul Citron,** Medtronic, Inc. (Retired)
**Richard M. Duffy,** International Association of Fire Fighters
**Patricia A. Gleason,** Safety Equipment Institute
**Jimmy Perkins,** University of Texas Health Science Center
**Daniel K. Shipp,** International Safety Equipment Association
**Debra Stoe,** Department of Justice
**Jeffrey O. Stull,** International Personnel Protection, Inc.
**Paul F. Vinger,** Lexington Eye Associates
**Sharon Welbel,** John H. Stroger Jr. Hospital

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by

**Richard Merrill,** University of Virginia, and **Edward B. Perrin,** University of Washington. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

# Preface

Conformity assessment is key to ensuring that the products we purchase are effective and perform to specifications; as users we are not expected to know or be engaged in the actual intricacies of how products are tested and verified to make sure that they meet performance requirements. This report focuses on conformity assessment for occupational personal protective technologies (PPT)—ensuring that PPT are effective in preventing or reducing hazardous exposures or situations that workers face in their jobs. Because respirators already have an extensive testing and conformity assessment process in place, the charge to this committee was to address conformity assessment processes for other types of PPT, including eye and face protection, gloves, hearing protectors, and protective clothing.

The impetus for this study comes from the recommendations of a 2009 Institute of Medicine and National Research Council report that reviewed the PPT Program at the National Institute for Occupational Safety and Health (NIOSH). The report identified gaps and inconsistencies in the certification and other conformity assessment processes for non-respirator PPT and urged that this issue be further explored.

As the committee surveyed the current state of conformity assessment for PPT products, it became evident that a number of varied approaches are currently in place with the involvement of multiple organizations and federal agencies. Processes differed in the rigor of the testing, the extent of independent third-party involvement in the process, requirements for quality manufacturing processes, and follow-up efforts to identify post-marketing concerns. The need for a greater emphasis on a consistent and risk-based approach to PPT conformity assessment was identified as a priority by the committee. In workplaces where there are

greater risks to the health and safety of the worker if the PPT product does not perform effectively, increased levels of involvement and requirements for independent third-party testing and certification are deemed appropriate.

The NIOSH National Personal Protective Technology Laboratory (NPPTL) has a unique role to play as the nation's focal point for occupational PPT. NPPTL staff's depth of expertise is being used effectively in respirator testing and certification and in standards development efforts for non-respirator PPT. This expertise can be leveraged by increased collaborations with other federal agencies and organizations to enhance PPT conformity assessment efforts and by NPPTL serving as a central repository for research and dissemination of PPT conformity assessment information.

In exploring conformity assessment processes and the standards behind them, the committee had the opportunity to engage in discussions with a number of dedicated professionals in government agencies and in the private sector who work to develop and improve product standards and conformity assessment processes. The committee learned a great deal from its April 2010 workshop and in other conversations and greatly appreciates the time and effort that the workshop presenters, study sponsors, and many others provided in informing this study.

This report reflects the hard work and careful considerations of a dedicated committee. I want to thank each committee member and the IOM staff members for working first to get a handle on this complex topic and then to carefully consider and discuss the many facets of this issue.

The committee hopes this report will be a step forward in improving worker safety and health by ensuring consistent and rigorous testing of PPT products, thorough verification that products meet the performance criteria, and transparent and widespread dissemination of information on certified products.

Howard J. Cohen, *Chair*
Committee on the Certification of
Personal Protective Technologies

# Contents

# Acronyms

| | |
|---|---|
| AAMI | Association for the Advancement of Medical Instrumentation |
| AIHA | American Industrial Hygiene Association |
| ANSI | American National Standards Institute |
| ASSE | American Society of Safety Engineers |
| ASTM | originally, the American Society for Testing and Materials, now ASTM International |
| BVP | Bulletproof Vest Partnership |
| CBRN | chemical, biological, radiological, and nuclear |
| CDC | Centers for Disease Control and Prevention |
| CEL | Certified Equipment List |
| CFR | Code of Federal Regulations |
| CPSC | Consumer Product Safety Commission |
| CSA | Canadian Standards Association |
| DHS | Department of Homeland Security |
| DoD | Department of Defense |
| DOJ | Department of Justice |
| DOL | Department of Labor |
| EC | European Commission |
| EEC | European Economic Community |
| EPA | Environmental Protection Agency |
| EU | European Union |

| | |
|---|---|
| FAR | Federal Acquisition Regulations |
| FDA | Food and Drug Administration |
| FFFIPP | Fire Fighter Fatality Investigation and Prevention Program |
| GAO | Government Accountability Office (prior to 2004, General Accounting Office) |
| HECC | Hockey Equipment Certification Council |
| HEROES | Homeland Emergency Response Operational and Equipment Systems |
| HHE | Health Hazard Evaluation |
| HHS | U.S. Department of Health and Human Services |
| IAB | InterAgency Board for Equipment Standardization and Interoperability |
| IAFF | International Association of Fire Fighters |
| IEC | International Electrotechnical Commission |
| IOM | Institute of Medicine |
| ISEA | International Safety Equipment Association |
| ISO | International Organization for Standardization |
| MAUDE | Manufacturer and User Device Experience |
| MedSun | FDA Medical Product Safety Network |
| MedWatch | FDA Safety Information and Adverse Event Reporting Program |
| MSHA | Mine Safety and Health Administration |
| NCSCI | National Center for Standards and Certification Information |
| NEISS | National Electronic Injury Surveillance System |
| NFPA | National Fire Protection Association |
| NIJ | National Institute of Justice |
| NIOSH | National Institute for Occupational Safety and Health |
| NIST | National Institute of Standards and Technology |
| NLECTC | National Law Enforcement and Corrections Technology Center |
| NORA | National Occupational Research Agenda |
| NPPTL | National Personal Protective Technology Laboratory |
| NRC | National Research Council |

| | |
|---|---|
| NRR | noise reduction rating |
| NRTL | Nationally Recognized Testing Laboratories |
| NTTAA | National Technology Transfer and Advancement Act |
| NVFC | National Volunteer Fire Council |
| NVLAP | National Voluntary Laboratory Accreditation Program |
| OMB | Office of Management and Budget |
| OSHA | Occupational Safety and Health Administration |
| PFD | personal flotation device |
| PMA | premarket approval application |
| PPE | personal protective equipment |
| PPT | personal protective technologies |
| QA | quality assurance |
| SCBA | self-contained breathing apparatus |
| SCSR | self-contained self-rescuer (respirator) |
| SEI | Safety Equipment Institute |
| SENSOR | Sentinel Event Notification System for Occupational Risks |
| UL | Underwriters Laboratories |
| USBM | U.S. Bureau of Mines |
| USCG | U.S. Coast Guard |
| USDA | U.S. Department of Agriculture |

# Summary

When you purchase a product, you expect it to work. Construction workers on high-rise buildings need to be confident that their safety harnesses will arrest a fall. Firefighters need to know that their gloves and other protective equipment can withstand high temperatures. Healthcare workers administering highly toxic chemotherapy agents need to know that their gloves will withstand penetration. For personal protective technologies (PPT)—where the major purpose of the product is to protect the wearer against a hazard—a deficit in product effectiveness can mean injury, illness, or death. Examining the extent to which products meet specific performance or design criteria is the focus of conformity assessment efforts. For PPT conformity assessment, the ultimate goal is preventing worker illness, injury, or death from hazardous working conditions.

In 2009, the National Institute for Occupational Safety and Health (NIOSH) requested that the Institute of Medicine convene an expert committee to assess the certification or conformity assessment mechanisms needed to ensure the efficacy and effectiveness of non-respirator PPT (Box S-1).

## WHY CERTIFY? WHY CONFORM?

Although safety and health professionals rank it low on the hierarchy of hazard controls, personal protective technologies continue to provide the primary means of risk reduction in workplace settings where risks or exposures change rapidly, where process change or engineering controls

**BOX S-1**
**Committee on the Certification of Personal Protective Technologies Statement of Task**

The Institute of Medicine (IOM) will convene an expert committee to assess the certification* mechanisms needed to ensure the efficacy of non-respirator personal protective technologies (PPT). National Institute for Occupational Safety and Health certification of respirators has had a significant positive impact on the quality of respirators available in the workplace; however, there is no analogous federal process for ensuring certification of the efficacy of non-respirator PPT (e.g., eye protection, hearing protection, medical masks, protective clothing).

The IOM committee will examine various approaches to certification (e.g., federal laboratory certification, third-party certification, federal certification of non-governmental laboratories) and will make recommendations on certifying non-respirator PPT. As part of its data-gathering efforts, the committee will plan and conduct a public workshop to examine the various approaches used to certify the efficacy of other types of products used for protection (e.g., bullet-proof vests, personal flotation devices), as well as to examine relevant standards and regulations and the benefits of certification to worker safety.

The context for the study will emphasize efforts to certify personal protective technologies (other than respirators) for healthcare workers during an influenza pandemic, although the effort will be relevant to other types and uses of PPT.

A report will be issued that includes the committee's recommendations on mechanisms for certifying and ensuring the efficacy of non-respirator PPT.

*Defined broadly to encompass conformity assessment.

are deemed to be impractical (e.g., construction, maritime), or where exposures are poorly characterized (e.g., spill response, hazardous waste remediation, firefighting). Approximately 5 million U.S. workers are required to wear respirators in 1.3 million U.S. workplaces. In some occupations, such as construction and firefighting, PPT is the primary or only line of defense against hazardous exposure. PPT effectiveness can be seen every day in the survival and lack of harm experienced by most firefighters. In 2008, U.S. firefighters responded to 1,451,500 calls and suffered 36,595 injuries and 29 deaths on scene at fire incidents.

Conformity assessment in the arena of occupational health has several advantages for the various stakeholders involved, from the manufacturer who designs and builds the product, to the consumer comparing features of the product to make a decision to purchase, and to the regulator who must assess claims about product design or performance. For the consumer, conformity assessment provides confidence in the claims made about the product by the manufacturer and may assist the consumer with purchasing decisions in determining the fitness of a product for its intended use. Conformity assessment may also allow the consumer or worker to differentiate among product choices with confidence in the labeling claims, have confidence a product meets a specific performance standard, and understand the limitations of its use or benefit.

## WHAT'S INVOLVED IN CONFORMITY ASSESSMENT?

*Conformity assessment* is defined as the "demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled." The broad array of conformity assessment activities involves manufacturers, distributors, purchasers, end users, testing laboratories, certifying organizations, accrediting organizations, and government agencies. In discussions on product conformity assessment, the term *first party* refers to the manufacturer, *second party* to the purchaser, and *third party* to an independent entity, which is neither the seller nor the buyer.

Conformity assessment processes for products in the marketplace are focused on product effectiveness—verifying and ensuring that a product meets specific criteria. To make this happen, conformity assessment involves the following components:

- *Standards*—A prerequisite to conformity assessment, well-defined criteria must be in place so that there is a measure against which to assess the product.
- *Testing or inspection*—The product is subjected to the required assessments.
- *Accreditatio*n—Accreditation ensures that testing and certifying procedures are being carried out properly and that testing laboratories, certifying organizations, and other entities are evaluated.
- *Attesting to conformity assessment*—An entity has the responsibility for examining the test results and attesting to whether the product met the requirements or standards.

- *Communication*—Purchasers need to be able to identify which products meet the test criteria.
- *Post-marketing testing and evaluation, and health surveillance*—Post-marketing testing and evaluation involves the ongoing process of monitoring product manufacturing and products used in the workplace to ensure consistency in the quality and effectiveness of the products and recall defective products from the workplace. Health surveillance includes collecting and analyzing data on the impacts of PPT use on the health and safety of workers.

## THE ROLE OF FEDERAL AGENCIES IN CONFORMITY ASSESSMENT

Many U.S. government agencies have been and continue to be active in ensuring the consistency and safety of products and services through a wide range of activities. The committee explored the range of possible roles for federal agencies by examining the current conformity assessment processes for respirators, healthcare worker PPT, firefighter and emergency responder PPT, ballistic-resistant body armor, hearing protective devices, and personal flotation devices (Table S-1).

The role of federal government agencies ranged from an all-encompassing role in each phase of conformity assessment (e.g., respirators) to more specific roles such as standardized labeling (e.g., Noise Reduction Rating labels for hearing protection devices). Many of the variations had multiple roles for government agencies, including specifying or accrediting testing laboratories and certifying organizations. Products that have extensive conformity assessment processes often are those whose failure could significantly impact the health or safety of the worker.

## A COMPREHENSIVE RISK-BASED FRAMEWORK FOR PPT CONFORMITY ASSESSMENT

Given the wide range of current approaches used to conduct conformity assessment for PPT products, the committee saw the need for a structured framework to evaluate products protecting against comparable risks. This framework can be used to identify gaps, prioritize resources,

**TABLE S-1** Summary of Standards and Conformity Assessment Approaches for Selected Examples of Personal Protective Technologies (PPT)

| | Respirators | Healthcare Worker PPT | Body Armor | Firefighter PPT | Hearing Protection Devices | Personal Flotation Devices |
|---|---|---|---|---|---|---|
| **STANDARDS** | | | | | | |
| Voluntary consensus | | ✓ | | ✓ | | ✓ |
| Government standards | ✓ | | ✓ | | ✓[a] | ✓ |
| **TESTING** | | | | | | |
| First party | | ✓ | | | ✓ | ✓[f] |
| Third party | ✓ | | ✓ | ✓[b] | | |
| **DECLARATION OF CONFORMITY ASSESSMENT** | | | | | | |
| First party—Manufacturer's declaration | | | | | ✓ | |
| Third-party certification—Optional[c] | | | ✓[e] | ✓[b] | | |
| Third-party certification—Mandated | ✓ | ✓[d] | | | | ✓ |

NOTE: Second-party processes were not used in the examples described in this report.
[a]Environmental Protection Agency standards for noise reduction ratings.
[b]Not federally mandated, but required to meet National Fire Protection Association criteria.
[c]*Optional* is used to denote that third-party certification is not mandated by Occupational Safety and Health Administration or other federal regulatory agencies.
[d]Food and Drug Administration clearance or approval.
[e]Not federally mandated, but required for inclusion on the National Institute of Justice Compliant Products List.
[f]Third-party oversight of testing.

determine and direct conformity assessment efforts, and ensure consistent conformity assessment approaches. The necessary starting premise for PPT conformity assessment is that well-defined and adequate design specifications and performance standards with pass–fail criteria are in place for these products.

Developing and designing a framework for PPT conformity assessment should involve the following guiding principles:

- Conformity assessment efforts for PPT should be focused on reducing or eliminating the risks of worker injury, illness, or death; therefore the framework should be risk based.
- End users can provide realistic and practical input into the types of equipment needed to protect against job hazards and should be involved in developing and implementing conformity assessment processes.
- Adequate standards for product performance, use, and testing need to be clearly specified and serve as a prerequisite to conformity assessment.
- The burden and cost of conformity assessment processes need to be considered.
- A total life cycle approach is needed that includes postmarketing testing, evaluation, and surveillance, as well as an effective recall system.
- The conformity assessment process should promote and not inhibit product innovation.

The degree of potential risk to the user from the failure of a PPT product during use in a specific task should determine the rigor of the conformity assessment process, particularly decisions regarding whether the process calls for first-, second-, or third-party declaration of conformity. The potential risk is a function of the probability of product failure and the impact on user health and safety due to the failure, assuming proper use of the product. For instance, if a bullet-proof vest is penetrated by a projectile, the impact can be fatal for the user; therefore, the degree of potential risk due to failure is high. The probability of occurrence of failure will depend on the task in which the worker is engaged. Thus, the potential risk to the safety and health of the worker should be the key factor in determining the type of conformity assessment process that should be adopted; the greater the risk to the end user in the event of product failure, the greater should be the rigor of the conformity assess-

ment process. This could be implemented for PPT used in medium and high-risk work environments through independent third-party testing and certifying processes.

Estimates of the occupational health and safety risks due to hazardous exposures can be quantified based on knowledge about the exposure. However, health surveillance data on PPT use in the workplace are limited or missing, including data on the extent and nature of PPT use and on adverse outcomes that occur related to PPT use (those that occur due to PPT failures, while wearing PPT, and when not wearing PPT in work situations requiring PPT use). Without these types of data, there are no drivers to draw attention to PPT performance, use, failures, and interface problems that could be harmful to workers.

The proposed framework developed by the committee (Table S-2) emphasizes the risk to worker safety and health that would be encountered if the PPT were not working effectively. It also considers economic and other pragmatic factors (e.g., cost of conformance, impediments to innovation, risk to manufacturer's reputation due to poor product quality and/or product failure).

## RECOMMENDATIONS

### A Comprehensive Risk-Based Framework for PPT Conformity Assessment

The committee documented the wide range of approaches to PPT conformity assessment and the varied nature of government agency involvement in these processes. Current U.S. approaches to occupational PPT are fragmented, often by job sector. Little has been done to classify PPT products based on a comprehensive risk-based framework. Therefore, the first step needed for conformity assessment of non-respirator PPT products is to establish a framework that will categorize products based on the level of risk (low, medium, or high) to the health or safety of the worker that could result from failure of the product (equivalent to not using PPT), while also considering feasibility, cost, and other pragmatic factors. Conformity assessment requirements would be detailed for each category of products in the framework. Efforts will be needed to identify the gaps and inconsistencies in current approaches for specific types of PPT, particularly for those in the medium- and high-risk categories.

**TABLE S-2** Risk-Based Framework for Non-Respirator Personal Protective Technologies (PPT) Conformity Assessment

| | Conformity Assessment Responsibilities | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Degree of Risk to the User's Safety and Health[a] | Product Testing | Accredit Testing Labs | Declaration of Product Compliance | Conduct Post-Marketing Testing, Evaluation, Surveillance | Recall Products | Listing of Certified Products[b] | Institute Tracking Label | Provide Oversight to the Conformity Assessment Process |
| Low | First party | Voluntary | First party | Voluntary | First party | | | First party |
| Medium | Third party | Third party | Third party | Third party | Third party | Federal govt. agency | | Third party |
| High | Third party | Third party | Third party | Third party | Third party | Federal govt. agency | Third party | Federal govt. agency |

NOTE: The term *third party* is used to denote that the responsibility could be carried out by either private-sector organizations or federal government agencies that are independent of the product manufacturer.
govt. = government.
[a]Risk is based on the potential for illness and injury that would result from failure of the PPT product.
[b]Listing could provide links to lists of certified products from third-party private-sector and government certifying organizations and agencies.

**Recommendation 1: <u>Develop and Implement Risk-Based Conformity Assessment Processes for Non-Respirator PPT</u>**

**The National Institute for Occupational Safety and Health (NIOSH) should work with other relevant government agencies, certifying and accrediting organizations, manufacturers, and end users to develop, implement, and support conformity assessment processes for non-respirator PPT. These conformity assessment processes should be commensurate with the level of risk of injury, illness, or death that could result from failure of the PPT to protect the user from workplace hazards.**

**NIOSH's National Personal Protective Technology Laboratory (NPPTL) should serve in a leadership role and convene other relevant government agencies, certifying and accrediting organizations, manufacturers, and end users to develop and implement a comprehensive, tiered risk-based framework for the classification and conformity assessment of PPT products for specific applications. This framework should be based on the degree of risk to the safety and health of the user and other factors affecting the feasibility of implementing the proposed conformity assessment processes. To develop this framework and implement the conformity assessment processes, the committee recommends that**

- **Components of the tiered PPT conformity assessment framework include the following categories and actions:**
  - **Low risk—manufacturer's attestation to meet relevant standards,**
  - **Medium risk—third-party testing and certification, and**
  - **High risk—third-party testing and certification with government involvement to provide oversight and to assist in enforcement;**
- **Current processes and innovative models (e.g., probabilistic models) should be explored, where adequate data exist, for assessing the level of risk and incorporating other feasibility factors into categorizing PPT;**
- **NIOSH NPPTL should work with other relevant federal agencies, manufacturers, organizations, and end users to identify current gaps and priorities in conformity assessment for medium- and high-risk PPT use, and to subsequently engage in developing and implementing the appropriate conformity assessment processes;**

- **NPPTL and other government agencies should have the appropriate level of engagement in the conformity assessment processes for non-respirator PPT depending on the risk level; and**
- **Government contracts should specify that PPT used in work to fulfill those contracts must meet the requisite level of conformity assessment based on the comprehensive risk-based PPT framework.**

### Research, Surveillance, and Communication

NPPTL is already substantively involved in many aspects of conformity assessment for non-respirator PPT, particularly voluntary standards development and development of test methods. Continued efforts in standards setting would be enhanced with NPPTL working with other government agencies and stakeholder organizations to encourage and promote end-user involvement in the development of voluntary standards. As a research agency, NPPTL is well suited to furthering its ongoing efforts to develop test methods and conduct research that contributes to the development of voluntary consensus standards and other conformity assessment efforts for improving PPT. In particular, the committee emphasizes protective ensembles and believes that NPPTL should focus efforts on PPT interface and related issues that are important in ensuring the effective use of multiple types of PPT or integrated ensembles. A new area for exploration could be the development and evaluation of the effectiveness of integrated ensembles for healthcare worker infection control precautions.

Increased postmarket testing, evaluation, and surveillance are key factors in enhancing PPT products for worker use. The limited availability of data on product effectiveness across the life cycle of PPT products, and in particular on PPT use in the workplace (including use of PPT in emergency conditions), are currently hindering improvements in PPT and PPT conformity assessment processes. A surveillance network that draws on and expands current surveillance systems already in place could provide information needed to identify workplace tasks where injuries, illnesses, or deaths are occurring because of noncompliant and/or poorly manufactured PPT, inadequately or incorrectly labeled PPT, PPT not being provided by the employer, and/or any end-user performance

issues associated with PPT (e.g., the incorrect use of PPT due to inadequate or improper training that could shed light on PPT training needs).

The fragmented nature of current PPT conformity assessment has resulted in multiple and diverse sources of information that employers, workers, and others need to consult in order to identify certified equipment or find independent information on non-respirator PPT. NPPTL currently administers its Certified Equipment List, which details the respirators and respirator components that meet certification criteria. A single reputable source for certified PPT products needs to exist for consumers (employers and end users) to make informed PPT choices.

**Recommendation 2: Enhance Research, Standards Development, and Communication**

**NIOSH NPPTL should continue and expand its role in PPT conformity assessment. Specifically, NPPTL should**

- **Continue its involvement in standards-setting processes and committees and facilitate end-user participation in voluntary consensus performance-based standards;**
- **Expand research efforts on non-respirator PPT (based on risk assessment and opportunities) to include further efforts to establish standards and to develop test methods;**
- **Develop and maintain an online resource (available through a website and other sources) that provides access to listings of all non-respirator PPT products that meet third-party conformity assessment requirements;**
- **Expand its role and become the primary clearinghouse for reliable information on non-respirator PPT;**
- **Fund research and support standards development necessary to test and certify protective ensembles, develop criteria for standardized interfaces, and flag non-conforming ensemble components; and**
- **Expand its efforts in influenza pandemic-related research and conformity assessment for infection control ensembles.**

**Recommendation 3: Establish a PPT and Occupational Safety and Health Surveillance System**

**NIOSH should work with the Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), third-party certifying organizations, and other relevant organizations to establish an electronic PPT and Occupational Safety and Health Surveillance System that includes data on PPT product effectiveness in the workplace. This system would involve the collection and analysis of data across the life cycle of PPT products (from design and production to worker use and maintenance) on the use of PPT, the failure of PPT, and adverse outcomes (injury, illness, fatality) that occur while wearing PPT in the workplace, including information on the performance standards assessed and adherence to labeling requirements. These efforts should collect and analyze data on PPT product effectiveness in the field by collaborating with existing surveillance programs and expanding where needed to incorporate data collection on PPT use across industries including product recall information. The surveillance system should link to the expanded Certified Equipment List. Potential sources of collaboration include**

- **Other NIOSH surveillance and data collection systems, including the Fatality Assessment and Control Evaluation program, health hazard evaluations, and the Sentinel Event Notification System for Occupational Risk (SENSOR);**
- **CPSC's recall database, unsafe product reporting system, and the National Electronic Injury Surveillance System (NEISS);**
- **FDA's surveillance and adverse event reporting databases, such as the Medical Product Safety Network (MedSun), the FDA Safety Information and Adverse Event Reporting Program (MedWatch), and the Manufacturer and User Facility Device Experience (MAUDE) database; and**
- **OSHA's injury and fatality investigations and surveys to collect information about injuries or illnesses potentially due to the failure of PPT.**

## TOWARD A COMPREHENSIVE APPROACH TO SAFE AND EFFECTIVE PPT FOR WORKERS

To address the task of conformity assessment for non-respirator PPT, the committee has recommended a tiered risk-based approach that would categorize various types of PPT and apply consistent conformity assessment requirements. From the committee's perspective, this tiered approach has the advantage of addressing all types of non-respirator PPT and raising the quality of PPT conformity assessment. Although implementing this approach will be a major effort, it will incentivize non-respirator PPT developers and manufacturers to innovate and develop new products and technologies expeditiously to further enhance worker safety and health.

What will it take to make this change happen? First, government agencies, employers, workers, and other stakeholders must recognize that improving the health and safety of workers is of critical importance and impacts both economic and national security. Second, adequate resources and staffing will be required of relevant government agencies, labor and manufacturing organizations, standards-setting organizations, third-party testing and certifying organizations, and others. Third, PPT end users must actively participate in the process by providing feedback based on experience in using PPT in work and emergency situations. Fourth, demand for certified products need to be made evident. Professional organizations specific to various occupations (e.g., Joint Commission) must reinforce the requisite conformity assessment processes. Government and private-sector contracts need to specify that PPT used in that work must meet performance criteria. Finally and most importantly, regulatory requirements will largely drive whether change occurs. OSHA and the Mine Safety and Health Administration regulations that stipulate requirements for third-party testing and certification, where applicable, can provide the impetus to drive the change that will result in a more consistent, comprehensive, and risk-based approach to PPT conformity assessment. This commitment to improve non-respirator PPT by strengthening the conformity assessment processes also necessitates an equally strong commitment to training and use of PPT. The goal is ensuring and maintaining a safe and healthy workforce.

# 1

# Introduction

When you purchase a product, you expect it to work. Construction workers on high-rise buildings need to be confident that their safety harnesses will arrest a fall. Firefighters need to know that their gloves and other protective turnout gear can withstand high temperatures. Healthcare workers administering highly toxic chemotherapy agents need to know that their gloves will withstand penetration. For personal protective technologies (PPT)—where the major purpose of the product is to protect the wearer against a hazard—a deficit in product effectiveness can mean injury, illness, or death. Examining the extent to which products meet specific performance or design criteria is the focus of conformity assessment efforts. For PPT conformity assessment, the ultimate goal is preventing worker illness, injury, or death from hazardous working conditions.

Personal protective technologies, including respirators, gloves, protective clothing, protective eyewear, and hearing protection, are used by workers in many types of worksites. An estimated 5 million workers are required to wear respirators in 1.3 million workplaces in the United States (OSHA, 2010). The U.S. market for personal protective equipment was estimated at approximately $6.4 billion in 2007 (SBI Reports, 2008).

Currently, product testing and conformity assessment requirements in the United States vary considerably among the various types of PPT. This report details the different approaches, examines the various roles that government agencies play in all phases of conformity assessment, and provides the committee's recommendations for future conformity assessment efforts for PPT products.

## SCOPE OF THIS REPORT

In 2009, the National Institute for Occupational Safety and Health (NIOSH) requested that the Institute of Medicine (IOM) convene an expert committee to assess the certification or conformity assessment mechanisms needed to ensure the efficacy and effectiveness[1] of non-respirator PPT. The IOM committee was tasked with examining various approaches to conformity assessment and with making recommendations on conformity assessment processes for non-respirator PPT (Box 1-1). As part of its data-gathering efforts, the committee was asked to plan and conduct a public workshop to examine the conformity assessment approaches used for a range of products used for protection (e.g., bullet-proof vests, personal flotation devices) as well as to examine the benefits of certification to worker safety. The committee's task also focused on PPT for healthcare workers during an influenza pandemic with the recognition of the broader implications for modifying conformity assessment processes for PPT.

The committee's task did not focus on respirator certification because that is a well-established process codified in federal regulations and conducted by the NIOSH National Personal Protective Technology Laboratory (NPPTL). Additionally, the committee was not asked to examine the certification of personnel. Although PPT products are used by the general public in settings that range from hobbies to home repair and maintenance to protection against infectious disease, this report focuses on occupational use and does not specifically address PPT for use by the general public.

The committee held three meetings from January to July 2010. Two of those meetings included public sessions with input from many perspectives, including NIOSH staff, other federal agency staff, PPT manufacturers, professional association and labor union representatives, standards-setting organizations, third-party testing and certifying organizations, and other stakeholders (Appendixes A and B). The public sessions (one of which was organized as a workshop) provided background information to the committee; information gained in the presentations is referenced in the report.

[1] *Efficacy* refers to producing the intended results under optimal conditions of implementation, such as in a controlled laboratory environment. *Effectiveness* refers to producing the intended results under the normal conditions in which the product is used, such as in the workplace.

This study follows up on a recommendation of a 2008 IOM and National Research Council report that called for "an assessment of the certification mechanisms needed to ensure the efficacy of all types of PPT" (IOM and NRC, 2008, p. 117). Specifically, that report called for an assessment of NPPTL's role in conformity assessment for non-respirator PPT and that is one of the areas of focus of this report.

**BOX 1-1**
**Committee on the Certification of Personal Protective Technologies**
**Statement of Task**

The Institute of Medicine (IOM) will convene an expert committee to assess the certification* mechanisms needed to ensure the efficacy of non-respirator personal protective technologies (PPT). National Institute for Occupational Safety and Health certification of respirators has had a significant positive impact on the quality of respirators available in the workplace; however, there is no analogous federal process for ensuring certification of the efficacy of non-respirator PPT (e.g., eye protection, hearing protection, medical masks, protective clothing).

The IOM committee will examine various approaches to certification (e.g., federal laboratory certification, third-party certification, federal certification of non-governmental laboratories) and will make recommendations on certifying non-respirator PPT. As part of its data-gathering efforts, the committee will plan and conduct a public workshop to examine the various approaches used to certify the efficacy of other types of products used for protection (e.g., bullet-proof vests, personal flotation devices) as well as to examine relevant standards and regulations and the benefits of certification to worker safety.

The context for the study will emphasize efforts to certify personal protective technologies (other than respirators) for healthcare workers during an influenza pandemic, although the effort will be relevant to other types and uses of PPT.

A report will be issued that includes the committee's recommendations on mechanisms for certifying and ensuring the efficacy of non-respirator PPT.

---

*Defined broadly to encompass conformity assessment.

## PERSONAL PROTECTIVE TECHNOLOGIES

PPT are defined as the specialized clothing or equipment worn by workers for protection against health and safety hazards, as well as the technical methods, processes, techniques, tools, and materials that support their development, evaluation, and use (OSHA, 2002; NIOSH, 2007). The broad umbrella term of PPT is used in this report as it includes a wide range of protective products and technologies, including the personal protective equipment (PPE) worn by workers (e.g., hearing protection, gloves, protective clothing, respiratory protection, protective eyewear, and fall arrest harnesses) as well as technologies such as service life indicators and filtration. PPE is a subset of PPT and refers specifically to the various types of gear worn to prevent injury, illness, or death.

The use of PPT is a key element of the standard hierarchy of hazard control approaches that aims first to eliminate or minimize the risk in the work environment, then to modify the work environment or processes, and as needed to provide individual protective equipment to workers:

- *Substitution*—changing the environment to reduce or eliminate the hazard;
- *Engineering or environmental controls*—modifying the work environment (e.g., ventilation fans, negative pressure rooms);
- *Administrative controls*—changing the work processes and practices (e.g., limiting the number of hours worked in a specific area); and
- *Personal protective technologies*—use of equipment by individuals to provide protection from work hazards.

Although PPT is generally considered a last line of defense in the hierarchy of protective controls because it relies on the correct individual use and fit of protective equipment, in some jobs, such as firefighting, PPT is the only means available to minimize exposure to serious hazards.

Effective use of PPT requires proper selection, use, care, and maintenance of the product. For PPT products such as respirators, testing to ensure the proper fit (i.e., fit testing) is a critical element of ensuring worker safety and is a required component of the comprehensive respirator protection programs required by the Occupational Safety and Health Administration (OSHA) for workplaces with respiratory hazards.

## BASICS OF CONFORMITY ASSESSMENT

The International Organization for Standardization defines *conformity assessment* as the "demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled" (ISO/IEC, 2004). Conformity assessment is thus a broad term that encompasses an array of activities conducted by manufacturers, distributors, purchasers, end users, testing laboratories, certifying organizations, accrediting organizations, and government agencies. In discussions on product conformity assessment, the term *first party* refers to the manufacturer, *second party* to the purchaser, and *third party* to an independent entity, which is neither the seller nor the buyer (Breitenberg, 1997a; Gillerman, 2004).

### What's Involved in Conformity Assessment?

Conformity assessment for products in the marketplace is focused on product effectiveness—verifying and ensuring that a product meets specific criteria for use in workplaces and other locations. To make this happen, conformity assessment involves the following components:

- *Standards*—A prerequisite to conformity assessment, well-defined criteria must be in place so that there is a measure against which to assess the product.
- *Testing or inspection*—The product is subjected to the required assessments.
- *Accreditation*—Accreditation ensures that testing and certifying procedures are being carried out properly and that testing laboratories, certifying organizations, and other entities are evaluated.
- *Attesting to conformity assessment*—An entity has the responsibility for examining the test results and attesting to whether the product meets the requirements or standards.
- *Communication*—Purchasers need to be able to identify which products meet the test criteria.
- *Post-marketing testing and evaluation, and health surveillance*—Post-marketing testing and evaluation involves the ongoing process of monitoring product manufacturing and products used in the workplace to ensure consistency in the quality and effectiveness of the products and recall of defective products from the work-

place. Health surveillance includes collecting and analyzing data on the impacts of PPT use on the health and safety of workers.

Each of these components in conformity assessment is discussed in Chapter 2, and the various roles that federal agencies and other organizations play in each of these areas is explored with specific consideration as to what is needed to improve conformity assessment processes for non-respirator PPT.

## WHY CERTIFY? WHY CONFORM?

### Certification as a Public Health Function

In the 1988 IOM report *The Future of Public Health*, the mission of public health was described as fulfilling society's interest in assuring the conditions in which people can be healthy (IOM, 1988). Three core functions of public health agencies were described—assessment, policy development, and assurance—as means toward achieving that goal. Each function has a role in the focus of this current report, certifying PPT.

*Assessment* entails gathering data through case reviews or surveillance systems to determine the status of health and safety in specific industries and occupations. Examples include hazard identification and exposure assessment in specific work environments.

The second public health function, *policy development*, is the response crafted to address threats to safety and health identified in the assessment stage. For example, public health policy might be drafted to include use of PPE to minimize hazardous exposure and to prescribe certain performance criteria for that equipment.

The *assurance* function includes activities that assure adopted policies are implemented. Examples include OSHA enforcing the requirement of respirator use for workers exposed to an inhalation hazard or the use of gloves for workers exposed to blood-borne pathogens. The assurance function also includes requiring documentation of conformity to specified performance standards for a respirator or glove type.

Although this report has a focus on PPT with applications in occupational health, and the assurance of standards is a recognized function of the public health system, conformity assessment issues arise in part from the international trade community.

## Conformity Assessment and the Global Economy

With the advancement of international free trade agreements in the past several decades, the growth of emerging economies, and the removal of many historical geographic and political trade barriers, the marketplace has become global, permitting commercial activity among new and diverse partners. Both the number and diversity of new trading partners has imposed the need for a common international language with which to discuss the buying and selling of goods and services in this increasingly global marketplace. Central to this common language is the development and implementation of standards and descriptors of those goods and services that allow comparison of products and assist in judging product value. The elements of standards may describe both design and performance criteria, other requirements against which a product can be assessed, and test methods. The challenge for manufacturers may arise when varying conformity assessment processes and criteria are required to enter the marketplace in different countries and regions.

## Benefits of Conformity Assessment to Manufacturers, Consumers, and Regulators

Conformity assessment in the arena of occupational health has several advantages for the various stakeholders involved. Conformity assessment provides benefits to any party encountering a product throughout its life cycle, from the manufacturer who designs and builds the product, to the consumer comparing features of the product to make a decision to purchase, and to the regulator who must assess claims about product design or performance.

Manufacturers may gain valuable quality control feedback by having their products assessed for conformity to performance standards, which can enable consistency in maintaining product effectiveness. Such activities may also validate marketing claims for their products. This may differentiate their product from a competitor's, providing a marketing advantage.

For the consumer, conformity assessment provides confidence in the claims made about the product by the manufacturer and may assist the consumer with purchasing decisions in determining the fitness of a product for its intended use. Conformity assessment may also allow the consumer or worker to differentiate among product choices with confidence

in the labeling claims, have confidence a product meets a specific performance standard, and understand the limitations of its use or benefit.

The regulator benefits from the conformity assessment processes by having a designated pathway to follow to perform the assurance function to determine that product claims are valid and to verify the circumstances under which products were manufactured. This process also provides the platform from which to enforce health, safety, and environmental regulations pertaining to the product performance and manufacture.

## Benefits to Worker Safety and Health

Although standards may be an important communication tool in the marketplace, providing a common language to discuss a product, in the public health arena demonstrating a product's conformity to a standard may be the regulatory "floor" on which a minimum level of protection from hazardous work is built. Conformity to the critical performance characteristics of PPT literally has "life or death" consequences for the firefighter, for example.

In considering the need for and benefits of conformity testing for PPT, it is helpful to review the rationale for the current requirements for such testing for respiratory protection equipment. OSHA, in its 1998 Respiratory Protection Standard Final Rule, made reference in the Preamble to the meaning and benefits of a certification "mark," specifically that of NIOSH (OSHA, 1998). Having examined the existing requirements of the National Fire Protection Association's (NFPA's) standards that required NIOSH certification for respirators used in firefighting (NFPA 1981, *Standard on Open-Circuit Self-Contained Breathing Apparatus for Emergency Services*), the agency went on to more broadly require NIOSH certification for compliance with the OSHA respirator standard (29 CFR §1910.134).

Selected quotes from the Preamble (OSHA, 1998) describe the agency's rationale for this decision as informed by the comments received from the affected parties, also referenced:

> Paragraph (d)(1)(ii) requires the employer to select a NIOSH-certified respirator and to use the respirator only in ways that comply with the conditions of its certification. There was little controversy about this requirement, and there is no disagreement that respirators must be

> tested and found to be effective before they can be marketed. NIOSH has performed this function in the past and has begun to revise its certification requirements to ensure that its procedures continue to define the performance capabilities of acceptable respirator models, and to identify unacceptable models. The ISEA [International Safety Equipment Association] (Ex. 65–363), the trade association that represents most major respirator manufacturers, urged OSHA to require that only NIOSH-certified respirators be used to comply with this standard, and other commenters agreed (Exs. 54–187, 54–213, 54–387, 54–428).

Not only does NIOSH respirator certification pertain to the original selection and purchase of new equipment, but it also addresses the repair and maintenance of respirator equipment, according to OSHA (1998):

> The final provision of paragraph (h) deals with respirator repairs and adjustments. Final paragraph (h)(4) provides that respirators that fail inspections, or are otherwise defective, are to be removed from service and discarded, repaired, or adjusted according to the specified procedures. In addition, the employer shall ensure that repairs or adjustments to respirators are made only by persons appropriately trained to do so, and that they use only the respirator manufacturer's NIOSH-approved parts that are designed for the particular respirator. The repairs also must be made in accordance with the manufacturer's recommendations and specifications. Because components such as reducing and admission valves, regulators, and alarms are complex and essential to the safe functioning of the respirator, they are required to be adjusted and repaired only by the manufacturer or a technician trained by the manufacturer.
>
> Paragraph (j)—Identification of Filters, Cartridges, and Canisters. The Final Rule provides that the employer only use filter cartridges and canisters that are labeled and color coded with the NIOSH approval label and that the label not be removed or made illegible. This is similar to

> the parallel requirement in the proposal, which was supported by commenters (Exs. 54–361, 54–428, 54–455). OSHA has modified the proposed language in certain respects to add compliance flexibility while retaining the original objective, that is, assurance that these elements meet NIOSH's stringent requirements. These comments and modifications are discussed below.

Further endorsing the importance of having confidence in the meaning of a manufacturer's labeling, the agency remarked (OSHA, 1998):

> The changes from the previous standard recognize that employers who use respirators should be able to rely on labeling and color coding by respirator manufacturers for assurance that the respirators meet NIOSH requirements. This position is consistent with that taken by many commenters, who noted that the labeling and color coding of filters are the responsibility of the respirator manufacturer (Exs. 54–208, 54–218, 54–219, 54–278, 54–289) and are required by NIOSH for certification.

Expounding on the benefits that labeling provides in ensuring conformity to a standard, OSHA (1998) commented further:

> The NIOSH label serves several purposes. It ensures selection of appropriate filters for the contaminants encountered in the workplace and permits the employee using the respirator to check and confirm that the respirator has the appropriate filters before the respirator is used. . . . However, the employee is not the only one who uses the color coding and label. Color coding and labeling also allow fellow employees, supervisors, and the respirator program administrator to readily determine that the appropriate filters are being used by the employee. Cartridges that are appropriate for one operation may be inappropriate for another, and color coding and labeling allow respirator users with inappropriate filters to be identified in the workplace and potential respiratory hazards to be avoided.

OSHA makes the case that reliance on the meaning and assurance of a certification mark benefits both workers and employers where respiratory protection is used. These comments are also applicable to other types of PPT. The progression of conformity assessment efforts in response to injuries is illustrated in the efforts made to prevent eye injuries to ice hockey players (Box 1-2).

**BOX 1-2**
**Eye Protection for Ice Hockey Players**

**Eye Injuries**

The progression of conformity assessment efforts is illustrated in the history of eye guards and face protection in ice hockey. In Canada, a prospective study during the 1974–1975 ice hockey season identified 253 amateur players with eye injuries, 37 of whom were legally blinded in one eye due to participation in the sport (Pashby et al., 1975). By comparison, a study in the 1983–1984 ice hockey season found the incidence of eye injuries in amateur players had declined to 124 cases, with no face injuries in those wearing certified face protectors (Pashby, 1985). In the intervening years several changes had been put in place including changes in the penalties for stick infractions and mandatory requirements for certified face protectors to be worn by young hockey players. The average age of players with eye injuries was 14 in 1974–1975, and rose to 24 in 1983–1984 (Pashby, 1985).

**Standards and Certification**

After the early study and other reports (e.g., Horns, 1976; Vinger, 1976), the Canadian Standards Association (CSA) and ASTM International developed standards specific to eye and face protection in sports in an attempt to reduce injuries and prevent inadequate products from being purchased by the consumer. The standards committees consisted of consumers, manufacturers, sports organizations, and public officials who helped formulate standards for sports eye protection in the United States and Canada. International standards for head and face protection in ice hockey have been developed by the International Organization for Standardization (ISO 10256, *Head and Face Protection for Use in Ice Hockey*, *2003*).

Development of standards has been followed in the United States and Canada by the implementation of third-party testing and certification requirements for some uses of eye-protective equipment for ice hockey. In Canada, CSA International (an arm of CSA Group) is responsible for the testing and certification of a number of products, including eye protectors. Upon successful completion of the testing and certification of the product, the product receives a CSA certification mark. Canada's *Hazardous Products Act* prohibits the sale or importation of ice hockey helmets and face protectors that do not meet the requirements of the relevant standards (CAN/CSA-Z262.1-M90 and CAN 3-Z262.2-M78) (Health Canada,

*continued*

**BOX 1-2 CONTINUED**

2010). Beginning in 1981, the Canadian Amateur Hockey Association made certified CSA face protection a mandatory requirement for all of its minor players (Pashby, 1985).

In the United States, amateur ice hockey equipment is certified by the Hockey Equipment Certification Council (HECC), an independent, nonprofit organization established in 1978. HECC works through the third-party validating laboratory, Intertek Testing Services, to verify that helmets, goal-tenders headgear, full-face protectors, and visors meet ASTM or CSA standards (HECC, 2010a). The HECC label is affixed to products that meet the required standards. An online listing of certified products is available through the HECC website (HECC, 2010b). HECC-certified equipment is required by USA Hockey, the National Federation of State High School Associations, and the National Collegiate Athletic Association (facemasks only) (HECC, 2010c).

## U.S. Approach to Standards Development and Conformity Assessment

In the United States, many marketplace transactions rely on the manufacturer's declaration of product conformity (Breitenberg, 1997b)—in which the interaction is between the buyer and seller with no third-party involvement required by the government or private sector. However, varying levels of oversight are used for products that may significantly impact the health and safety of the consumer (e.g., pharmaceuticals, respirators, personal flotation devices). The use of a manufacturer's self-declaration is generally effective in the United States because of several factors: competition among manufacturers, the size of the U.S. market, laws regarding truth in labeling and advertising, the abundance of product comparison information available to the consumer, and the potential for penalties to be imposed by the judicial system for products found to be defective (Breitenberg, 1997b).

Federal legislation, in particular the *National Technology Transfer and Advancement Act* (NTTAA), Public Law 104-113, emphasizes the government's use of voluntary consensus standards and encourages the participation of government agency staff in the work of standards development organizations in the United States and globally. Specific to conformity assessment, the NTTAA specifies that the National Institute of Standards and Technology (NIST) is charged with coordinating federal, state, and local conformity assessment efforts with private-sector activi-

ties to eliminate duplication and reduce the complexities of the processes (OMB, 1998).

## Drivers of Conformity Assessment

Not all products have extensive conformity assessment requirements. But for those that do, what drives the considerable investment of time, funds, staffing, and other resources necessary to ensure that products go through required procedures before reaching the marketplace?

Spurring the investment are the incentives for conformity assessment. Reputable manufacturers aim to grow their share of the market by striving to maintain and enhance the company's reputation for producing quality products. Taking an active role in developing standards and adhering to conformity assessment procedures can be a major part of quality assurance efforts. For some products, consumer or purchaser demand for certified products is a strong incentive. This demand can translate into financial incentives when the requirements for certified products are written into purchasing contracts. For example, a number of law enforcement departments write specifications into their contracts that they will purchase only body armor certified by the National Institute of Justice and therefore listed on the Body Armor Compliant Products List. Grants or contracts that specify that funds can only be awarded if they are used to purchase certified equipment are another strong incentive (e.g., the Bulletproof Vest Partnership, see Chapter 3). Additionally, a competitive market can motivate manufacturers to ensure that their product line meets the required conformity assessment procedures and can therefore be marketed with the relevant certification mark or label.

Beyond incentives, the drivers for conformity assessment include requirements for compliance as well as disincentives for noncompliance. For example, OSHA regulations stipulate that employers provide NIOSH-certified respirators in workplaces with respiratory hazards. Penalties and regulations are in place for a number of conformity assessment processes that provide the legal and/or financial ramifications for noncompliance. However, the use of fraudulent certification marks or misrepresentations of conformity assessment continue to be reported by third-party certifying organizations.

## RELEVANT AGENCIES AND ORGANIZATIONS

In the United States, the testing, regulation, and use of PPT involve a number of government and nongovernmental agencies and organizations. In the federal government, oversight responsibilities for the safety of consumer products fall under agencies different from those responsible for worker health and safety. The *Occupational Safety and Health Act of 1970* created two federal agencies to address civilian worker safety and health: NIOSH (in the Department of Health and Human Services, or HHS) was designated with responsibilities for relevant research, training, and education, and OSHA (within the Department of Labor) for developing and enforcing workplace safety and health regulations. The Occupational Safety and Health Act also included the general duty clause regarding the duty of employers to ensure safe workplaces.

NIOSH conducts and funds research in PPT and plays an integral role in the development of relevant voluntary consensus standards for many types of PPT. In 2001, the congressional mandate to expand NIOSH's research included a directive for NIOSH to establish NPPTL. The congressional intent, which resulted in the inception of NPPTL in 2001, was outlined in Senate Report 106-293:

> [I]t has been brought to the Committee's attention the need for design, testing and state-of-the-art equipment for this nation's 50 million miners, firefighters, healthcare, agricultural, and industrial workers. . . . The Committee encourages NIOSH to carry out research, testing, and related activities aimed at protecting workers, who respond to public health needs in the event of a terrorist incident. The Committee encourages CDC [the Centers for Disease Control and Prevention] to organize and implement a national personal protective equipment laboratory.

This comprehensive approach to PPT has been an ongoing goal for NPPTL, although a large percentage of NPPTL's current efforts and budget are necessary to meet their mandated task of testing and certifying respirators (IOM and NRC, 2008). NPPTL also conducts and funds research in non-respirator PPT and is the only federal entity focused solely on PPT.

OSHA regulates the use of PPT products in most U.S. workplaces; the Mine Safety and Health Administration (MSHA) regulates PPT use in the mining industry. As part of the requirements for a comprehensive respiratory protection program, OSHA and MSHA require that respirators used by workers must be certified by NIOSH to meet specific performance criteria (29 CFR §1910.134). OSHA also has a general regulatory standard (29 CFR §1910.132) and related regulations for the maritime, construction, and mining industries that govern all other forms of PPT. Several regulatory standards include requirements that occupational PPT must meet specific voluntary consensus standards. MSHA and NIOSH jointly certify respirators for mining applications.

Other federal agencies also have a role in testing and improving PPT for specific worker groups and the general public. The Consumer Product Safety Commission has oversight responsibilities for PPT products sold in the consumer retail marketplace. The Department of Defense develops and tests PPT for military applications. The Department of Homeland Security focuses on emergency response PPT and works to coordinate and improve standards and equipment-related issues. The National Institute of Justice has responsibilities for certifying body armor and other protective technologies for law enforcement officers. The Environmental Protection Agency addresses PPT issues relevant to hearing protection, pesticide exposures, and emergency response readiness. The Food and Drug Administration (in HHS) has federal regulatory authority to provide manufacturers with the approval or clearance to market personal protective devices used in health care. NIST, within the Department of Commerce, is designated to coordinate and assist with standards and conformity assessment efforts throughout the government.

## OVERVIEW OF THIS REPORT

In the remaining chapters of this report the committee discusses issues related to conformity assessment of PPT and provides its recommendations. Chapter 2 takes a step-by-step approach through each of the components of conformity assessment and discusses potential roles for government agencies in conformity assessment efforts for non-respirator PPT. Chapter 3 provides examples of current approaches to conformity assessment for PPT by highlighting the range of diverse approaches currently in use, including those used for certification of healthcare PPT, respirator certification, and certification of body armor for law enforce-

ment personnel. Chapter 4 examines the limited data available on the impact of conformity assessment processes, and then delves into issues specific to PPT, including the complexities of certifying protective ensembles, user training, and risk assessment. In outlining an approach to conformity assessment for non-respirator PPT, the committee provides its framework in Chapter 5, and in Chapter 6 outlines its findings and recommendations. The report concludes in Chapter 7 with the committee's thoughts on opportunities for moving forward in improving conformity assessment for non-respirator PPT with the goal of improving worker safety and health.

## REFERENCES

Breitenberg, M. A. 1997a. *The ABCs of the U.S. conformity assessment system*. NISTIR 6014. Gaithersburg, MD: National Institute of Standards and Technology. http://ts.nist.gov/Standards/conformity/primer.cfm (accessed August 18, 2010).

Breitenberg, M. A. 1997b. *The U.S. certification system from a governmental perspective*. NISTIR 6077. Gaithersburg, MD: National Institute of Standards and Technology. http://ts.nist.gov/standards/information/govcer.cfm (accessed August 10, 2010).

Gillerman, G. 2004. Making the confidence connection. *ASTM Standardization News*. http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html (accessed April 5, 2010).

Health Canada. 2010. *Canadian regulatory requirements for ice hockey helmets and face protectors*. http://www.hc-sc.gc.ca/cps-spc/advisories-avis/info-ind/helmets_hockey-casques-eng.php (accessed August 10, 2010).

HECC (Hockey Equipment Certification Council). 2010a. *Product certification testing*. http://www.hecc.net/prodtest.html (accessed August 10, 2010).

HECC. 2010b. *Current listing of certified products*. http://www.hecc.net/certprods.html (accessed July 26, 2010).

HECC. 2010c. *About HECC*. http://www.hecc.net (accessed August 10, 2010).

Horns, R. C. 1976. Blinding hockey injuries. *Minnesota Medicine* 59(4):255–258.

IOM (Institute of Medicine). 1988. *The future of public health*. Washington, DC: National Academy Press.

IOM and NRC (Institute of Medicine and National Research Council). 2008. *The Personal Protective Technology Program at NIOSH*. Washington, DC: The National Academies Press.

ISO/IEC (Organization for International Standardization/International Electrotechnical Commission). 2004. *Conformity assessment: Vocabulary and general principles*. ISO/IEC 17000:2004.

NIOSH (National Institute for Occupational Safety and Health). 2007. *Evidence for the National Academies' Review of the NIOSH Personal Protective Technology Program*. http://www.cdc.gov/niosh/nas/ppt/pdfs/PPT_EvPkg_090707_FinalR.pdf (accessed August 18, 2010).

OMB (Office of Management and Budget). 1998. *Circular No. A-119, revised. Federal participation in the development and use of voluntary consensus standards and in conformity assessment activities*. http://www.whitehouse.gov/omb/circulars_a119/ (accessed August 10, 2010).

OSHA (Occupational Safety and Health Administration). 1998. Respiratory protection. *Federal Register* 63:1152–1300.

OSHA. 2002. *OSHA factsheet: What is personal protective equipment*. http://www.osha.gov/OshDoc/data_General_Facts/ppe-factsheet.pdf (accessed August 13, 2010).

OSHA. 2010. *Respiratory protection*. http://www.osha.gov/SLTC/respiratoryprotection/index.html (accessed July 14, 2010).

Pashby, T. J. 1985. Eye injuries in Canadian amateur hockey. *Canadian Journal of Ophthalmology* 20 (1):2–4.

Pashby, T. J., R. C. Pashby, L. D. J. Chisholm, and J. S. Crawford. 1975. Eye injuries in Canadian hockey. *Canadian Medical Association Journal* 113:663–665.

SBI Reports. 2008. *Personal protective equipment in the U.S.* http://www.sbireports.com/Personal-Protective-Equipment-1487862 (accessed July 14, 2010).

Vinger, P. F. 1976. Ocular injuries in hockey. *Archives of Ophthalmology* 94(1):74–76.

# 2

# Role of Government Agencies in Conformity Assessment

*1852* Congress passed a law requiring all commercial steamboats to carry a personal flotation device for every passenger on board and to set up a Board of Supervising Inspectors (*Steamboat Act of 1852*)

*1906* *Meat Inspection Act*
U.S. Department of Agriculture became responsible for domestic meat inspection

*1910* Bureau of Mines was established; developed a program of respirator research, performance testing, and analysis (Public Law 61-179)

*1938* *Federal Food, Drug, and Cosmetic Act* (Public Law 75-717)
Act required new drugs to be shown safe before marketing—starting a new system of drug regulation

Many U.S. government agencies have been and continue to be active in ensuring the consistency and safety of products and services through a wide range of activities. This chapter explores the range of possible roles for federal agencies, provides examples of how these roles are implemented both for personal protective technologies (PPT) and for other consumer and industrial products, and highlights the committee's thoughts on the strengths and limitations of these roles as specifically related to improving non-respirator PPT for worker safety and health.

For many products there is no federal role, or only a limited role, in conformity assessment. Many products go directly into the marketplace, where consumer preferences, pricing, product recalls, market compliance

surveys, and other market forces (e.g., liability, manufacturer reputation) help sort out the effective or consumer-preferred products. Products may be designed to meet specific voluntary consensus standards, but with limited or no testing to see if the product meets the standard. Other products may have little or no production testing or inspection to ensure that they continue to meet their design parameters. Products that have extensive conformity assessment processes often are those whose failure could significantly impact health or safety.

In keeping with the study task, this report focuses on the role of agencies at the federal level. However, it is important to note that state and local government agencies also often play a critical role in standards development and conformity assessment. For example, water quality testing is largely under state and local jurisdiction (Breitenburg, 1997b; EPA, 2010).

This chapter discusses each of the following conformity assessment functions (Figure 2-1) and potential roles for government agencies with the committee's appraisal of the strengths and challenges of those roles as it relates to conformity assessment efforts for non-respirator PPT:

- Standards development, a precursor to conformity assessment;
- Product testing;
- Accreditation of laboratories and certifying organizations;
- Declaration of conformity and product certification;
- Communication;
- Incentives and enforcement;
- Surveillance and post-marketing testing and evaluation; and
- Other roles, including conducting research to inform standards and develop test methods, convening of stakeholders, and training.

## STANDARDS DEVELOPMENT

The antecedent to a strong conformity assessment process is having rigorous standards in place. Once standards are available that set the criteria for product performance, testing, and test methods, then a conformity assessment process can be developed to assess the product's ability to meet those criteria. Where possible, standards specify performance criteria rather than design criteria to allow for greater flexibility in developing

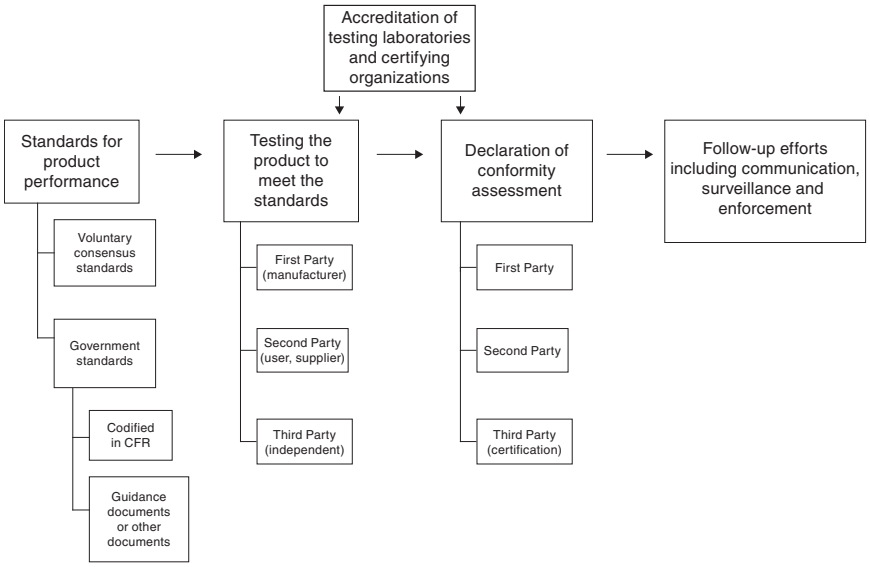


**FIGURE 2-1** Overview of conformity assessment options.
NOTE: CFR = Code of Federal Regulations.

innovative products. In addition to setting the specifications for minimum requirements for acceptable products, standards also can provide a basis for comparing products, as well as outlining preferred approaches for selection, use, care, and maintenance. Testing methods are either referenced or included in the standards along with pass–fail criteria so that conformance can be assessed consistently among testing entities and determinations can be made regarding the product's ability to meet the required specifications. Standards development organizations and government agencies are the two sources for PPT product standards.

## Voluntary Consensus Standards

Voluntary consensus standards for the manufacturing, performance, and testing of products are developed by national and international standards development organizations. These organizations work through expert committees consisting of representatives from government agencies, manufacturers, employers, academia, and end users. In the United States,

standards for PPT are developed by ASTM International (formerly American Society for Testing and Materials), the Association for the Advancement of Medical Instrumentation, and the National Fire Protection Association (NFPA), as well as by many organizations under the auspices of the American National Standards Institute (ANSI), which sets the requirements for consensus and balance, oversees the standards development process, and approves standards that bear the ANSI name.[1] Among the organizations developing ANSI standards for PPT are the American Industrial Hygiene Association, American Society of Safety Engineers, American Welding Society, and the International Safety Equipment Association. In Canada, PPT standards are developed by the Canadian Standards Association (CSA), which is also a third-party certification body. European standards for PPT are set by the European Committee for Standardization (CEN). For some types of PPT, efforts are underway to develop international standards through the International Organization for Standardization (ISO).

Each standards development organization has its own set of rules (e.g., frequency of updating standards, membership requirements), with a number of the standards organizations receiving ANSI accreditation. Some organizations develop test specifications while others develop standards that include a set of requirements for conformity assessment (e.g., NFPA's PPT standards specify a requirement for third-party certification; see Chapter 3).

Voluntary consensus standards can be used as the basis for government conformity assessment programs, such as the Food and Drug Administration's (FDA's) use of ASTM and other voluntary consensus standards for medical devices. Additionally, voluntary consensus standards may be specified in government regulations, such as Occupational Safety and Health Administration (OSHA) requirements for protective helmets to meet ANSI Z89.1 standards (29 CFR §1910.135). Government agency staff members often participate in the development of voluntary consensus standards, and in some cases take leadership roles in moving these standards through the consensus process. National Personal Protective Technology Laboratory (NPPTL) staff members actively participate in voluntary standards development by serving on a number of standards committees for ASTM, ANSI, ISO, and NFPA (Box 2-1).

[1]Although it does not develop standards itself, ANSI is recognized as the national standards body of the United States and administers the U.S. participation in international standards bodies, such as the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC), where membership is by country.

**BOX 2-1**
**Examples of NPPTL Participation in Voluntary Standards and Guidelines Development**

AIHA committees on respiratory protection and protective clothing and equipment
ANSI committee on eye and face protection
ANSI Z88 committees on respiratory protection
ASTM E54 committees on homeland security applications
ASTM E56 committee on nanotechnology
ASTM F23 committees on personal protective clothing and equipment
IAB committees on equipment standardization for homeland security
ISO committees on respiratory protection, human factors, and eye and face protection
NFPA technical committees on fire-protective clothing, respiratory protection, and safety equipment
NIJ Special Technical Committee on law enforcement CBRN protective ensembles

NOTES: AIHA = American Industrial Hygiene Association; ANSI = American National Standards Institute; ASTM = ASTM International (formerly the American Society for Testing and Materials); IAB = InterAgency Board for Equipment Standardization and Interoperability; ISO = International Organization for Standardization; NFPA = National Fire Protection Association; NIJ = National Institute of Justice.

In general, the voluntary standards organization has no vested interest or specific role to play in the testing of PPT. Some certified products will have the name of the standards organization on its label (e.g., NFPA), while others will use the certifying organization's or accredited testing laboratory's mark on their product label (e.g., the "UL" mark from Underwriters Laboratories).

## Government Standards

For some products, state or federal government agencies have the responsibility for developing and revising design, performance, and testing standards. These are often the result of long-standing legislatively mandated commitments (e.g., personal flotation devices regulations, respirator regulations, hearing protection ratings) or are in areas where federal agencies have specific responsibilities often not filled by other organizations.

As will be discussed in Chapter 3, testing and certification requirements for respirators are detailed in the Code of Federal Regulations (CFR) in 42 CFR Part 84. The National Institute for Occupational Safety and Health's (NIOSH's) NPPTL is responsible for drafting and submitting changes to the regulations through the federal rulemaking processes. Respirator regulations are often specific for each class of respirators (e.g., air-purifying, self-contained breathing apparatus). NIOSH has adopted a modular approach to updating the respirator regulations and is involved in various stages of the rulemaking process on changes to specific sections. Other standards developed by government agencies include the military specifications and military standards developed and used by the U.S. Department of Defense (DoD); DoD continues to move toward increased use of voluntary consensus standards and commercial specifications where available (GAO, 1994).

Government's involvement in conformity assessment often involves a combination of federal requirements and voluntary consensus standards. Environmental Protection Agency (EPA) regulations require that hearing protective devices be tested according to an ANSI standard, while the requirements regarding noise reduction ratings for hearing protective devices are detailed in federal regulations found in 40 CFR Part 211. The FDA's process for approving medical devices incorporates voluntary consensus standards into FDA guidance documents. Similarly, the National Institute of Justice (NIJ) standards for ballistic-resistant body armor are detailed in NIJ standards documents.

## Committee Comments

One of the challenges of using codified government standards or regulations is the amount of time and effort required to propose and implement changes. Changes to the CFR go through multiple cycles of comment, revision, and changes. The slow process can stifle innovation. Barriers to frequent revisions may also have an impact on available resources. For example, the CFR schedule that details financial fees charged to manufacturers for respirator testing has not changed since 1972 and is inadequate for meeting current costs of respirator testing and certification (IOM and NRC, 2008). Other parts of the NIOSH budget are therefore being used to address those costs.

Innovative technologies and products that are developed to mitigate new hazards or the same hazard in a different environment are often the

genesis of new voluntary consensus standards, which can provide performance criteria in a timely manner. For non-respirator PPT standards, development of voluntary consensus standards is the preferred avenue. Although these standards can also take time to develop and revise (e.g., NFPA standards are normally on a 5-year rotating revision plan), new standards can be added or revisions made to adapt to innovations in the marketplace. The *National Technology Transfer and Advancement Act* (Public Law 104-113) encourages federal government agencies to be involved in relevant voluntary consensus standards development. NPPTL is active in this area, and efforts to continue this involvement are encouraged.

The committee emphasizes the need for standards to be performance-based, to the extent possible, to allow for greater innovation than design-based requirements. Pass–fail criteria and detailed test methods are keys to ensuring consistent testing and reporting. Increased attention is being paid to issues of integrating the various types of PPT into wearable and effective PPT ensembles, as will be further discussed in Chapter 4.

The development of valid standards that have relevant application to PPT use in the workplace requires input from a wide range of stakeholders. Often voluntary standards organizations have difficulty achieving proper balance in their standards committees as parties other than manufacturers, particularly end users, may have financial constraints that do not allow them to attend meetings. ANSI accreditation of standards development organizations includes the requirement for balanced committees and stipulates that it is incumbent upon the standards development organizations to maintain this balance. Innovative methods need to be used that allow other groups such as end users to participate in standards development in order to achieve meaningful results. The committee is optimistic that, with new communication tools (e.g., remote/virtual meetings), voluntary standards will achieve such balance. Where NPPTL or other government agencies choose to directly participate in voluntary standards committees, committee balance and underrepresentation of key interest groups needs careful consideration.

## PRODUCT TESTING

Testing to meet product standards is conducted either in-house, by the manufacturer or purchaser, or by an independent third-party laboratory, each of which may be an accredited laboratory. Some certifying or-

ganizations (e.g., UL) have accredited in-house testing facilities and others (e.g., Safety Equipment Institute [SEI]) use outside accredited third-party laboratories. Valid product testing follows specific testing methodologies outlined in the standards or in other approved documents. Independent testing laboratories can be private, public, nonprofit, or for-profit.

First-party testing is conducted by the product manufacturer. Many manufacturing companies have extensive testing facilities and test their own products and those of their competitors. In many cases, when product testing is performed through a first-party laboratory paradigm, it is done in situations where low risk is associated with noncompliance. If users are dissatisfied with the product, they can purchase another product or brand in the marketplace. Generally, the government is not involved in this type of testing or assessment. For example, a consumer product, such as cell phone batteries, may undergo internal testing only, or the manufacturer may decide to get input from an independent third-party testing and certification process to determine if the batteries conform to Institute of Electrical and Electronics Engineers (IEEE) standards (UL, 2010). The batteries pose low hazardous risk to the consumers and, if dissatisfied with the product, consumers can purchase other brands.

Second-party testing is conducted by the retailer or the purchaser. Although not as common as first- or third-party testing, some retailers put considerable resources into verifying that the product meets the requirements (e.g., lead levels in children's toys) through second-party testing.

Third-party testing is conducted by an independent laboratory or certifying organization. In many cases third-party testing is done by private-sector laboratories, although this work is also conducted by government laboratories. For example, UL and SEI conduct or oversee third-party testing and offer voluntary third-party certification programs for protective helmets and eyewear (testing to meet ANSI and ASTM standards). For body armor, private-sector laboratories are approved by the National Law Enforcement and Corrections Technology Center to conduct testing. Government laboratory testing includes respirator testing at NPPTL.

For some non-PPT products and marketable goods, federal and state government agencies are also involved in inspections that involve assessments of product characteristics that do not need laboratory testing or are not easily tested in the lab (Gillerman, 2004). Federal responsibilities can involve both laboratory testing and onsite inspections. For example, federal and state meat inspection procedures involve on-site inspections

of slaughtering or processing facilities and live animal and carcass inspections as well as laboratory tests of tissue samples (USDA, 2008).

### Committee Comments

Independent testing by accredited third-party laboratories and certifying organizations provides greater and more transparent assurance that the product meets the required criteria; this is especially important for PPT used to reduce moderate to high risk of worker injury or illness. One major reason for government agencies to do the testing is to provide an independent assessment of the product. However, for most products this role can also be filled by accredited third-party private-sector laboratories and certifying organizations. Issues such as fees for product testing are more easily handled and updated in private-sector organizations.

NPPTL devotes a significant portion of its resources to do rigorous testing and the associated conformity assessment efforts for respirators. As noted above, challenges in this process include updating the manufacturer fee schedules because the schedules are part of federal regulations. From the committee's perspective, NPPTL can use its extensive expertise in PPT to effectively provide input on product testing processes including research on test methods.

## ACCREDITATION OF LABORATORIES AND CERTIFYING ORGANIZATIONS

Accreditation organizations verify whether the testing laboratory or certifying organization is equipped and capable of performing the required test methods and evaluations and whether it meets other operational requirements that include independence, staff qualifications, strong quality assurance programs, and acceptable recordkeeping requirements (Breitenberg, 1991; Gillerman, 2004). International standards for accreditation are detailed in ISO standards, e.g., ISO 17025:2005 and ISO Guide 65 (ISO/IEC, 1996, 2005). In addition to laboratory accreditation, which is done by federal, state, local, and private-sector programs, there are also organizations that accredit the accrediting bodies and ensure a further level of adherence to quality testing and certification processes. NFPA standards require that the certifying organizations and the accrediting bodies be accredited to meet ISO standards, but do not specify

which organization is used to conduct the accreditations. NFPA standards state that the certifying organization shall be "accredited for personal protective equipment in accordance with ISO Guide 65, *General Requirements for Bodies Operating Certification Systems*. The accreditation shall be issued by an accreditation body operating in accordance with ISO 17011, *General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*" (NFPA 1994). In the private sector there are accreditation bodies, such as ANSI and the American Association for Laboratory Accreditation (A2LA), that accredit testing laboratories and certification bodies to ISO 17025 and ISO 65.

Several laboratory accreditation programs are operated by federal agencies (Breitenberg, 1991). OSHA's Nationally Recognized Testing Laboratories (NRTL) program accredits third-party, private-sector laboratories that test (and often certify) electrical equipment and other workplace materials (OSHA, 2010b). Under this voluntary program, each NRTL-accredited laboratory must be reviewed at least once every 5 years. The NRTL program specifies the product standards used in testing and requires that the laboratories be independent of the product's manufacturer, supplier, and vendor. Laboratories accredited in the NRTL program are required to perform inspections of factory production runs and conduct field inspections to ensure that the certifier's identifying mark or label is present on the product. The NRTL program is available for laboratories in the United States as well as internationally if that foreign country accepts U.S. certification.

The National Institute of Standards and Technology (NIST) conducts the National Voluntary Laboratory Accreditation Program (NVLAP). This program accredits laboratories to conduct one or more of a wide range of testing or calibration protocols. Accreditation programs under NVLAP include those for chemical calibration, information technology security testing, personal body armor, energy-efficient light products, thermal insulation materials, and a wide variety of commercial products (NIST, 2010). The NVLAP accreditation program is available for participation by commercial laboratories, manufacturer's in-house laboratories, university laboratories, and government laboratories. Each laboratory must renew its accreditation annually.

In addition to federal programs, there are a number of private-sector for-profit and not-for-profit laboratory accreditation programs. The Consumer Product Safety Commission (CPSC), for example, mandates that third-party testing laboratories must be accredited by an International Laboratory Accreditation Cooperation–Mutual Recognition Arrangement

signatory accrediting body and the accreditation must be registered with and accepted by the CPSC (CPSC, 2010a).

### Committee Comments

The committee identified a number of organizations that accredit laboratories and certifying organizations to test and certify non-respirator PPT. For future new conformity assessment processes for these products, the committee believes the primary stipulation could be that accrediting laboratories and certifying organizations meet ANSI/ISO standards for quality assurance.

## DECLARATION OF CONFORMITY AND CERTIFICATION

Who declares or attests that the product meets the requirements and standards? What data are used to attest to the conformity? These questions have many varied answers. Certain products pose little risk to the end user, and in those cases the consumer and the marketplace sort out the high-quality products from those of low quality. For some products it is easy for the consumer to determine if the product works consistently over time, but for other products the only way to know if a product will be effective is to test it. Consumers need verification that tests have been conducted, and that the product has met the expected criteria. The attestation or declaration of conformity can be done by the manufacturer (first party), by the purchaser (second party), or by an independent third party.

### First-Party Declaration of Conformity

For many products sold in the United States, the manufacturer declares that the product conforms to relevant requirements and meets the industry standards. This declaration is based in some cases on data generated in the manufacturer's laboratory and in other cases on data generated by a third-party testing laboratory. For example, manufacturers of hearing protective devices attest to the noise reduction level. Although a manufacturer's declaration is often termed *self-certification*, as noted below, the term *certification* is more narrowly defined.

### Second-Party Declaration of Conformity

Purchasers become involved in conformity assessment, particularly when they serve as a link between the manufacturer and the general public or end-user consumer. Wholesalers or retailers may verify that a product meets standards before putting the merchandise on store shelves. Second-party declarations may also be made by manufacturers who verify and attest that the component parts from other manufacturers meet the requisite standards and can thus enter the assembly process.

### Third-Party Declaration of Conformity

Although the term *certification* is often used interchangeably and colloquially to encompass all forms of conformity assessment, the term has a much more specific definition that requires independent third-party involvement. ISO defines certification as "third-party attestation related to product, processes, systems, or persons," with attestation defined as the "issue of a statement, based on a decision following review that fulfillment of specified requirements has been demonstrated" (ISO/IEC, 2004). Certification encompasses both a verification of testing data and follow-up product and manufacturing audits. Third-party attestation of conformity provides the verification by an organization that is not the seller or buyer and thus offers a more independent appraisal. Third-party declaration is based in some cases on testing or inspection data from the manufacturer, and in other cases on data generated by a third-party testing laboratory.

Examples of the range of approaches include the FDA's drug approval process, which provides an assessment by FDA reviewers of data supplied by the pharmaceutical or medical device manufacturers or related entities (see Chapter 3). The NIOSH respirator certification process conducted by NPPTL follows a different model in which the testing is done by the government laboratory charged with verifying that the products meet the requisite standards. In both processes there are post-marketing testing and evaluation components, including product audits and manufacturing site audits. Requirements and timelines for recertification vary.

### Committee Comments

The committee believes each conformity declaration approach has value. Each serves a purpose, depending on the type of product and the nature of the marketplace. Given that most PPT products are designed specifically to prevent worker illness, injury, or death, third-party certification (declaration of conformity) would be the preferred approach. Independent verification and attestation that the product meets the requisite standards gives increased assurance to the worker of product effectiveness. Currently, many approaches to conformity assessment for non-respirator PPT require only first-party declaration of conformity. For example, OSHA regulations for protective helmets used in the workplace require that the products meet a specific standard, but third-party certification is not required. Voluntary third-party certification is available from several private-sector testing and certifying organizations. For example, SEI and UL offer certification programs for protective helmets and fall protection harnesses. Manufacturers can have their products certified and thus meet employer and worker demands for certified fall prevention equipment. Further efforts are needed to explore whether third-party certification should be federally mandated for some non-respirator PPT products or what incentives could be put in place to encourage third-party testing and certification.

## COMMUNICATION: CERTIFICATION MARKS AND LABELS

Because the entire conformity assessment process is focused on getting safe and effective products to the end users and consumers, informed purchasing decisions need to be made—and communication is critical. Purchasers need to know what products have been deemed to meet the relevant standards and what products have not. Communicating conformity assessment generally takes the form of either a certification mark or the inclusion of the product on a list of certified or approved products. Additionally, certificates of conformity are used to indicate that all essential characteristics of the product have been assessed and have met certain standards. The owner of the certification mark is responsible for the certification, including determining the requirements for certification. Certification marks are often, but not always, registered marks with the U.S. Patent and Trademark Office (Breitenberg, 1997a; USPTO, 2010).

Many private-sector organizations have a specific logo or mark; for example, the Woolmark issued by Australian Wool Innovation Limited attests to wool quality and performance criteria (AWI, 2010). Private-sector PPT-related certification marks include the UL, SEI, and CSA designations.

According to the U.S. Patent and Trademark Office, three types of certification marks are used: (1) those that certify goods or services originate from a certain region (e.g., Florida orange juice); (2) those that certify goods or services that meet certain quality, material, safety, or manufacturing standards; and (3) those that certify the maker of the product or service (e.g., work or labor performed by a member of a union) (USPTO, 2010). The certification mark does not need specific wording—in fact, a design can be used. The accompanying proof of conformity, however, should indicate: "the identity of the certification body (and any other testing body if applicable) and any relationship that the body(s) may have to the manufacturer; the lot, batch, or other production information to allow traceability to the production source and time of production; the date when the certificate was issued; and the officer of the company responsible for its issuance" (Breitenberg, 1997a). In addition, the supplier, type or model number, and all important safety and maintenance instructions should be included.

Government agencies can issue certification marks; for example, the Federal Communications Commission uses a mark for computers and other electronics (FCC, 2010). Detailed certification labels are used by NIJ and NIOSH to denote certified products. These agencies also use online lists of certified products as another way to communicate which products have met testing criteria. The NIOSH Certified Equipment List provides details on certified respirators, including the related components (NIOSH, 2010d); NIJ's Body Armor Compliant Products List also provides product information (NIJ, 2010). The InterAgency Board for Equipment Standardization and Interoperability (IAB)[2] provides a Standardized Equipment List through the Responder Knowledge Base on its website as a guideline for local, state, and federal responder units involved in preparing for and responding to hazardous events (IAB, 2010). Private-sector third-party certifying organizations, such as SEI, UL, and CSA, also maintain online certified product lists. Public listing is re-

[2]Founded by the DoD and the Department of Justice in 1998, the IAB brings together local, state, and federal agencies and organizations to prepare for and respond to emergencies and disasters. The IAB focuses on issues relevant to interoperability, compatibility, and standardization of response equipment and processes.

quired as part of meeting the ISO requirements to receive accreditation as a certifying entity.

A major challenge in conformity assessment is enforcing the certification mark and identifying and policing fraudulent use. NIOSH has had several occasions in recent years in which respirators with labels that indicated NIOSH certification were determined not to be NIOSH-certified products. In those cases, NIOSH has contacted the manufacturers of mislabeled products and requested that the product be relabeled or recalled. NPPTL staff have also sent out user notices and posted the information identifying the fraudulent respirators on the NIOSH website (NIOSH, 2010c). Manufacturers of certified products are often vigilant in identifying non-certified products offered by their competitors.

### Committee Comments

Communication about certified products is a valuable role for government agencies to fulfill because the agencies can provide websites or other tools that offer lists of certified products from multiple certifying organizations. No comprehensive list is currently available of non-respirator PPT products that meet the required standards or other regulations. In December 2009, NPPTL released its Respirator Trusted Source Information Page (NIOSH, 2010a). A similar effort with a central database website for other types of PPT would be a valuable resource. An information source would be especially important for small and large employers that may not be affiliated with a consolidated purchasing arrangement, for self-employed individuals, and for low-wage temporary workers so they can make informed decisions about quality PPT. Manufacturers also have responsibilities to provide product use instructions that can be readily understood.

## INCENTIVES AND ENFORCEMENT

Investing in and adhering to conformity assessment processes can be driven by positive incentives or by legal mandates or penalties. Worker, union, and employer demand for certified products is one of the positive driving forces for fire protection PPT. Local fire departments often stipulate that contracts be awarded for PPT products that meet NFPA standards as evidenced by third-party testing and certification. Similarly,

financial incentives can include stipulations in federal contracts that only certified products can be purchased using federal grant funds (see Chapter 4). This is demonstrated by the success of the Bulletproof Vest Partnership Program with the Department of Justice (DOJ, 2010). Since 1999, more than 13,000 jurisdictions have participated in the Bulletproof Vest Partnership Program, which provides matching funds to law enforcement agencies if they purchase body armor from the NIJ Compliant Product List (NIJ, 2010). The Department of Homeland Security (DHS) also requires that all emergency response equipment purchased with grant funds must be on the IAB's Authorized Equipment List.

Some government agencies have the jurisdiction to issue regulatory requirements, issue stop use alerts, or impose penalties for the use of noncompliant products. For example, OSHA requires workplaces to use NIOSH-certified respirators and U.S. Coast Guard-approved personal flotation devices, and can issue citations and penalties for noncompliance. Both the CPSC and the EPA have the authority to impose fines for noncompliance with safety standards.

### Committee Comments

NIOSH does not have regulatory authority for nonrespirator PPT and cannot require or enforce requirements for conformity assessment processes. Current OSHA regulations specify the voluntary consensus standards that should be met for various types of non-respirator PPT (see, e.g., Table 3-8), but do not specify a requirement for conformity assessment processes to ensure that those standards are being met. If deemed appropriate for other types of PPT (particularly PPT used in medium- and high-risk work environments), OSHA and the Mine Safety and Health Administration could establish regulations requiring third-party declaration of conformity (certification).

## SURVEILLANCE AND POST-MARKETING TESTING AND EVALUATION

Monitoring to ensure ongoing compliance is an integral part of third-party certification and is also built into other conformity assessment systems. Pre- and post-marketing testing and evaluation efforts include the manufacturing and product audits conducted on the products and manu-

facturing sites (Gillerman, 2004). Product assessments may include testing of products selected at random from retailers or from the production line. These ongoing efforts help ensure consistency in product quality and aim to avoid selection bias, that is, having manufacturers choose a "golden sample" for analysis.

In addition, health surveillance efforts are needed to assess the impact on the health and safety of the worker. Occupational health surveillance is defined as the systematic collection and analysis of occupational injuries, illnesses, hazards, and exposures (NIOSH, 2010e).

The FDA, for example, has several communication avenues for the reporting and communication of adverse events and conducts manufacturing and import inspections. The NIOSH respirator certification program involves both site and product audits in addition to several specific follow-up programs (see Chapter 3). New initiatives for body armor are requiring further efforts in post-market testing and evaluation. As discussed in Box 2-2, the CPSC is tasked with oversight of the safety of thousands of consumer products, including PPT for the general public. To conduct surveillance and post-marketing follow-up, CPSC has several data collection systems in place that allow consumers to report problems with unsafe products directly through an online reporting system (CPSC, 2010b) and that collect data on emergency room visits in which consumer products are involved through the National Electronic Injury Surveillance System (CPSC, 2010c). These systems serve as examples of the potential for comparable efforts in occupational health surveillance and/or may be areas of collaboration in collecting worker safety information relevant to PPT.

## Committee Comments

Only limited data exist on the performance of PPT in the workplace. Data are needed so that problems with PPT performance or use can be identified and resolved. The committee believes that stronger and more comprehensive efforts to collect and analyze health surveillance data are needed, particularly on PPT use in the workplace and adverse outcomes associated with the non-use of PPT, defective PPT, whether the PPT was certified or not, any issues with PPT misbranding or adulteration, and/or end-user issues with PPT.

**BOX 2-2**
**CPSC Product Safety Surveillance**

With an annual average of 23,000 deaths and more than 32.7 million injuries associated with consumer products, the Consumer Product Safety Commission (CPSC) is responsible for regulating 15,000 consumer products to protect Americans from unreasonable risk of injury (CPSC, 2003). The CPSC is tasked with identifying hazards; developing and monitoring safety standards; compliance and enforcement; public outreach; and intergovernmental coordination (CPSC, 2009). In late 2007, toy manufacturers were required to recall millions of toys due to hazardous lead levels and unsafe toy components (Merle, 2007). The extensive toy recalls and increasing public concern surrounding toy safety led Congress to pass the *Consumer Product Safety Improvement Act* (Public Law 110-314) in August 2008. It included a mandate for third-party testing for certain children's products.

The wide scope of products under the purview of the CPSC has necessitated the development of a number of surveillance mechanisms, including the National Electronic Injury Surveillance System, which is in place in many hospital emergency rooms to transmit incident information regarding product-related events. Incident information can be transmitted electronically, in some cases within 24 hours after an occurrence. The CPSC also reviews mortality data in the form of approximately 8,700 death certificates annually covering unintentional product-related deaths. Consumers, manufacturers, healthcare professionals, and others can also report product problems directly through the CPSC website (CPSC, 2010b).

NPPTL is currently exploring health surveillance opportunities relevant to PPT use. Several ongoing surveillance or data collection efforts could possibly be expanded to allow for collection of information on PPT and PPT use in the workplace, including NIOSH surveillance activities such as the Fatality Assessment and Control Evaluation (FACE) program, health hazard evaluations, and the Sentinel Event Notification System for Occupational Risk (SENSOR). Health hazard evaluations conducted by NIOSH offer another opportunity for information on PPT use. For example, in 2008 a health hazard evaluation was conducted to evaluate potential hazards associated with repackaging of reflective glass beads; safety glasses were recommended to prevent eye injury (NIOSH, 2008). NIOSH also conducts follow-up investigations, including a recent evaluation of healthcare respirators in California (NIOSH, 2010b). More information on the extent and nature of PPT use in the workplace would inform improvements in both PPT products and their use.

Workplace injury and illness reporting systems may be another potential source of information. Currently, the OSHA Injury and Illness Recordkeeping Standard (29 CFR §1904) mandates that injuries and illnesses are recorded on the OSHA 300 form, which gathers one to two lines of information on the injury. The OSHA forms are employer-based systems, which could be modified to collect data about PPT use, misuse, or failure. Additionally, the Bureau of Labor Statistics conducts an annual Survey of Occupational Injuries and Illnesses that requests information from a stratified sample of employers on injuries and illnesses listed on the OSHA 300 log. This survey could be another source for PPT information if that data were required.

## OTHER GOVERNMENT ROLES

Federal agencies are active in a number of other roles that facilitate and provide the foundation for conformity assessment efforts, including research, training, and convening roles. Additionally, as mentioned above, serving as an information clearinghouse to provide a reliable source of information on PPT selection, use, care, and maintenance is a critically important role.

### Research

Federal agencies often play a vital role in conducting or funding research efforts that provide the foundation for test methodologies or that illuminate the criteria needed to assess a product's effectiveness in real-world use. In part this may be research that is not of high interest to individual manufacturers, or the market niche may be so narrow for some types of PPT that federal agencies are best suited as funders. In addition to strengthening the conformity assessment process, these types of research are vital to protecting worker safety and health and are needed for reducing liability risk for purchasers and manufacturers.

NPPTL has been active in research on test methods in a number of areas, including chemical permeation through protective clothing materials. A partnership involving NPPTL, NIST, and North Carolina State University conducted interlaboratory testing and validation of the stored-energy test method; stored-energy testing is needed to avoid skin burns when wearing firefighter turnout gear. This ASTM standard will be con-

sidered for incorporation into the next edition of NFPA 1971, *Standard on Protective Ensembles for Structural Fire Fighting and Proximity Fire Fighting*.

As discussed in Chapter 4, research is needed on testing methods and standards criteria for protective ensembles and the interface among multiple types of PPT (e.g., respirator, hearing protection, eye protection, protective helmet).

## Convening Role

Another role for federal agencies is in convening the range of stakeholders involved in specific issues and promoting discussion among the groups. Currently, NPPTL holds an annual stakeholder meeting as well as a number of other public meetings to receive input on specific issues. Discussions with stakeholders, including end users, regarding conformity assessment for non-respirator PPT would be valuable.

## Training

PPT effectiveness is highly dependent on the consistent provision of PPT by the employer and the correct use of PPT; therefore end-user education and training is critical. Consistent and performance-based training can have a large impact on the selection, use, care, and maintenance of PPT. OSHA has extensive requirements for the training of employees who use respirator protection (29 CFR §1910.134); similar efforts for non-respirator PPT training and certification of training personnel could be explored.

## REFERENCES

AWI (Australian Wool Innovation Limited). 2010. *Australian Wool Innovation Limited.* http://www.wool.com (accessed August 10, 2010).

Breitenberg, M. A. 1991. *Laboratory accreditation activities in the United States, NISTIR 91-4576*. http://gsi.nist.gov/global/docs/pubs/NISTIR_4576.4576.pdf (accessed October 7, 2010).

Breitenberg, M. A. 1997a. *The ABCs of the U.S. conformity assessment system*. NISTIR 6014. http://ts.nist.gov/Standards/Conformity/primer.cfm (accessed September 27, 2010).

Breitenburg, M. A. 1997b. *The U.S. certification system from a governmental perspective.* NISTIR 6077. Gaithersburg, MD: National Institute of Standards and Technology.

CPSC (Consumer Product Safety Commission). 2003. *CPSC strategic plan*. http://www.cpsc.gov/cpscpub/pubs/reports/2003strategic.pdf (accessed May 14, 2010).

CPSC. 2009. *CPSC 2009 annual report*. http://www.cpsc.gov/cpscpub/pubs/reports/2009rpt.pdf (accessed May 17, 2010).

CPSC. 2010a. *CPSC registration for third-party testing laboratories user's guide*. http://www.cpsc.gov/about/cpsia/labreguserguide.pdf (accessed September 28, 2010).

CPSC. 2010b. *Report unsafe products.* http://www.cpsc.gov/talk.html (accessed October 1, 2010).

CPSC. 2010c. *National Electronic Injury Surveillance System.* http://www.cpsc.gov/library/neiss.html (accessed October 1, 2010).

DOJ (U.S. Department of Justice). 2010. *Bulletproof vest partnership*. http://www.ojp.usdoj.gov/bvpbasi/ (accessed May 4, 2010).

EPA (Environmental Protection Agency). 2010. *Clean Water Act enforcement*. http://www.epa.gov/oecaerth/civil/cwa/index.html (accessed September 28, 2010).

FCC (Federal Communications Commission). 2010. *Equipment authorization.* http://www.fcc.gov/oet/ea/procedures.html#sec2 (accessed October 4, 2010).

GAO (U.S. General Accounting Office). 1994. *Acquisition reform: DoD begins program to reform specifications and standards*. GAO/NSIAD-95-14. Washington, DC: GAO.

Gillerman, G. 2004. Making the confidence connection. *ASTM International Standardization News*. December. http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html (accessed August 9, 2010).

IAB (InterAgency Board for Equipment Standardization and Interoperability). 2010. *Standardized equipment list*. https://iab.gov/SEL.aspx (accessed July 30, 2010).

IOM and NRC (Institute of Medicine and National Research Council). 2008. *The Personal Protective Technology Program at NIOSH*. Washington, DC: The National Academies Press.

ISO/IEC (International Organization for Standardization/International Electrotechnical Commission). 1996. *General requirements for bodies operating product certification systems*. ISO/IEC Guide 65.

ISO/IEC. 2004. *Conformity assessment: Vocabulary and general principles*. ISO/IEC 17000:2004.

ISO/IEC. 2005. *General requirements for the competence of testing and calibration laboratories*. ISO/IEC 17025.

Merle, R. 2007. Mattel recalls more Chinese-made toys. *The Washington Post*, August 15.

NIJ (National Institute of Justice). 2010. *Models that comply with the NIJ standard-0101.06 for ballistic-resistance of body armor*. http://www.justnet.org/pages/BallisticCPL.aspx (accessed May 19, 2010).

NIOSH (National Institute for Occupational Safety and Health). 2008. *Evaluation of employees' chemical exposures while blending and repackaging glass beads for road markings*. HETA 2008-0017-3095. http://www.cdc.gov/niosh/hhe/reports/pdfs/2008-0017-3095.pdf (accessed August 9, 2010).

NIOSH. 2010a. *Respirator trusted-source information page*. http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html (accessed July 30, 2010).

NIOSH. 2010b. *NIOSH investigation of 3M Model 8000 filtering facepiece respirators as requested by the California Occupational Safety and Health Administration, Division of Occupational Safety and Health*. HETA 2010-0044-3109. http://www.cdc.gov/niosh/hhe/reports/pdfs/2010-0044-3109.pdf (accessed July 30, 2010).

NIOSH. 2010c. *NIOSH respirator user notices*. http://www.cdc.gov/niosh/npptl/usernotices (accessed August 17, 2010).

NIOSH. 2010d. *Certified equipment list*. http://www.cdc.gov/niosh/npptl/topics/respirator (accessed August 9, 2010).

NIOSH. 2010e. *Surveillance*. http://www.cdc.gov/niosh/topics/surveillance (accessed October 5, 2010).

NIST (National Institute of Standards and Technology). 2010. *National Voluntary Laboratory Accreditation Program.* http://ts.nist.gov/standards/accreditation/index.cfm (accessed September 28, 2010).

OSHA (Occupational Safety and Health Administration). 2010a. *OSHA forms for recording work-related injuries and illnesses*. http://www.osha.gov/recordkeeping/new-osha300form1-1-04.pdf (accessed September 28, 2010).

OSHA. 2010b. *Nationally recognized testing laboratories*. http://www.osha.gov/dts/otpca/nrtl/index.html (accessed September 28, 2010).

UL (Underwriters Laboratories). 2010. *CTIA Battery Certification Program*. http://www.ul.com/global/eng/pages/offerings/industries/hightech/batteries/program/ (accessed August 4, 2010).

USDA (U.S. Department of Agriculture). 2008. http://www.fsis.usda.gov/Fact_Sheets/Slaughter_Inspection_101/index.asp (accessed August 10, 2010).

USPTO (U.S. Patent and Trademark Office). 2010. *Trademark manual of examining procedure—6th ed., rev. 2: Service marks, collective marks, and certification marks.* Washington, DC: USPTO. http://tess2.uspto.gov/tmdb/tmep/1300.htm (accessed August 17, 2010).

# 3

# Current PPT Conformity Assessment Processes

> *The employer shall select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability. The employer shall select a NIOSH-certified respirator. The respirator shall be used in compliance with the conditions of its certification.*
>
> 29 CFR §1910.134(d)

> *All compliant product that are labeled as being compliant with this standard shall meet or exceed all applicable requirements specified in this standard and shall be certified.*
>
> NFPA 1971, Protective Ensembles for Structural Fire Fighting and Proximity Fire Fighting

Because workers face a wide range of hazards in the workplace, the types of personal protective technologies (PPT) used to prevent or reduce exposures, injuries, or fatalities differ widely among occupations. Requirements for thermal and respiratory protection needed by firefighters differ from fall protection needed on high-rise construction sites, which differ from the dermal and respiratory protection needed by agricultural pesticide operators.

The committee was charged with examining a variety of approaches used to conduct conformity assessment efforts. This chapter provides overviews of several approaches to conformity assessment, specifically those for respirators, healthcare worker PPT, firefighter and emergency responder PPT, ballistic-resistant body armor, hearing protection devices, personal flotation devices, and PPT for pesticide operators. For each, the process is described briefly, and the committee's assessment is provided on the strengths and weaknesses of these approaches particularly as they

relate to conformity assessment for non-respirator PPT. The chapter also briefly discusses the conformity assessment approach used in the European Union for PPT products. These examples provide the details for the steps in the conformity assessment process described in Chapter 2 and throughout the remainder of the report.

## RESPIRATOR CERTIFICATION

The National Institute for Occupational Safety and Health (NIOSH) is the principal governmental agency with responsibility for testing and certifying respirators. Certification testing and related research is conducted at NIOSH's National Personal Protective Technology Laboratory (NPPTL) in Pittsburgh, Pennsylvania. NIOSH's work in post-marketing testing and evaluation efforts, including product and manufacturing audits, is also conducted by NPPTL. Testing and certification requirements are detailed in federal regulations (42 CFR Part 84).

The U.S. federal government has been involved in evaluating respiratory protection since the early 1900s. With the *Organic Act of 1910* (Public Law 61-179), the U.S. Bureau of Mines (USBM) was founded to deal with a wave of catastrophic mine disasters. Early goals of the USBM were aimed at determining whether fatalities from coal mine explosions were caused by injury or suffocation. The mission of USBM expanded over the years to testing and certifying respirators. The USBM was solely responsible for testing and certifying respirators until NIOSH was established in 1971 with a broader health and safety focus on all occupations. In 2001, NIOSH received a congressional mandate to expand occupational safety and health research. As part of this direction, NIOSH established NPPTL as a new laboratory focused on PPT and responsible for respirator certification.

### Standards

Standards for respirator testing and certification are set in federal regulations as part of the Code of Federal Regulations (CFR). In 1972, NIOSH and USBM jointly published updated respirator certification regulations as 30 CFR Part 11. NIOSH undertook primary responsibility for performance testing of respirators in 1973. Respirator responsibilities for USBM, and subsequently the Mine Safety and Health Administration

(MSHA), focused on products and issues specific to mining applications. In the early 1980s, NIOSH, MSHA, and the respirator stakeholder community revised the regulations to meet changing needs in the workplace. The resulting new regulations, 42 CFR Part 84, were first published for public comment in August 1987 and finalized in 1995. Efforts to change the regulations involve a complex and lengthy federal rule-making process often taking at least 2 to 3 years and often much longer, from development of the performance criteria and background documents, through the comment period and revisions, to enactment of the Final Rule (IOM and NRC, 2008). NPPTL is currently revising the regulations by using a modular approach that addresses changes to specific sections, with the goal of completing two regulatory modules per year (IOM and NRC, 2008).

## Conformity Assessment

The conformity assessment process for respirators is a third-party certification effort, with all phases conducted by NIOSH. Respirator manufacturers register with NIOSH to obtain a manufacturer's code, which allows for quality assurance evaluations. Samples are sent by the manufacturers to NPPTL and undergo a series of test procedures that vary depending on the category of respirator. Tests include evaluations of filter efficiency, determination of exhalation valve leakage, and evaluations of breathing resistance (NIOSH, 2010a). The goal for turnaround time for testing is no more than 90 days (IOM and NRC, 2008). NPPTL is currently undergoing International Organization for Standardization (ISO) accreditation as a testing laboratory. Manufacturers may also send prototypes of upcoming products and receive results on how they performed in testing. Respirators and respirator components that meet the testing criteria are listed on the NIOSH Certified Equipment List, and manufacturers are given approval to affix the NIOSH certified label to their products.

NIOSH conducts site and product audits, although program resources for these purposes are limited (IOM and NRC, 2008). Each manufacturing site undergoes a site audit at least every 2 years. Additionally, NIOSH has a product auditing program where a limited number of respirators are purchased commercially and then tested. Self-contained, self-rescuer respirators used in mining environments are routinely pulled from the workplace and tested by NIOSH. The agency also tests certain

respirators that are alleged to be defective by wearers or others (e.g., a recent study examined N95 respirators submitted by the state of California [NIOSH, 2010b]), and runs a Certified Product Investigation Process. Once a respirator is certified, the manufacturer is not required to resubmit the device for further testing unless modifications are made. Manufacturers are charged a fee for testing and certification; however, fees are based on 1972 fee schedules and do not reflect NIOSH's total costs for performing this work (IOM and NRC, 2008).

### Requirements and Incentives

The Occupational Safety and Health Administration (OSHA) requires that all respirators used in workplaces be NIOSH certified. OSHA also requires a complete respiratory protection program at the worksite, including fit testing of respirators where relevant (29 CFR §1910.134). OSHA's penalties for infractions—in addition to the demand by employers, workers, and unions for certified respirators—work to ensure that the products purchased for employee use are NIOSH certified. Responsible manufacturers also make efforts to ensure that their products meet the testing criteria and are certified.

Although funds for post-market evaluations are limited, NIOSH has recently identified several respirators for which the manufacturer made fraudulent claims of NIOSH certification (NIOSH, 2010c). NIOSH NPPTL can revoke certification and, to the extent possible, actively pursues these cases to make sure that the labeling is changed or that the devices are removed from the marketplace. This action is limited to NIOSH approval holders. As noted in the 2008 Institute of Medicine (IOM) and National Research Council (NRC) report that assessed the NIOSH PPT Program, post-marketing evaluation and efforts to disseminate revocation notifications need to be expanded.

### Committee Comments

NPPTL conducts rigorous testing of respirators and is actively involved in updates to respirator standards. The respirator conformity assessment process (summarized in Table 3-1) involves an active role for NPPTL in all phases of the process, including post-marketing testing and

**TABLE 3-1** Overview of the Conformity Assessment Process for Respirators

| | |
|---|---|
| Standards | Government regulations (42 CFR Part 84) |
| Testing | Third party: NIOSH |
| Attestation of conformity assessment | Third party: NIOSH certification |
| Laboratory accreditation | ISO 17025 accreditation of NPPTL in progress |
| Surveillance and post-market testing and evaluation | NIOSH NPPTL conducts manufacturing and product audits, respirator equipment investigations, the Long-Term Field Evaluation Program for mine escape respirators, and the Firefighter Fatality Investigation and Prevention Program |
| Incentives/enforcement | OSHA requires NIOSH-certified respirators in the workplace |

evaluation of respirators (albeit with limited funds for this purpose), with extensive stakeholder input into all phases of the conformity assessment efforts (IOM and NRC, 2008). In 2007, 81 percent of applications for air-purifying and air-supplied respirator certification were processed within 90 days[1] (IOM and NRC, 2008). However, this federally intensive process presents challenges. NIOSH testing standards are slow to change due to tedious legal requirements, and as a result, the overall process can tend to stifle innovation. Furthermore, this extensive certification process is resource intensive. Given that the costs are not covered by the fees charged to manufacturers, it is unlikely that future NIOSH budgets will have enough funding to extend the current testing and certification model used for respirators to other types of PPT (e.g., protective clothing). Regarding the shortfall in respirator certification fees, a recent IOM/NRC committee concluded, "NIOSH should revise the respirator certification fee schedules so that certification fees paid by respirator manufacturers fully cover the cost of certification. NIOSH's research budget for PPT research should not be eroded by the costs of certification" (IOM and NRC, 2008, p. 15).

[1]The committee did not have comparison data on the average length of time required for other (nonrespirator) certification processes.

## HEALTHCARE WORKER PPT

The Food and Drug Administration (FDA) has federal regulatory authority to ensure the safety and effectiveness of medications and medical devices brought to market in the United States. PPT for healthcare workers are considered medical devices and are subject to FDA evaluation and oversight.

### Standards

The standards for healthcare PPT include those issued by ASTM International, the American National Standards Institute (ANSI), the Association for the Advancement of Medical Instrumentation, and others. The FDA recognizes voluntary consensus standards and incorporates them into its guidance documents for manufacturers of medical devices. The standards are not codified in federal regulations. Federal regulations for healthcare PPT provide a broad description of the product and identify the medical device class (e.g., 21 CFR §880.6265, examination glove).

### Conformity Assessment

The FDA categorizes medical devices into three classes associated with low, intermediate, and high risk to patients or users of the device; specific approval processes are defined for each class (FDA, 2010). Class I devices are considered low risk. This category includes items such as tongue blades, shoe covers, caps, and patient examination and surgery gloves (Box 3-1). Class II devices are deemed intermediate risk. PPT in this category include surgical gowns, surgical masks, and respirators. Class III devices are deemed high risk and include those devices that are "life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury" (21 CFR §860.3). Implantable cardiac pacemakers, breast implants, and cochlear implants are among these devices.

The class to which a medical device is assigned determines the process by which the FDA evaluates safety and effectiveness. All medical

**BOX 3-1**
**Medical Gloves**

Medical gloves, including those used for surgery and medical examination, are Class I medical devices, but manufacturers are required to submit a 510(k) application prior to bringing product to market. Manufacturers must be in compliance with general controls and Good Manufacturing Practices for medical glove manufacture. Broadly, this includes quality management and organization, device design, production and process controls, packaging and labeling controls, device evaluation, distribution, complaint handling, servicing, and records.

FDA requires that manufacturers of surgeon and medical examination gloves demonstrate substantial equivalence to gloves already approved for market. Voluntary consensus standards are recognized by the FDA, and manufacturer compliance with the recognized standards serves to demonstrate substantial equivalence. This includes, for example, ASTM standards for detection of holes and tests for residual powder (FDA, 2008). Recommendations for gloves with special attributes are also included in the FDA guidance. For chemotherapy gloves, for example, in addition to conformance with the recognized standards (or equivalent) for medical gloves, the FDA application stipulates inclusion of: "(1) the product labeling that specifies the chemical(s) that the glove provides protection against; (2) the results of a controlled scientific study to substantiate the claim; (3) a comprehensive description of the test method used; (4) the complete test protocol; (5) an analysis of test results; (6) a discussion as appropriate and conclusions" (FDA, 2008). Third-party testing is not required.

devices are subject to a range of general controls, which include predefined Good Manufacturing Practices. This umbrella Quality System Regulation, defined in 21 CFR Part 820, provides a framework that all device manufacturers must follow with regard to device design, production and packaging controls, evaluation, servicing, recordkeeping, and other factors. These controls are deemed sufficient to ensure the safety and effectiveness of Class I devices, so these devices can be registered and listed without further rigorous premarket evaluation. Class II devices, because they are intermediate risk, are expected to meet or exceed defined controls or standards in addition to adherence to general controls.

Class II devices are most often approved by demonstration of "substantial equivalence" to a previously approved product already on the market, known as the "predicate." This process is known as approval via a 510(k) application, as defined by Section 510(k) of the *Federal Food, Drug, and Cosmetic Act* (Public Law 75-717). If a device differs substantially from previously marketed products, particularly in a way that

brings its safety and effectiveness into question, then a full Premarket Approval (PMA) process is required. The reporting requirements of a PMA are more rigorous and far more substantive than that required by the 510(k) application and subsequently increase processing time and cost. The FDA identifies the devices that are determined to be high risk and therefore require the PMA process, including most Class III devices. PPT used by healthcare workers are currently categorized as Class I and II devices (Table 3-2); no PPT are categorized Class III devices. Some Class I devices, such as medical examination gloves, are also required to comply with the 510(k) process.

The FDA also oversees post-market evaluation, surveillance, and enforcement processes, including both voluntary and mandatory adverse event reporting systems that rely on manufacturers, hospitals, long-term care facilities, and individual practitioners and patients to report device-related adverse outcomes (FDA Medical Product Safety Network [MedSun] and FDA Safety Information and Adverse Event Reporting Program [MedWatch]). The FDA manages a publicly available database of adverse event reports, the Manufacturer and User Facility Device Experience Database (MAUDE). The FDA augments this passive surveillance for some devices with post-approval review of literature or clinical trials, establishment and maintenance of mandated registries, and routine and targeted field inspections. When problems are identified, the FDA may conduct a more intensive investigation.

**TABLE 3-2** FDA Classification of PPT-Related Equipment

| Class | Risk to Patient or Device Wearer | Requirements | Healthcare PPT and Related Devices[a] |
|---|---|---|---|
| I | Low | General standards for good manufacturing processes; most Class I devices are exempt from 510(k) submissions | • Surgeons' gloves (510[k] required)<br>• Examination gloves (510[k] required)<br>• Other surgical apparel (isolation gowns, shoe covers, caps, hoods, operating room shoes) (510[k] exempt) |

**TABLE 3-2** Continued

| Class | Risk to Patient or Device Wearer | Requirements | Healthcare PPT and Related Devices[a] |
|---|---|---|---|
| II | Intermediate | 510(k) submission | • Surgical gowns<br>• Surgical masks<br>• Surgical respirators |
| III | High | Subject to pre-market approvals; must submit clinical evidence of safety and effectiveness | None |

NOTE: The FDA uses the terms *surgical gowns*, *isolation gowns*, *surgical masks*, and *surgical respirators* and defines each in guidance documents.
[a]Protective eyewear used as PPT is not regulated by the FDA as a medical device.
SOURCE: IOM (2008).

## Requirements and Incentives

For healthcare PPT, the FDA has the authority to promulgate public health advisories and safety alerts, issue warning letters to manufacturers, recall or seize products, suspend or revoke device approval, and recommend criminal prosecution. FDA regulations are focused on the manufacturer.

OSHA regulations address whether employers are providing appropriate PPT and training. When the potential exists for healthcare workers to be exposed to blood-borne pathogens, OSHA requires use of PPT that "does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used" (29 CFR §1910.1030). OSHA does not specifically require that PPT used by healthcare workers be FDA approved or cleared, but OSHA does require many of the same standards that form the basis for FDA clearance and approval decisions.

In addition to OSHA regulations, a further incentive to healthcare facilities seeking accreditation by the Joint Commission are the Joint Commission's standards regarding infection control, which include expectations that respirator fit testing is conducted and updated.

### Committee Comments

The FDA conformity assessment process used for healthcare PPT (summarized in Table 3-3) is based on conformity to a "predicate," already approved for market. Voluntary consensus standards, recognized by the FDA, are incorporated into guideline documents to assist manufacturers to demonstrate substantial equivalence to the predicate. Because these standards are not codified in federal regulations, they can potentially be amended more rapidly than federal regulations. The standards currently recognized by the FDA for PPT establish the required physical attributes but not necessarily its performance in the healthcare setting. The committee emphasizes the need for conformity assessment processes that examine performance of the PPT against workplace hazards and exposures. Increased input from healthcare workers on standards development committees is important in improving these processes.

The FDA's conformity assessment processes for PPT products are dependent on testing data submitted by the manufacturers and do not require third-party testing (except for respirators). For some types of PPT used by healthcare workers for which failure of the PPT product could result in injury or illness of workers, more rigorous conformity assessment requirements are needed. Recent studies by the Government Accountability Office (GAO) report that the FDA medical device approval system is facing large volumes of applications for increasingly complex devices from U.S. and international manufacturers. The GAO reports noted concerns about the lack of adequate resources at the FDA to address the demand, a reduced emphasis on the PMA process, and fewer inspections of manufacturing facilities (GAO, 2008, 2009). The 510(k) process is currently being reviewed by the Institute of Medicine (IOM, 2010).

**TABLE 3-3** Overview of the Conformity Assessment Process for Healthcare Worker PPT (Non-Respirator)

| | |
|---|---|
| Standards | Voluntary consensus standards incorporated into FDA guidance documents |
| Testing | First party: Manufacturers submit required information to FDA |
| Attestation of conformity assessment | Third party: FDA reviews product data for Class II and Class III products |
| Laboratory accreditation | Not applicable |

**TABLE 3-3** Continued

| | |
|---|---|
| Surveillance and post-market testing and evaluations | FDA |
| Incentives/enforcement | FDA and OSHA regulations, Joint Commission standards |

The FDA's medical device approval process relies on determining equivalence to predicate devices. The requirements for FDA clearance or approval are determined by an initial categorization of the type of device as to the level of risk that could be posed to the patient or user. Products used in work tasks with widely differing potential risk may be classified in the same risk category. For example, as noted in Box 3-1, chemotherapy gloves are a subcategory of patient examination gloves, both categorized as Class I products, even though failure of a chemotherapy glove likely presents much more risk to the wearer given skin exposure to toxic and often carcinogenic drugs. The FDA is currently requiring additional data for clearance of chemotherapy gloves even though they are still categorized as a Class I device.

The FDA's regulatory authority for enforcing compliance is a strength of the medical device approval process, although a concern is whether resources are adequate to conduct site inspections and surveillance efforts. The requirements that manufacturers meet Quality System Management regulations specified by the FDA could be bolstered by specifying that relevant ANSI/ISO standards (e.g., ISO 9000 standards for quality management systems) need to be met.

## FIREFIGHTER AND EMERGENCY RESPONDER PPT

Conformity assessment for most firefighter and emergency responder PPT (excluding respirators) follows a voluntary third-party certification process. The National Fire Protection Association (NFPA) is recognized as the primary national source of standards for firefighter and emergency responder protective clothing and equipment. NFPA committees have developed standards for a wide variety of PPT, including standards for protective ensembles for structural, proximity, and wild land firefighting as well as standards for garments for protection of industrial personnel against flash fire. Additionally, NFPA standards cover a broad range of emergency response applications beyond firefighting applications, in-

cluding standards for protective ensembles for technical rescue incidents, ensembles for hazardous materials response, and PPT for emergency medical operations. NFPA standards are voluntary consensus standards, and the organization does not evaluate, test, or approve any product or PPT system. NFPA standards for fire and emergency services PPT do require that the products be certified by third-party, private-sector certifying organizations if the manufacturer chooses to assert that the product meets applicable NFPA standards.

## Standards

The NFPA employs a structured process to develop standards for firefighter and emergency responder PPT. This process is designed to maximize opportunity for public and stakeholder input, with emphasis on participation from firefighters and the emergency responder community. Standards technical committees are constituted to address standards development for specific categories of PPT. The technical committees are balanced to include participation by manufacturers, fire service and emergency responders, government agency staff, and general interest members, including those from certifying organizations. NFPA standards are frequently updated and revised, typically on a 5-year schedule. Standards are developed in scheduled phases, proceeding from public announcement to development of a first draft of the standard by the technical committee. The draft standard is made available as a proposal for public comment. The technical committee then produces a report requiring that each public comment be addressed with respect to incorporation into the standard. Each technical committee that is responsible for specific categories of PPT operates with oversight from a technical correlating committee. The NFPA Standards Council is responsible for final approval of the PPT standard.

## Conformity Assessment

Each NFPA PPT standard document contains a full chapter describing the requirements for certification to that standard. All products that are labeled as being compliant to the NFPA standard must meet or exceed all applicable requirements of the standard. The testing, certification, and labeling of the product is done by an accredited certifying or-

ganization. NFPA standards require that the certifying organization be an independent third-party organization accredited to ISO 65, *General Requirements for Bodies Operating Product Certification Systems*. The certifying organization is responsible for inspection, evaluation, and testing to NFPA standards to determine product compliance. The certifying organization's laboratories must be accredited to ISO 17025 requirements for testing and calibration laboratories. Furthermore, NFPA requires that the organization that accredits the certification organizations must meet ISO 17011 requirements for accrediting conformity assessment bodies. NFPA standards do not specify which organization is used to conduct the accreditations.

NFPA standards require that for conforming products, the certifying organization's label, symbol, or identifying mark be permanently attached to the product label or be part of the product label. It further requires that the certifying organization perform quality assurance audits and requires annual verification of product compliance by the certifying organization. NFPA PPT standards specify that manufacturers provide a quality assurance program that meets requirements specified in the standard. The certifying organization is required to establish procedures to be followed when situations are reported in which a compliant product is subsequently found to be hazardous. The certifying organization must require manufacturers to investigate complaints and returns in accordance with ISO 9001 requirements for investigating written complaints and returned products. Furthermore, the certification program requires that the manufacturer investigate product hazards and have programs for safety alerts and product recall.

### Requirements and Incentives

NFPA standards and the accompanying certification are not federally mandated, but there is strong demand by workers, unions, and fire and emergency response departments for certified products. The U.S. Department of Homeland Security specifies in its grants that include purchase of PPT, that NFPA standards and third-party certification requirements must be met to use grant funds (see also Chapter 4).

## Committee Comments

The NFPA standards and their detailed requirements for conformity assessment provide a strong example of effective voluntary consensus standards coupled with a rigorous third-party certification system (Table 3-4). NFPA standards are true performance standards with pass–fail criteria developed with significant input from the stakeholder community. The standards approval process is organized and systematic, with regularly scheduled revisions. Each of the NFPA standards committees relies on substantial involvement by firefighters and emergency response personnel. The NFPA process benefits from participation and support of worker unions and associations, including the International Association of Firefighters and the National Volunteer Fire Council. While applauding the current level of involvement, the committee believes that any mechanisms that will facilitate increased end-user participation in the NFPA standards development process would contribute to further improving the standards.

It is important to recognize that the NFPA does not certify PPT; rather, the NFPA standards call for certification by private-sector certifying

**TABLE 3-4** Overview of the Conformity Assessment Process for Firefighter and Emergency Responder PPT (Excluding Respirators)

| | |
|---|---|
| Standards | Voluntary consensus standards: NFPA |
| Testing | To state that the product conforms to NFPA standards requires third-party testing |
| Attestation of conformity assessment | To state that the product conforms to NFPA standards requires third-party certification |
| Laboratory accreditation | NFPA details the criteria for accreditation, including meeting the relevant ISO standards |
| Surveillance and post-market testing and evaluation | Conducted by the certifying organization |
| Incentives/enforcement | Worker and employer demand, grant requirements |

organizations and specify requirements for certification and quality assurance. The NFPA standards are thorough in stipulating that the third-party certifying organization needs to establish procedures to be followed if a compliant product is subsequently found to be hazardous, and the standards require a program of corrective action in the case of complaints, including safety alerts and product recall. One issue that was raised at the committee's workshop was that the NFPA does not actively pursue false or fraudulent uses of assertions on product labels that the product meets NFPA standards. The committee notes that any mechanism that could potentially strengthen the enforcement aspects of compliance to NFPA standards would be worthy of consideration, including strengthening the enforcement of the incorrect use of the term "NFPA approved" on product labeling to ensure that only certified products make this assertion.

## BALLISTIC-RESISTANT BODY ARMOR

Law enforcement officers wear multiple types of PPT depending on the circumstances of their work. This section focuses on the conformity assessment processes specific to ballistic-resistant body armor. From 1966 to 1971, the number of law enforcement officers killed in the line of duty each year more than doubled from 57 to 129 (NIJ, 2001). Shortly thereafter, efforts began at the U.S. Department of Justice to explore the development of lightweight, ballistic-resistant body armor and the establishment of performance standards. In 1972, the National Institute of Justice (NIJ) released the first draft standards for performance of ballistic-resistant body armor used by law enforcement personnel.[2] Current efforts to certify the effectiveness of these products involve NIJ, the National Institute of Standards and Technology (NIST), and NIJ-funded centers collectively known as the National Law Enforcement and Corrections Technology Center (NLECTC). An estimated 3,000 lives have been saved by protection from effective body armor (NIJ, 2008b).

[2]A similar course of events also led to the 2000 NIJ performance standards for stab- and puncture-resistant body armor in response to requests from the correctional officers' community (NIJ, 2001).

## Standards

The original NIJ set of standards for body armor focused on penetration of the vest by a bullet (NIJ, 2001); subsequent iterations examined the effects of blunt trauma, the degradation of the armor when wet, and the effects of angled shots and multishot assaults. The most recent edition was developed through a collaboration between NIJ and the NIST Office of Law Enforcement Standards and was released in 2008 (NIJ, 2008a). The impetus for many of the recent changes was serious injury to a law enforcement agent in 2003 from bullet penetration of a certified vest (Miller, 2010). Analysis of the failed vest determined that its service life was significantly shorter than originally believed due to premature degrading of the protective fibers. The 2008 standard requires more rigorous testing, including the determination of service life by artificial aging as well as the stipulation that an increased number of vests undergo testing and further post-market assessments.

## Conformity Assessment

Since 1985, NIJ has administered a voluntary compliance testing program for ballistic-resistant body armor involving pre- and post-market testing carried out by accredited independent laboratories. This effort is coordinated primarily through the NLECTC.[3] More than 5,000 models have been tested since 1987, and approximately half have met the requirements for certification (Miller, 2010). Five independent private-sector laboratories are currently accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) to conduct ballistic-resistant body armor testing in accordance with the 2008 NIJ standard. In addition to NVLAP accreditation, NIJ specifies that laboratories be within the United States and be fully independent from armor manufacturers. Testing costs are paid by the manufacturers, with cost structures determined by each laboratory.

The current program requires that manufacturers submit armor models and an application package to the NLECTC National Center for ini-

[3]Five NLECTC centers are funded by NIJ to work with federal, state, local, and tribal law enforcement agencies as well as corrections and criminal justice agencies on issues related to technology needs and challenges. The NLECTC National Center has responsibility for managing the Compliance Testing Program and maintaining the Compliant Products List.

tial review. Upon acceptance, the manufacturer submits samples to one of the independent laboratories for testing. Tested samples are maintained by the NLECTC for potential future comparison and analysis. Products that meet the standard are provided an NIJ Notice of Compliance and manufacturers are authorized to use the NIJ compliance label. The label also provides information on the date of manufacture and issue. Certified products are listed on the NIJ Compliant Products List, available online (NIJ, 2010). The list provides information on the threat-level protection of the body armor, manufacturer contact, and warranty information. Renewal of compliance is required after 5 years (NIJ, 2009). The compliance-testing program includes an appeals process. Efforts are under way by NIJ and the NLECTC to implement a new post-market testing program. The follow-up program will monitor ongoing performance by randomly selecting subsequent production samples and submitting them for a subset of the original certification tests (NIJ, 2009).

### Requirements and Incentives

Many law enforcement agencies base their purchasing decisions for body armor on the NIJ Compliant Products List. Additionally, the Department of Justice's Bulletproof Vest Partnership Program, which provides matching funds to law enforcement agencies for the purchase of vests, requires that those vests be on the NIJ Compliant Products List. Since 1999, more than 13,000 jurisdictions have participated in the program and an estimated 800,000 vests have been purchased with $277 million in federal funds (DOJ, 2010).

### Committee Comments

The standards and conformity assessment processes for body armor (summarized in Table 3-5) have evolved over the past 30 years. The NIJ standards (developed in conjunction with NIST) are performance based, with a clear testing protocol and well-defined pass–fail criteria. Law enforcement officers are significantly involved in the development of the standards.

The conformity assessment process for body armor is an example of third-party certification with critical involvement and oversight provided

by a federal agency. This level of conformity assessment is appropriate given the high degree of risk posed to law enforcement and military personnel if the product fails to provide protection. Since 2008, safety alerts about any noncompliant product have been posted on the NIJ website to inform consumers, and a well-organized list of compliant products is available online. Surveillance efforts include data collected by the Federal Bureau of Investigation on deaths of law enforcement officers that occur in the line of duty (FBI, 2008).

The Bulletproof Vest Partnership Program is an innovative example of government involvement in providing funds so that law enforcement agencies can afford to buy compliant products. These types of creative solutions are needed to promote and maintain worker safety and could be used for other types of PPT.

Although this is a voluntary conformity assessment process, factors such as worker and employer demand, purchasing requirements, potential product liability, and manufacturer reputation positively influence body armor manufacturers to obtain certification. As with respirators, issues regarding training and use of equipment also need to be addressed.

**TABLE 3-5** Overview of the Conformity Assessment Process for Ballistic-Resistant Body Armor

| | |
|---|---|
| Standards | Standards developed by NIJ and NIST |
| Testing | Third-party testing |
| Attestation of conformity assessment | Third-party certification by NIJ through NLECTC |
| Laboratory accreditation | NVLAP accreditation; laboratories are also required to be independent of the manufacturer and be located in the United States |
| Surveillance and post-market testing and evaluation | NLECTC |
| Incentives/enforcement | Bulletproof Vest Partnership Program, worker and employer demand |

NOTE: NIJ = National Institute of Justice; NIST = National Institute of Standards and Technology; NLECTC = National Law Enforcement and Corrections Technology Center; NVLAP = National Voluntary Laboratory Accreditation Program.

## HEARING PROTECTION DEVICES

Approximately 30 million people in the United States are occupationally exposed to hazardous noise levels (OSHA, 2010). The *Noise Control Act of 1972* (Public Law 92-574) vested the U.S. Environmental Protection Agency (EPA) with authority to regulate and enforce product noise emission standards and the labeling of products entering U.S. commerce regarding noise emissions and noise-reducing properties. The primary responsibilities for noise control are under the purview of state and local governments (EPA, 2010).

### Standards

Since 1979, the EPA has required (40 CFR Part 211) that manufacturers of hearing protection devices provide a noise reduction rating (NRR) on the packaging. The NRR was designed to provide information to prospective purchasers and users regarding the amount of protection provided by a given device. When the labeling requirement was first proposed, the most frequent method used to characterize sound attenuation was the real ear attenuation at threshold method (described in ANSI S3.19-1974) (NIOSH, 1998).

### Conformity Assessment

Manufacturers are responsible for attesting to the conformity of their products to meet the NRR designated on the product label. Hearing protection devices are tested either by the manufacturer themselves or by an independent laboratory, which then provides the testing results to the manufacturer. At the committee workshop, participants noted that EPA does not require accreditation of manufacturers' laboratories or independent testing laboratories because the industry is composed of mostly small companies and limited product lines. Initial and recurring costs of laboratory accreditation or other third-party certification processes would increase costs of compliance with the regulation without quantifiable benefits to the public (Feith, 2010).

EPA, through an interagency agreement with the Centers for Disease Control and Prevention and NIOSH, conducts spot checks of products in the marketplace. Penalties for manufacturers who falsify certification information include product recall; a $25,000 fine for each initial product

violation; and a $50,000 fine for each subsequent product violation or up to a year in jail (Feith, 2010).

OSHA mandates that employers select hearing protection devices based on their NRR values when employees are exposed to noise at or above the Permissible Noise Exposure (90 decibels averaged over 8 hours and measured on the A scale) and requires employees who have a permanent threshold shift (hearing loss) to wear protective devices at 85 decibels averaged over 8 hours (29 CFR §1910.95). OSHA currently requires that the NRR value be reduced by 7 decibels to account for the fact that NRR testing is done on a different sound scale than the one used by OSHA.

The EPA is currently revising its 1979 regulations regarding hearing protection devices, and final regulations have not been published. Proposed revisions to the current regulations would require periodic testing and renewals in attesting to product conformance. The proposed changes will also address the following issues:

- Stating a range of NRR values rather than one numerical value to provide users with information on the least and greatest levels of protection that can be achieved when used according to manufacturer instructions and product fit;
- Revising the product label to be more user-friendly and to provide information needed to make informed decisions about the product's level of protection (NRR values) and suggested use environment;
- Requiring recurrent testing during the life of a product;
- Relabeling when modifications and retesting of a product's NRR values differ by a minimum of 3 decibels as compared to previous labeled NRR values; and
- Introducing adjustments for "A"-weighted noise exposure and noise spectra to eliminate arbitrary product derating (EPA, 2009).

## Committee Comments

An advantage of the conformity assessment process used for hearing protection devices (summarized in Table 3-6) is that it minimizes the cost to the manufacturers by requiring only first-party conformity assessment.

**TABLE 3-6** Overview of the Conformity Assessment Process for Hearing Protection Devices

| | |
|---|---|
| Standards | EPA |
| Testing | First party: Manufacturers |
| Attestation of conformity assessment | First party: Manufacturers |
| Laboratory accreditation | Not required |
| Surveillance and post-market testing and evaluation | EPA and NIOSH |
| Incentives/enforcement | EPA |

This can allow product innovation to easily be introduced. Current issues with this approach are focused on the test standard and testing methodology and on the length of time that has elapsed between revisions of the standard. The EPA's proposed change to provide a range rather than a single NRR value may help to address this issue. As with respirators, fitting the hearing protection devices is also emphasized as a critically important component of the effectiveness of hearing protection devices (Neitzel et al., 2006).

The approach used by the EPA also works well because of specific regulatory authority granted through legislation that allows the EPA to impose penalties that are sufficient to discourage manufacturers from falsifying data. Whether such an approach can prohibit unscrupulous distributors from importing hearing protection devices and falsifying the NRR values is not clear. Such distributors and offshore manufacturers may not have assets that the EPA can access. Similar regulatory authority to impose significant penalties for noncompliance or fraudulent claims is not in place for other types of PPT.

## PERSONAL FLOTATION DEVICES

Personal flotation devices (PFDs) are used in both occupational and recreational settings. Federal government involvement in conformity assessment for PFDs began in the mid-1800s after the loss of lives from explosions of ship boilers. The *Steamboat Act of 1852* prescribed, among other measures, that passenger-carrying steamboats have on board life preservers made of suitable floating materials for all passengers. To

oversee compliance with this and other safety laws, nine supervisory inspectors were appointed and in the late 1800s the Steamboat Inspection Service (a forerunner of the U.S. Coast Guard) was established. A 1904 disaster on a New York City excursion vessel, the *General Slocum,* prompted the further development of a set of federal regulations. Of the ship's 1,358 passengers, at least 955 died; few life preservers were used, and of those that were used, a number of safety violations were found. The most egregious was the concealment of 8-ounce bars of iron within the cork blocks that were fraudulently put in the life preservers to bring them up to the required weight (U.S. Commission, 1904). The regulations that resulted included the standardization of factory testing procedures and the use of an inspection mark.

Currently, four types of PFDs are specified for commercial or recreational selection depending on the intended use and time to rescue.[4]

- Type I PFDs/Off-shore life jackets: Best for all waters where rescue may be slow coming.
- Type II PFDs/Near-shore buoyant vests: Good for calm, inland waters, or where there is a good chance for fast rescue.
- Type III PFDs/Flotation aids: For general boating or the specialized activity that is marked on the device such as water skiing, hunting, fishing, canoeing, kayaking, and others.
- Type V PFDS/Special use devices: Only for special uses or conditions (e.g., boardsailing vests, commercial whitewater vests) (USCG, 2010c).

## Standards

The U.S. Coast Guard (USCG) is responsible for the conformity assessment processes for PFDs under its jurisdiction. Buoyancy, strength, and design standards that PFDs are required to meet are outlined both in the CFR (46 CFR Part 160) and in voluntary consensus standards developed by ANSI/Underwriters Laboratories (UL). The CFR also outlines the requirements for acceptance of testing laboratories and the conformity assessment processes described below. USCG has examined the feasibility of probabilistic risk-based compliance standards and risk-based quality assurance processes for PFDs (Box 3-2).

[4]Type IV PFDs are throwable devices including ring buoys and seat cushions (USCG, 2010c).

**BOX 3-2**
**Risk-Based Standards and Quality Assurance Processes**

The U.S. Coast Guard has provided grant funds for, and the personal flotation device (PFD) industry has supported, development of probabilistic risk-based compliance standards (Ayyub, 2008) and risk-based quality assurance processes for PFDs (Ayyub, 2002). The risk-based compliance standards are intended to quantify the probability of a PFD saving the life of a user from drowning as a result of a marine event. For this task, risk-based models have been developed for various buoyancy methods and use environments that account for all the major scenarios leading to drowning or surviving an accidental immersion. The risk-based quality assurance for PFDs is designed to provide for varying levels or frequencies of sampling, testing, and inspections based on trends in product compliance resulting from the manufacturers' quality assurance program and its implementation. These approaches to standards and conformance assessment could be applied to the evaluation and design of conformance assessment programs for various kinds of personal protective technologies (see Chapter 4).

## Conformity Assessment

USCG is responsible for the issuance of a certificate of approval for PFDs that meet carriage requirements for a specific vessel. States generally rely on USCG approval to regulate PFDs that are used to meet their carriage and use requirements; however, for activities on private waters or where use is not regulated, non-approved PFDs can be used. For example, a number of manufacturers have been producing competition vests that have no standards or regulations other than the various rules for water skiing and wakeboarding competition.

USCG conducts a preapproval review of any new concept or design before the product is submitted for testing (46 CFR Part 160). Once a manufacturer receives Coast Guard Type Approval, a Certificate of Approval is issued for 5 years and remains valid if product sample and quality control requirements are met (USCG, 2010b). Oversight for the subsequent conformity assessment processes is conducted by a USCG-recognized laboratory. Currently, UL is the only testing and certifying organization authorized by USCG. Production testing of PFDs to meet the required standards is conducted by the manufacturer under the oversight of UL. After testing requirements have been met, the product is given USCG approval and a UL listing. UL releases labels to the manufacturer that have the required text, including specification that the prod-

uct was "Inspected and tested in accordance with U.S. Coast Guard regulations" and stating the manufacturer's or distributor's name and address as well as the lot number (46 CFR Subpart 160.002).

UL is also tasked with ensuring that manufacturers maintain quality control programs as detailed in USCG regulations. The extent of manufacturing site inspections is determined in a product sampling plan based on the number of devices produced and the nature of the quality controls used (USCG, 2010a). As part of the post-marketing testing and evaluation efforts, manufacturers are required to send samples of wearable recreational PFDs to UL testing facilities once a year for inspection and testing.

## Requirements and Incentives

Incentives for PFD conformity assessment include demand for certified products from workers, employers, passengers, recreational boaters, and other individuals involved in water activities. In the United States, commercial passenger watercraft and recreational watercraft are required to have USCG-approved PFDs for each passenger on board (with some exceptions). USCG has the authority to enforce requirements for use of PFDs within its jurisdiction.

## Committee Comments

The conformity assessment processes for PFDs are summarized in Table 3-7. As noted above, codifying standards in federal regulations has pros and cons. The regulations provide USCG with enforcement authority, but changes to the standards require more lengthy processes. For example, standards for inflatable PFDs were specified for adults, but at the time these standards were developed it was unknown whether children or youth could cope with the backup inflation needed in case of automatic inflation system failure. Experience and study have shown that children at least 12 years and older can handle inflatable PFDs (Young et al., 2009), and the need for more comfortable PFDs makes it desirable for the USCG to approve inflatable PFDs for this group. Regarding probabilistic models for risk-based standards (Box 3-2), the development of these models requires extensive resources and should likely be considered only for PPT where failure of the products could result in death or serious injury.

**TABLE 3-7** Overview of the Conformity Assessment Process for Personal Flotation Devices

| | |
|---|---|
| Standards | USCG and voluntary consensus standards |
| Testing | First party, with third-party oversight |
| Attestation of conformity assessment | Third party |
| Laboratory accreditation | Approved by USCG |
| Surveillance and post-market testing and evaluation | Conducted by third-party certifying organization |
| Incentives/enforcement | USCG penalties |

NOTE: USCG = U.S. Coast Guard.

Longstanding third-party testing and certification processes have been refined by the USCG. The committee did not examine the implications of having only one testing and certifying organization, but acknowledges that the system has been working for many years.

## PROTECTIVE CLOTHING FOR PESTICIDE OPERATORS

In the United States, protective clothing required for pesticide operators is under the jurisdiction of the EPA. The requirements are mandated through CFR 40 with details provided as part of 40 CFR Part 170, *Worker Protection Standard,* and 40 CFR Part 171, *Certification of Pesticide Applicators*. A conformity assessment process does not currently exist, however, for assessing the protective performance of these garments. Therefore, inclusion of performance-based criteria is being proposed as part of the two CFR sections that are currently undergoing revision.

### Standards

In 2009, ASTM Standard F2669, *Standard Performance Specification for Protective Clothing Worn by Operators Applying Pesticides,* was approved as a performance specification for protective clothing for pesticide operators. An equivalent ISO standard draft is now under review.

The technical requirements of the two standards are similar, with input provided by individuals representing relevant federal agencies, the crop protection industry, garment manufacturers, researchers, and users. The performance specification standards categorize the protective clothing into low, medium, and high levels of protection. Testing and other requirements in ASTM F2669 reflect the level of protection provided by the garment, with more stringent requirements for higher levels of protection.

### Conformity Assessment

A risk-based conformity assessment process based on use of the three levels of protection specified in ASTM F2669 is being explored by the EPA, NPPTL, and other agencies and organizations. An approach being considered is the use of potential risk to the operator (calculated as part of the risk assessment for pesticide registration) being the basis for determining protective clothing requirements. The conformity assessment details are still being developed, with a proposal to require first-party declaration of conformity for Class 1 products (low potential risk) and third-party certification required for Classes 2 and 3 (medium and high potential risks).

### Committee Comments

The proposed process provides an opportunity for EPA and NPPTL to work together to address the health and safety of pesticide operators using a performance-based conformity assessment process. EPA, with jurisdiction over pesticide registration and enforcement of the regulations, could draw on the PPT expertise provided by NPPTL.

## OTHER PPT

In the United States, the certification of PPT other than respirators is not federally mandated in OSHA or MSHA regulations. If a manufacturer chooses to certify the performance of its PPT products (other than respirators), third-party certifying organizations can test the product to determine if specific ASTM, ANSI, or other standards have been met. For example, Safety Equipment Institute (SEI), UL, and CSA International are private-sector organizations that administer third-party certification

programs by testing and certifying a broad range of safety and protective products used occupationally and recreationally. Third-party organizations generally undergo accreditation processes to affirm that the specific certification program meets ISO Guide 65 and other required standards. As noted in Table 3-8, voluntary third-party certification programs are available for a number of types of PPT. Some certifying organizations have the testing conducted by a set of accredited third-party laboratories, while others use internal testing facilities and capacity.

### Committee Comments

Although OSHA regulations specify voluntary consensus standards that need to be met for non-respirator PPT, third-party testing or certification of these products (including head, foot, and fall protection) is not mandated. Where the use of these products is required because of high-risk worksites, third-party testing and, in many cases, third-party certification could be a mechanism for reducing the risk to workers and enhancing the certainty that the PPT products meet performance requirements.

**TABLE 3-8** Examples of Voluntary Consensus Standards and Certifying Organizations

| | Examples of Relevant Standard(s)[a] | Examples of Certifying Organizations |
|---|---|---|
| Head protection, hard hats | ANSI Z89.1-2003, 1997, 1986[b] | SEI, UL, CSA International |
| Protective footwear | ASTM F2412-2005; ANSI Z41-1999, 1991[c] | SEI, CSA International |
| Eye and face protection | ANSI Z87.1-2003, 1989[d] | SEI, UL, CSA International |

NOTE: SEI = Safety Equipment Institute; UL = Underwriters Laboratories.
[a]As specified in OSHA regulations (29 CFR §1910). Third-party certification programs are also available to certify firefighter protective equipment to meet NFPA standards.
[b]29 CFR §1910.135.
[c]29 CFR §1910.136.
[d]29 CFR §1910.133.

## PPE CONFORMITY ASSESSMENT IN THE EUROPEAN UNION[5]

The countries of the European Union (EU) work through the European Commission and other organizations to ensure the safety and effectiveness of personal protective products. European standards and technical specifications for product performance, testing, and certification are developed by the European Committee for Standardization, which works in many cases with ISO to harmonize international standards, to the extent possible.

Two EU directives are focused on personal protective equipment (PPE). Directive 89/656/EEC is a social directive and discusses the health and safety of individuals. Directive 89/686/EEC is a commercial directive and focuses on issues related to conformity assessment and sale of PPE products in the member countries. The directives are applicable to all uses of PPE, including, but not limited to, occupational uses. The PPE directives in the EU stipulate that products meet both a set of essential requirements as well as additional requirements based on the relevant category specific to that product (Box 3-3). The health and safety essential requirements directive details basic requirements related to ergonomics, comfort, sizing, and compatibility of different types of PPE designed for simultaneous use. To be sold in EU countries, all PPE must have the EU's conformance mark, the CE marking (conformité européenne), with appropriate information as specified by the product category. In cases where third-party testing is required, testing must be conducted by notified bodies—laboratories accredited by various organizations in accordance with ISO 17025.

### Committee Comments

The committee did not identify any available data that compared worker safety before and after the conformity assessment requirements were implemented in the EU. U.S. efforts relevant to categorizing PPT will need to closely examine data that become available. The mandate that all PPT products sold in the EU have the CE mark is the major driver of conformity assessment efforts, and similar mandates are not available for non-respirator PPT in the United States. Issues facing the EU

[5]The European Union's documents use the term personal protective equipment (PPE).

process include ensuring adequate participation by all the stakeholders, including worker-related organizations.

**BOX 3-3**
**European Union Certification Categories for PPE**

- **Category 1:** Includes personal protective equipment (PPE) of simple design and with minimal risk, where the user can assess the level of protection provided. Examples include gardening gloves, swimming goggles, and sunglasses. Manufacturers of PPE in this category submit the European Commission (EC) declaration of conformity stating that the product complies with all relevant provisions of the directive. Signing the declaration authorizes the manufacturer to affix the CE marking to each product.
- **Category 2:** Includes any PPE that does not fit in Categories 1 or 3. Examples include sports helmets, eye protection (except swimming goggles or eye protection against high temperatures, electrical risks, or ionizing radiation). Products in Category 2 are required to undergo third-party testing with a notified body and to carry a CE marking after the EC declaration of conformity is issued by the notified body.
- **Category 3:** Includes PPE of complex design and PPE designed to "protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time" (EC, 2010b). Examples include fall protection, respiratory protective equipment, and clothing designed for high- or low-temperature environments. Products in this category are required to undergo third-party testing by a notified body and also undergo one of two product monitoring procedures: (1) checks on the final product—the notified body carries out random production quality checks at least annually and selects an adequate sample of products for testing, or (2) monitoring of production with supervision—meeting ISO quality control systems with random audits by the notified body. The CE marking for Category 3 products includes the assigned number of the notified body responsible for the production control phase.

The term Category 0 has also been used to include equipment excluded from the scope of the PPE directive. Surgical masks are in this category as they are covered in another directive. However, in cases where surgical masks are intended to be used to protect the wearer against microbial or viral infections, they are specified as Category 3 PPE. PPE products designed and manufactured specifically for the armed forces are not covered by this directive.

SOURCES: EC (2010a, 2010b).

## SUMMARY

As evidenced by the descriptions throughout this chapter and summarized in Table 3-9, conformity assessment is conducted in a number of different ways, even within the field of PPT. Moving toward a more systematic and consistent approach to PPT conformity assessment is the topic of the following chapters.

## REFERENCES

Ayyub, B. 2002. *Quality assurance for manufacturing personal flotation devices*. Potomac, MD: BMA Engineering, Inc.

Ayyub, B. 2008. *Reclassification and risk-based compliance: Personal flotation device risk and reclassification analysis.* Potomac, MD: BMA Engineering, Inc.

DOJ (Department of Justice). 2010. *Bulletproof vest partnership*. http://www.ojp.usdoj.gov/bvpbasi/ (accessed May 4, 2010).

EC (European Commission). 2010a. *Guidelines on the application of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the member states relating to personal protective equipment*. http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/ppe_guidelines_en.pdf (accessed August 18, 2010).

EC. 2010b. *Guide to application of the directive 89/686/EEC on personal protective equipment—appendix*. http://ec.europa.eu/enterprise/sectors/mechanical/documents/guidance/personal-protective-equipment/appendix/index_en.htm (accessed August 18, 2010).

EPA (Environmental Protection Agency). 2009. *Proposed revisions to the product noise labeling regulation for hearing protection devices: Fact sheet.* http://www.epa.gov/air/pdfs/HPDFactSheetAugust32009.pdf (accessed August 19, 2010).

EPA. 2010. *Summary of the Noise Control Act*. http://www.epa.gov/lawsregs/laws/nca.html (accessed August 19, 2010).

FBI (Federal Bureau of Investigation). 2008. *Law enforcement officers killed and assaulted*. http://www.fbi.gov/ucr/ucr.htm#leoka (accessed August 20, 2010).

FDA (Food and Drug Administration). 2008. *Guidance for industry and FDA staff: Medical glove guidance manual.* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073359.pdf (accessed August 24, 2010).

FDA. 2010. *Device classification*. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm#introduction (accessed August 20, 2010).

**TABLE 3-9** Summary of Standards and Conformity Assessment Approaches for Selected Examples of Personal Protective Technologies (PPT)

| | Respirators | Healthcare Worker PPT | Body Armor | Firefighter PPT | Hearing Protection Devices | Personal Flotation Devices |
|---|---|---|---|---|---|---|
| **Standards** | | | | | | |
| Voluntary consensus | | ✓ | | ✓ | | ✓ |
| Government standards | ✓ | | ✓ | | ✓[a] | ✓ |
| **Testing** | | | | | | |
| First party | | ✓ | | | ✓ | ✓[f] |
| Third party | ✓ | | ✓ | ✓[b] | | |
| **Declaration of Conformity Assessment** | | | | | | |
| First party—Manufacturer's declaration | | | | | ✓ | |
| Third-party certification—Optional[c] | | | ✓[e] | ✓[b] | | |
| Third-party Certification—Mandated | ✓ | ✓[d] | | | | ✓ |

NOTE: Second-party processes were not used in the examples described in this report.
[a]Environmental Protection Agency standards for noise reduction ratings.
[b]Not federally mandated, but required to meet NFPA criteria.
[c]*Optional* is used to denote that third-party certification is not mandated by OSHA or other federal regulatory agencies.
[d]Food and Drug Administration clearance or approval.
[e]Not federally mandated, but required for inclusion on the NIJ Compliant Products List.
[f]Third-party oversight of testing.

Feith, K. 2010. *Labeling of hearing protection devices*. Presentation to the Institute of Medicine Committee on the Certification of Personal Protective Technologies, Washington, DC, April 13.

GAO (Government Accountability Office). 2008. *Medical devices: Challenges for FDA in conducting manufacturer inspections*. GAO-08-428T. Washington, DC: GAO.

GAO. 2009. *FDA should take steps to ensure that high-risk device types are approved through the most stringent premarket review process*. GAO-00-190. Washington, DC: GAO.

IOM (Institute of Medicine). 2008. *Preparing for an influenza pandemic: Personal protective equipment for healthcare workers*. Washington, DC: The National Academies Press.

IOM. 2010. *Public health effectiveness of the FDA 510(k) clearance process: Balancing patient safety and innovation. Workshop report*. Washington, DC: The National Academies Press.

IOM and NRC (Institute of Medicine and National Research Council). 2008. *The Personal Protective Technology Program at NIOSH*. Washington, DC: The National Academies Press.

Miller, L. 2010. *NIJ's Body Armor Safety Initiative and Revised Body Armor Compliance Testing Program*. Presentation to the Institute of Medicine Committee on the Certification of Personal Protective Technologies, Washington, DC, April 13.

Neitzel, R., S. Somers, and N. Seixas. 2006. Variability of real-world hearing protection attenuation measurements. *Annals of Occupational Hygiene* 50(7): 679–691.

NIJ (National Institute of Justice). 2001. *Selection and application guide to personal body armor: NIJ guide 100–01*. http://www.ncjrs.gov/pdffiles1/nij/189633.pdf (accessed August 23, 2010).

NIJ. 2008a. *Ballistic-resistance of body armor, NIJ standard-0101.06*. http://www.ojp.usdoj.gov/nij/pubs-sum/223054.htm (accessed August 23, 2010).

NIJ. 2008b. *Body armor*. http://www.ojp.usdoj.gov/nij/topics/technology/body-armor/welcome.htm (accessed August 23, 2010).

NIJ. 2009. *National Institute of Justice Body Armor Compliance Testing Program: Administrative manual*. http://www.justnet.org/Documents/Body%20Armor%20Documents/NIJ_BA_CTP_Administrative_Manual_August_5.pdf (accessed August 23, 2010).

NIJ. 2010. *Models that comply with the NIJ standard-0101.06 for ballistic-resistance of body armor*. http://www.justnet.org/pages/BallisticCPL.aspx (accessed August 23, 2010).

NIOSH (National Institute for Occupational Safety and Health). 1998. *Occupational noise exposure: Criteria for a recommended standard*. NIOSH 98-126. http://www.cdc.gov/niosh/docs/98-126/default.html (accessed August 23, 2010).

NIOSH. 2010a. *Respirator testing*. http://www.cdc.gov/niosh/npptl/stps/respirator_testing.htm (accessed July 30, 2010).

NIOSH. 2010b. *NIOSH investigation of 3M model 8000 filtering facepiece respirators as requested by the California Occupational Safety and Health Administration, Division of Occupational Safety and Health*. HETA 2010-0044-3109. http://www.cdc.gov/niosh/hhe/reports/pdfs/2010-0044-3109.pdf (accessed August 18, 2010).

NIOSH. 2010c. *NIOSH respirator user notices.* http://www.cdc.gov/niosh/npptl/usernotices (accessed August 18, 2010).

OSHA (Occupational Safety and Health Administration). 2010. *Noise and hearing conservation.* http://www.osha.gov/SLTC/noisehearingconservation/index.html (accessed July 26, 2010).

U.S. Commission of Investigation Upon the Disaster to the Steamer "General Slocum." 1904. *Report of the United States Commission of Investigation Upon the Disaster to the Steamer "General Slocum," October 8, 1904*. Washington, DC: U.S. Government Printing Office. http://marinecasualty.com/documents/Slocum.pdf (accessed October 5, 2010).

USCG (U.S. Coast Guard). 2010a. *Approval guidance for recreational PFDs/life jackets.* http://www.uscg.mil/hq/cg5/cg5214/recpfd.asp (accessed August 23, 2010).

USCG. 2010b. *Approval guidance for commercial PFDs/life jackets*. http://www.uscg.mil/hq/cg5/cg5214/commpfd.asp (accessed August 23, 2010).

USCG. 2010c. *PFD selection, use, wear, and care*. http://www.uscg.mil/hq/cg5/cg5214/pfdselection.asp (accessed August 23, 2010).

Young, S. L., J. J. Isaacson, and E. C. Wisniewski. 2009. *Inflatable lifejacket testing for children 15 years and under, and adult non/weak swimmers*. Ann Arbor, MI: Applied Safety and Ergonomics.

# 4

# Impact and Issues in Conformity Assessment for PPT

*For most public health concerns, multiple preventive measures contribute to protection against injury or disease, and determining the extent of attribution of any one preventive measure or action is complex.* (IOM and NRC, 2008)

Although safety and health professionals rank it low on the hierarchy of hazard controls, personal protective technologies (PPT) continue to provide the primary means of risk reduction in workplace settings where risks or exposures change rapidly, where process change or engineering controls are deemed to be impractical (e.g., construction, maritime), or where exposures are poorly characterized (e.g., spill response, hazardous waste remediation, firefighting). Reliable risk reduction using PPT requires an often complex web of tasks performed by product designers or engineers, manufacturers, employers, safety and health professionals, supervisors, and trained workers. Assessing the conformity assessment of PPT products is one part of the efforts needed across the life cycle of the product to ensure effectiveness; these efforts also encompass careful attention to design, quality manufacturing practices, end-user training, and evaluation of product performance in real-world use. For PPT to provide effective risk reduction, several criteria must be met:

- PPT standard test methods must consistently reflect field conditions and technology performance;
- Standards must include an adequate margin of safety to accommodate exposure variation in the work process and expected misuse;

- Manufacturing systems standards such as quality control must be adequate to assure each PPT item performs at least to minimum standards;
- Selection of PPT for specific work practices must conform to expected use;
- Potential interference of PPT with the functions of other ensemble components or planned work tasks needs to be characterized and potential adverse impacts of PPT examined;
- Use instructions, training, and supervision regarding PPT to ensure proper work practices must be addressed;
- Replacement cycles, field checks, maintenance, cleaning, storage, packaging, and durability standards must assure continued field performance over the normal lifetime of the PPT;
- Product labeling must be accurate;
- Consumers need to be aware of any recalls due to product failure; and
- Post-marketing testing and recalls must be used to correct process issues, be timely and comprehensive, and be a mechanism for continuous performance improvement.

Standards development and conformity assessment efforts may address selected aspects of these criteria in order to increase the likelihood of effective implementation and risk reduction.

This chapter explores the limited types of data that are available on the impact of PPT conformity assessment on worker safety and health. The chapter also explores issues that pose particularly challenging questions for implementing and sustaining conformity assessment processes for PPT products.

## IMPACT OF CONFORMITY ASSESSMENT ON SAFETY AND HEALTH

Assessing the impact of PPT use on reductions in worker injury or death can be challenging, particularly in occupations where multiple safety measures are implemented, where exposures are intermittent or variable, or where risks are poorly characterized. A greater challenge is finding data to assess the impact of PPT conformity assessment on worker safety and health. To address the question regarding the impact of con-

formity assessment posed in the committee's charge, the committee first took a broader look at the impact of PPT.

What is clear throughout the many successes in the fields of public health and occupational health and safety is that reducing or eliminating hazardous exposures leads to reductions in injuries and deaths. Examples include reductions in cigarette smoking and increases in seat belt use (IOM, 2003). PPT products are designed to reduce hazardous exposures. Improvements in the effectiveness of PPT products—including those resulting from conformity assessment testing and certification—should lead to a greater beneficial impact on worker safety and health.

As noted in the Institute of Medicine and National Research Council report (2008, p. 81), which assessed the National Institute for Occupational Safety and Health (NIOSH) PPT Program,

> Trying to gauge to what extent disease or injury is prevented or is minimized usually involves assessing multiple potential causes and an array of individual and environmental influences. For most public health concerns, multiple preventive measures contribute to protection against injury or disease, and determining the extent of attribution of any one preventive measure or action is complex.
>
> Quantitatively determining the extent to which personal protective technologies (PPT) contribute to worker well-being is a difficult matter. Engineering and administrative controls play a significant role in preventing hazardous exposures. Additionally, because the use of PPT is an individual-based measure, with effectiveness determined in large part by user decisions and quality of the fit, there can be wide variation in the apparent effectiveness of PPT products in preventing illness or injury. The many types of PPT products (e.g., respirators, protective clothing, hearing protection, eye protection, gloves, shoes, helmets, fall protection) and the fact that PPT is used in numerous occupational settings, each with its unique exposures and workplace demands, create a further challenge in attributing the impact.

## Data on the Use of PPT in Reductions in Injuries or Deaths

Approximately 5 million U.S. workers are required to wear respirators in 1.3 million U.S. workplaces (OSHA, 2010). In some occupations, such as construction and firefighting, PPT is the primary or only line of defense against hazardous exposure. PPT effectiveness can be seen every day in the survival and lack of harm experienced by most firefighters. In 2008, U.S. firefighters responded to 1,451,500 calls and suffered 36,595 injuries and 29 deaths on scene at fire incidents (NFPA, 2010).

Researchers have found that individual firefighters not wearing PPT had an increased risk of respiratory health problems. For example, a study of New York firefighters found that individuals who did not wear protective respiratory equipment had statistically significant decrements in acute pulmonary function (Brandt-Rauf et al., 1989). Similar results were found in a study of the effectiveness of respiratory protection for coal miners in West Virginia (Li et al., 2002). In New York City, Prezant and colleagues (1999) found an 85 percent reduction in lower extremity burn injuries, a 65 percent reduction in upper extremity burn injuries, and a significant reduction in head burn injuries in firefighters who used more protective uniforms and hoods.

In successful outcomes to some disaster situations, wearing PPT has played a major role. In 2006, miners in West Virginia used NIOSH/Mine Safety and Health Administration-certified self-contained, self-rescuer respirators, which chemically generate breathable oxygen, in their successful escape from a hazardous mixture of dense smoke and deadly concentrations of carbon monoxide after a mine fire (MSHA, 2006).

## Construction Fall Arrest and Prevention PPT

In the committee's efforts to identify data on the impact of conformity assessment efforts, the data from falls by construction workers were examined. Data collection for evaluating a reduction in fatality rates associated with certification of fall prevention and arrest PPT systems is limited. Falls are the leading cause of U.S. construction worker deaths with on average 363 deaths due to falls annually from the period 1992 to 2005 (CPWR, 2008). Falls are also the second most frequent cause of non-fatal injuries in this industry (CPWR, 2008).

Fall arrest technology has changed rapidly, and Occupational Safety and Health Administration (OSHA) regulations and voluntary consensus

standards have played, and continue to play, an important role in risk reduction. OSHA regulations (29 CFR §1926.502d) prohibiting the use of body belts for fall arrest and requiring full-body harnesses went into effect on January 1, 1998. However, there is no government mandate for the testing or certification of these products. The first American National Standards Institute (ANSI) standard (ANSI Z359) was approved in 1992 and was an important driver in the process that led to the eventual OSHA regulatory change in 1998. NIOSH research (e.g., whole body anthropometry for informing design of fall arrest harness sizing) has been instrumental in informing the regulatory changes and is outpacing changes in practice, such that more aggressive research to practice and standards/certification development efforts are needed.

The impact of regulatory and standards changes regarding fall prevention and fall arrest PPT is difficult to quantify. Recent data on construction worker deaths do not show a change in fatalities due to falls from height. Although the overall death rate of construction workers declined between 1992 and 2005, the number of fatal falls in construction increased (CPWR, 2008). Information on PPT use is often unreported on injury logs and fatality records. In general, assessing the impact of a preventive intervention, that is, proving that a negative outcome did not occur because a preventive measure is taken, is difficult. For that reason, quantifying the impact of PPT is challenging as the goals for using PPT are that a hazardous exposure or event will not occur and that workers will remain safe and healthy.

## Data Needs

Estimates of the occupational health and safety risks due to hazardous exposures can be quantified based on knowledge about the exposure. However, health surveillance data on PPT use in the workplace are limited or missing, including data on the extent and nature of PPT use and on adverse outcomes that occur related to PPT use (those that occur due to PPT failures, while wearing PPT, and when not wearing PPT in work situations requiring PPT use). Without these types of data, there are no drivers to draw attention to PPT performance, use, failures, and interface problems that could be harmful to workers. These types of data are needed to focus PPT standards development and conformity assessment efforts in areas that will significantly improve worker health and safety.

## CONFORMITY ASSESSMENT ISSUES FOR PPT

Several issues regarding testing and certifying PPT products are worth highlighting including PPT interfaces and ensembles, user training, varied work tasks, unintended consequences of wearing PPT, contractual requirements for PPT, and risk assessment.

### Protective Ensembles and Interfaces

Workers wear items of protective equipment to protect against varied workplace hazards, including noise, falling objects, projectiles, dust, fumes, liquid aerosols, and chemical, thermal, radiological, and biological exposure. In many cases workers are provided with individual items of PPT equipment that do not work together or fit together and do not have a seamless interface or seal between pieces of equipment to provide adequate total protection. The cumbersome or ineffective interface among multiple items can often prevent the combination from providing the optimum level of protection. Examples of these problems include wearing both ear muff-style protectors and safety glasses (due to the temples of the glasses) or a half-mask respirators and safety glasses. Similarly, interfaces between coverall sleeves and gloves or between coverall cuffs and boots may result in gaps, overlap, or unprotected areas. The ability of the ensemble to protect the worker depends on the following factors:

- Proper design, manufacturing, and testing of the individual components and the interfaces among components to meet appropriate design specifications and performance standards;
- Ensuring that the combination of individual personal protective equipment items does not degrade the performance of any of the items in the ensemble; and
- Properly training the worker about the workplace hazards and how to assemble, evaluate, wear, clean, store, maintain, and replace the ensemble or any of the items and their components.

A few examples point to the possibilities of developing and implementing ensemble specifications or standards: the National Aeronautics and Space Administration specifications for a propellant handler's ensemble (Stull et al., 1996); the National Fire Protection Association

(NFPA) standard for protective ensembles for structural firefighting (NFPA 1971); the NFPA standard on protective ensembles for first responders to CBRN (chemical, biological, radiological, nuclear) terrorism incidents (NFPA 1994); and the recent National Institute of Justice's CBRN protective ensemble standard for law enforcement (NIJ 0116.00).

For the most part, performance specifications and voluntary consensus standards have been developed to assess the performance of specific personal protective equipment items and do not address issues regarding the interface with other protective equipment or interchange of parts. PPT products are generally manufactured and marketed as individual stand-alone items, and there are no marketplace drivers to incentivize or address interface concerns. Additionally, current marketing and purchasing practices often focus on individual products. NIOSH certification of respirators requires that all components be tested and evaluated, and replacing a component with an aftermarket substitute from a different manufacturer can void the approval.

OSHA has attempted to address the interface issues relevant to respirators by requiring that during mandatory respirator fit testing, the employee also wear other types of PPT (e.g., head protection, hearing protection, eye protection) that could affect respirator performance. Appendix A to OSHA 29 CFR §1910.134 states, "The fit test shall be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit." However, many respirators are used in the workplace without fit testing, making this requirement generally ineffective at identifying and addressing PPT interface issues.

NIOSH and its National Personal Protective Technology Laboratory (NPPTL), working with manufacturers, users, and other stakeholders, can play an important leadership role in efforts to move toward performance standards and test methods for protective ensembles and individual PPT items that address interface issues. Because there are no economic or market incentives for the private sector to develop ensemble or interface standards, it is incumbent on federal agencies, in particular, NPPTL, to expand work on PPT ensembles and interface development. NPPTL's participation in the collaborative approach used to develop a new firefighter's ensemble, Project HEROES (Homeland Emergency Response Operational and Equipment Systems) can be used as a model to develop other PPT ensembles. Specific ensemble performance standards will need to be developed to overcome the current focus on individual PPT items. Given the numerous possible combinations of protective equip-

ment that individual workers could assemble, it is likely that ensembles will need to be designed and used for specific job requirements or that the design of interfaces will need to be standardized so that parts from different manufacturers are interchangeable, although the latter presents numerous challenges.

The healthcare sector is one work sector among many that would benefit from work on protective ensemble standards development and conformity assessment. The committee was asked to address conformity assessment issues relevant to preparing healthcare workers for an influenza pandemic. The issues relevant to conformity assessment for healthcare worker PPT are similar to those for PPT for other occupations; improvements in these processes will result in protective equipment in the marketplace that meets the specified criteria. The one specific issue relevant to this area would be efforts to develop and certify infection control PPT ensembles. Further research clarifying the mode(s) of influenza transmission will inform the development and selection of appropriate PPT ensembles.

Research on protective ensembles for healthcare workers should address infection control precautions at each level of use from standard precautions to the three levels of transmission-based precautions (contact, droplet, and airborne) (Siegel et al., 2007). Healthcare workers face issues of donning and doffing gowns, gloves, medical masks or respirators, shoe and hair covers, and in some cases face shields or other protective equipment. This is especially challenging in emergency situations.

## User Training and Instruction

Another challenge with PPT products is that full protective capabilities of the product are only realized when they are made available by the employer and correctly fitted and used. Respiratory protection programs are mandated by OSHA to ensure that employees are fit tested and go through the training to know how to use respirators (29 CFR §1910.132). Because an effective product is only one component of correct use, greater attention may need to be paid to certifications of trainers and training materials. Personnel certification is addressed separately from product certification in voluntary standards, such as ANSI/ISO/IEC (International Organization for Standardization/International Electrotechnical Commission) 17024, *General Requirements for Bodies Operating Certification of Persons*. In addition, greater attention should be paid to

the manufacturer user instructions that come with the PPT product, with criteria incorporated as part of the standards development and conformity assessment process. These criteria need to be more comprehensive and reflect the use of the individual PPT products with other types of PPT that, when used together, create an ensemble as well as addressing potential interface issues. Easy to read and culturally relevant documents on the selection, care, use, and maintenance of PPT are also critical for worker health and safety training.

Further work into standards that address the selection, use, maintenance, and care of PPT products are needed. For example, for fall arrest technologies to be effective, they must be integrated into practice or programs and must consider other components at the work site (anchorage points, guard rails, personnel nets, etc.). An example of a practice standard is ANSI/ASSE (American Society of Safety Engineers) A10.32, *Fall Protection Systems for Construction and Demolition Operations*. An example of a recent federal effort regarding guidelines is the *NIJ Law Enforcement CBRN Protective Ensemble Selection and Application Guide*, which will soon be released as a companion document to the product performance standard and the certification program requirements document (NIJ, 2010).

## Varied Work Tasks

As highlighted in Chapters 2 and 3, conformity assessment for PPT products involves a number of government agencies and private-sector organizations. The organizations and agencies vary depending on the type of PPT or in some cases its purpose. One of the constants is that all respirators used in occupational settings are required to be certified by NIOSH. Requirements for protective clothing, on the other hand, vary depending on the use (e.g., healthcare worker gowns need Food and Drug Administration [FDA] clearance; protective clothing for firefighters must be certified by third-party organizations to meet NFPA standards; construction hard hats, fall arrest harnesses, and arc flash protective clothing can be voluntarily assessed to meet ANSI-related standards by third-party laboratories and certifying organizations; and protective clothing products for agricultural workers are just beginning to enter the conformity assessment process).

One challenge that will need to be faced in determining the appropriate type and level of rigor needed for PPT conformity assessment

processes is the level of specificity needed for the same or similar products that are used in widely varying work tasks. For example, gloves for healthcare workers are being used for a variety of tasks, some of which place the user at much higher risk of injury, illness, or death if the PPT does not perform effectively. Specific requirements have been put in place that work toward addressing some of these issues, such as the voluntary consensus standards that are incorporated into the FDA guidance for gloves used to administer chemotherapy agents. Finding the appropriate level of differentiation among products for specific work tasks poses challenges to conformity assessment processes for non-respirator PPT.

## Unintended Consequences of Wearing PPT

Although PPT products are designed to protect the worker from various hazards, the use of PPT may affect the worker's productivity or ability to perform tasks due to physical discomfort or impaired senses. These unintended consequences include reduced peripheral vision or visibility, claustrophobia, breathing difficulty, impaired communication, reduced dexterity, increased slip and trip hazards, increased exertion or workload, overheating, static charge risks in explosive atmospheres, and skin abrasion and contact dermatitis. PPT requirements can make simple tasks such as climbing a ladder quite cumbersome. For healthcare workers, wearing respirators or face masks can interfere with communications with patients and their families. Wearing PPT may also give the worker a false sense of security, altering work behavior and thus presenting an increased risk of injury. When setting performance standards and outlining conformity assessment requirements for PPT, consideration needs to be given to reducing or eliminating unintended consequences of wearing PPT.

## Contractual Requirements for PPT

In addition to regulatory requirements mandating that employers provide appropriate PPT to protect their employees, contracts and subcontracts for services or for the purchase of PPT products may impose performance standards. To the extent that customers and regulators evaluate conformance with contractual standards, this provides market in-

centives to participate in various voluntary assurance and conformity assessment processes.

Federal contracts for PPT, or for construction or services, often impose safety and health or quality assurance requirements that extend beyond minimal OSHA compliance, where deemed to be advantageous. The contracts may incorporate additional testing protocols and performance standards (e.g., military specifications); contracts may refer directly to specific consensus standards (e.g., compliance with specific NFPA or ANSI-related standards); or they may incorporate PPT performance requirements by reference to more comprehensive documents such as the *U.S. Army Corps of Engineers Safety and Health Requirements Manual* (U.S. Army Corps of Engineers, 2005). Including specific standards or performance requirements by reference in a federal or federally funded contract is described or authorized under the Federal Acquisition Regulations (FAR 52.233-1 Accident Prevention). This incorporation by reference into contracts helps in simplifying and standardizing contract language across projects and over time, but publicly accessible data on compliance is very limited. Research evaluating the effectiveness of contract requirements or third-party audits of conformance would be valuable in determining whether PPT failures contributed to injury or illness. A research program similar to NPPTL's evaluation of PPT in firefighter fatalities but targeting federal contracts could guide improved public procurement policies.

Another example of incorporating PPT technical specifications by reference is the U.S. Department of Transportation's *Manual on Uniform Traffic Control Devices,* which must be followed on every highway project using federal funds. The manual stipulates adherence to ANSI/ISEA (International Safety Equipment Association) 107, *American National Standard for High-Visibility Safety Apparel and Headwear,* which is a performance standard for high-visibility safety clothing used in work zones.

A similar process of incorporating technical PPT requirements into contracts by reference is also common practice in the private sector. For example, a requirement to conform to the ICC (International Code Council) or BOCA (Building Officials and Code Administrators International) building codes would incorporate by reference the requirements for clothing, gloves, face shield, and safety shoes aimed a protecting workers from arc flash injuries around high-voltage equipment as defined in ANSI/NFPA 70E, *Standard for Electrical Safety in the Workplace*. Arc flash PPT is frequently inadequate and would benefit from a systematic

research program to identify and evaluate enhancements. Consensus NFPA standards are complemented by OSHA requirements for arc flash PPT under 29 CFR §1910.335.

Although tying conformity assessment requirements to a contract may provide much greater financial incentives to comply than relatively small OSHA fines, there are limited quantitative research data supporting the adequacy of the systems in place to ensure that the pass–fail criteria for meeting the performance standards are actually being met. Currently, product testing may be done by manufacturers or importers, either with or without third-party verification and quality assurance. Federal contracts incorporating PPT performance standards and requiring third-party testing with stipulations for follow-up research may provide valuable baseline data to determine the effectiveness of such interventions, similar to Executive Orders that have set aside selected federal building projects to serve as test beds for evaluating innovative "green" and energy-efficiency technologies.

## Risk Assessment

Unlike products that are designed for recreational, informational, computational, or other purposes, PPT products are designed to protect against and reduce hazardous exposures. As mentioned earlier, health risks from known hazardous exposures can be quantified for many work sites. However, categorizing PPT products by the level of risk against which they protect in multiple work sites and for various work tasks can pose challenges. Some current PPT conformity assessment approaches have attempted to categorize products by risk, while others have segmented the products by their use or other criteria.

NIOSH certification of respirators is not based on specific risk assessment. The certification test requirements vary with the type of respirator (e.g., air-purifying, self-contained breathing apparatus). NIOSH has a long-term field evaluation of self-contained, self-rescuer respirators used in mining environments. This may reflect the risk associated with mining environments, but other high-risk sectors (logging, fishing, construction) have an equivalent risk. Using a different approach, the Environmental Protection Agency's labeling regulations for protective devices intended to prevent noise-induced hearing loss do not follow a risk assessment approach. The devices are tested and given a Noise Reduction Rating, and the worker and employer must ensure that equipment

is selected to address the level of noise in the workplace. This is a labeling requirement, but it does not restrict or place mandates on manufacturing, sale, or use.

The European Union uses a three-category system for conformity assessment of PPT (Chapter 3). EU's Category III devices are described as "PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time" (EC, 2010). FDA clearance processes for medical devices are based on a broad assessment of the risk to both the wearer and to the patient. In addition to other requirements, Class I products are defined as "not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury" (21 CFR §860.3).

For personal flotation devices (PFDs), a probabilistic risk-based approach is being explored by the U.S. Coast Guard to categorize the devices based on the probability of a PFD saving the life of a user from drowning in a marine event (Chapter 3). This approach to standards and conformance assessment could be applied to the evaluation and design of conformance assessment programs for various kinds of PPT (Box 4-1).

**BOX 4-1**
**Probabilistic Risk-Based Approach to PPT Conformity Assessment**

The committee explored the use of a probabilistic risk-based approach to PPT conformity assessment that would evaluate and quantify the probability of the PPT product meeting the need to protect the user from the hazards, risks, and/or exposures associated with the user's tasks in the environment and conditions of the system in which he or she works. The result of the analysis might be a "Protection Compliance Index." The assessment would account for the probability and consequence of the occurrence of adverse events to determine risk, and the model would be calibrated based on the levels of risk currently tolerated in the workplace.

To develop a protection compliance index for a PPT product, questions about the product and its selection, use, care, and maintenance, such as the following would likely need to be addressed:

- What is the severity of the consequences of the PPT failure?
- What is the level of user knowledge and control of risk?

*continued*

**BOX 4-1 CONTINUED**

- What is the extent of first-, second-, or third-party involvement in the conformance assessment and what is the influence of those processes on the probability of conformance?
- What laws and regulations exist that impact degree of conformance?
- What are the incentives for producing compliant products and the deterrents to producing noncompliant products?
- Is more than one form of PPT being used in the work task and, therefore, are there interface issues that need to be addressed?
- What is the acceptable quality level in the quality assurance system?
- Are there adequate standards with performance criteria and test methods?
- How likely is a recall to get the products out of the hands of user?

Through investigation of questions such as these a model could be developed that would then be used to outline appropriate conformity assessment schemes and analyze conformity assessment for given products and uses.

## REFERENCES

Brandt-Rauf, P. W., B. Cosman, L. F. Fallon Jr., T. Tarantini, and C. Idema. 1989. Health hazards of firefighters: Acute pulmonary effects after toxic exposures. *British Journal of Industrial Medicine* 46(3):209–211.

CPWR (Center for Construction Research and Training). 2008. *The construction chart book: The U.S. construction industry and its workers*. Silver Spring, MD: CPWR.

EC (European Commission). 2010. *Guide to application of the Directive 89/686/EEC on personal protective equipment—appendix*. http://ec.europa.eu/enterprise/sectors/mechanical/documents/guidance/personal-protective-equipment/appendix/index_en.htm (accessed July 30, 2010).

IOM (Institute of Medicine). 2003. *The future of the public's health in the 21st century*. Washington, DC: The National Academies Press.

IOM and NRC (Institute of Medicine and National Research Council). 2008. *The Personal Protective Technology Program at NIOSH*. Washington, DC: The National Academies Press.

Li, H., M. L. Wang, N. Seixas, A. Ducatman, and E. L. Petsonk. 2002. Respiratory protection: Associated factors and effectiveness of respirator use among underground coal miners. *American Journal of Industrial Medicine* 42(1):55–62.

MSHA (Mine Safety and Health Administration). 2006. *Aracoma Coal Company, Inc., Aracoma Alma Mine #1. Fatal mine fire*. http://www.msha.gov/FATALS/2006/ARACOMA/ARACOMAREPORT.ASP (accessed October 11, 2010).

NFPA (National Fire Protection Association). 2010. *Firefighter activities, injuries, and deaths*. http://www.nfpa.org/itemDetail.asp?categoryID=955&itemID=23605&URL=Research/Fire%20statistics/The%20U.S.%20fire%20service&cookie%5Ftest=1 (accessed August 2, 2010).

NIJ (National Institute of Justice). 2010. *Fact sheet: NIJ CBRN Protective Ensemble Standard for Law Enforcement*. http://www.justnet.org/ListsJUSTNET% (accessed September 20, 2010).

OSHA (Occupational Safety and Health Administration). 2010. *Respiratory protection*. http://www.osha.gov/SLTC/respiratoryprotection/index.html (accessed June 9, 2010).

Prezant, D. J., K. J. Kelly, K. S. Malley, M. L. Karwa, M. T. McLaughlin, R. Hirschorn, and A. Brown. 1999. Impact of a modern firefighting protective uniform on the incidence and severity of burn injuries in New York City firefighters. *Journal of Occupational and Environmental Medicine* 41(6):469–479.

Siegel, J. D., E. Rhinehart, M. Jackson, L. Chiarello, and the Healthcare Infection Control Practices Advisory Committee. 2007. *Guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings, 2007*. http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf (accessed October 12, 2010).

Stull, J. O., K. G. Thompson, and N. Vahdat. 1996. Developing and applying a material specification for NASA's propellant handlers ensemble. In *Performance of protective clothing*, Vol. 5, edited by J. S. Johnson and S. Z. Mansdorf. ASTM STP 1237. American Society for Testing and Materials.

U.S. Army Corps of Engineers. 2005. *Safety and health requirements manual. EM 385-1-1, Section 5. Personal protective and safety equipment*. http://www.usace.army.mil/CESO/Documents/SECTION%2005.pdf (accessed August 12, 2010).

# 5

# Conformity Assessment for Non-Respirator PPT: A Risk-Based Framework

Given the wide range of current approaches used to conduct conformity assessment that are described in part in Chapters 2 and 3, the committee saw the need for a structured framework to evaluate personal protective technologies (PPT) products protecting against comparable risks. This chapter begins by establishing guiding principles that the committee believes are critical to determining the role of government in conformity assessment processes. The chapter then details the committee's proposed tiered approach to conformity assessment that is based on a systems engineering approach[1] to risk assessment. The necessary starting premise for PPT conformity assessment is that well-defined and adequate design specifications and performance standards with pass–fail criteria are in place for these products; the committee recognizes that further work on product standards is needed in some cases.

## GUIDING PRINCIPLES FOR CONFORMITY ASSESSMENT

In discussions on conformity assessment issues, the committee realized that several overarching principles were guiding its considerations. To determine the optimal approach for conformity assessment and then

[1]Systems engineering is an interdisciplinary approach to product development across the cycle from conceptualization to production to operation. The process begins with defining customer needs and required functionality early in the development cycle, documenting requirements, and then proceeding to design synthesis and system validation while considering the complete product cycle: operations, performance, manufacturing, testing, cost and schedule, training and support, and disposal (INCOSE, 2010).

implement that approach, the committee deemed the following as underlying principles to a conformity assessment framework:

- Conformity assessment efforts for PPT should be focused on reducing or eliminating the risks of worker injury, illness, or death; therefore the framework should be risk based.
- End users can provide realistic and practical input into the types of equipment needed to protect against job hazards and should be involved in developing and implementing conformity assessment processes.
- Adequate standards for product performance, use, and testing need to be clearly specified and serve as a prerequisite to conformity assessment.
- The burden and cost of conformity assessment processes need to be considered.
- A total life cycle approach is needed that includes postmarketing testing, evaluation, and surveillance, as well as an effective recall system.
- The conformity assessment process should promote and not inhibit product innovation.

## Risk-Based Approach

The degree of potential risk to the user from the failure of a product during use in a specific task should determine the rigor of the conformity assessment process, whether the process calls for first-, second-, or third-party declaration of conformity. The potential risk is a function of the probability of product failure and the impact on user health and safety due to the failure, assuming proper use of the product. For instance, if a bulletproof vest is penetrated by a projectile, the impact can be fatal for the user; therefore, the degree of potential risk due to failure is high. The probability of occurrence of failure will depend on the task in which the worker is engaged. Thus, the potential risk to the safety and health of the worker should be the key factor in determining the type of conformity assessment process that should be adopted; the greater the risk to the end user in the event of product failure, the greater should be the rigor of the conformity assessment process. This could be implemented for PPT used in medium and high-risk work environments through independent third-party testing and certifying processes.

## Pragmatic Factors

In addition to this *health and safety* perspective, a set of factors should be considered from a *pragmatic* perspective in the selection of the type of conformity assessment process. The pragmatic factors include the following:

- Complexity of the product—design, manufacturing, and use;
- Cost—economic and time:
  - Cost of nonconformance or penalty to manufacturers, including legal liability,
  - Cost of the conformity assessment process and the financial burden on manufacturers, especially with respect to the production volume,
  - Length of the conformity assessment process and its impact on the introduction of innovative technologies, and
  - Duration of validity of certification and the cost and time associated with periodic recertification;
- Degree of competition in the marketplace for the specific PPT and the barriers to entry for innovative products or new companies;
- Availability of reliable test methods for effectively determining compliance;
- Globalization of PPT production and deployment;
- Follow-up and penalties on fraudulent products; and
- Implications from a public health perspective.

As the complexity of the product increases—in design, manufacturing, or use—the chances of error or nonconformity increase. Moreover, if the product is part of an ensemble, the opportunities for interface-related errors increase, and these could potentially compromise performance in the field. In such instances, the conformity assessment process becomes very important. If the cost of nonconformance is high for the manufacturer either because of severe penalties or loss of business, there may be a greater incentive for the manufacturer to ensure the conformity of the product.

A cost is associated with the conformity assessment process. If the cost is prohibitively high, especially if the production volumes are low, the cost may deter manufacturers from seeking conformity assessment or they might attempt to pass on the increased cost to the customer, especially if the degree of competition is low, opportunities for substitution

are minimal, or supply is limited, among many factors. Such increases in costs could potentially deter end-user organizations from procuring the necessary PPT due to budgetary constraints. If the duration of the conformity assessment process is long and arduous, it may delay the introduction of newer technologies on an ongoing basis; in the extreme case, manufacturers may decide not to release newer technologies just to avoid the high conformity assessment costs. Of course, the manufacturer's behavior will be governed by the degree of competition in the field for that PPT. Absence of competition or low levels of competition may cause manufacturers to delay introduction of newer technologies to avoid the cost of the conformity assessment process.

If the manufacturing capabilities (equipment, infrastructure, and other resources) required for entering the market are significant, manufacturers who could potentially engage in the production of inferior products may be deterred. If defects in products can readily be seen or recognized by the user prior to use, the conformity assessment process may not need to be highly rigorous. If standard test methods have been defined and are readily available for assessing the conformance of the product to specifications, the conformity assessment process will be easier to implement. The costs and time associated with periodic recertification are also important to the manufacturer. The PPT industry and marketplace are becoming increasingly global, which means production processes are distributed around the world as manufacturers attempt to respond to user needs and also reduce production costs. Consequently, strict process and quality control systems are needed in manufacturing, thus requiring a rigorous conformity assessment process. Finally, the use of such a process can serve as a deterrent to the entry of low quality, ineffective, or counterfeit products in the marketplace that could potentially compromise the user's safety and health.

Thus, in selecting the level of conformity assessment process for PPT, a holistic view of the *health and safety* and *pragmatic* perspectives must be considered, with the ultimate objective of ensuring that the *right* PPT is used by the worker for the task at hand.

## A TIERED APPROACH TO PPT CONFORMITY ASSESSMENT

The basis for the tiered framework for non-respirator PPT conformity assessment is the level of potential risk to the user in the event of product failure (equivalent to the worker not using PPT for the task) and other pragmatic considerations such as the size of the population using the product; the economics of the conformity assessment process; and other factors discussed earlier. In looking at the potential conformity assessment approaches, federal agencies could play several roles, ranging from no intervention to complete oversight of the conformity assessment process. Other potential roles include laboratory accreditation, involvement in the standards-setting process, development and assessment of potential test methods, post-marketing testing and evaluation, health surveillance, enforcing penalties or providing incentives, and serving as an information clearinghouse.

The committee considered other approaches currently in use that apply risk categorization to conformity assessment for PPT and other devices. As described in earlier chapters, the European Union has a risk-based approach to PPT conformity assessment and the Food and Drug Administration (FDA) uses a broader risk-based categorization of medical devices. While the framework developed by the committee is also risk-based, it does not attempt to duplicate or emulate those methodologies.

The committee's analysis and consideration of a wide range of conformity assessment approaches and issues detailed throughout this report have led to the proposed risk-based tiered categorization approach for PPT that is summarized in Table 5-1. Prior to implementing the conformity assessment approaches, it would be the government's responsibility to specify the required standards that must be met for PPT products used in the workplace, which is in keeping with the current role of the Occupational Safety and Health Administration (OSHA) and other regulatory agencies.

### PPT with Low Degree of Potential Risk

For products that present a low risk of injury, illness, or death to the user in the event of product failure, first-party testing and declaration of the product's conformance to voluntary consensus standards would be

**TABLE 5-1** Risk-Based Framework for Non-Respirator Personal Protective Technologies (PPT) Conformity Assessment

| | Conformity Assessment Responsibilities | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Degree of Risk to the User's Safety and Health[a] | Product Testing | Accredit Testing Labs | Declaration of Product Compliance | Conduct Post-Marketing Testing, Evaluation, Surveillance | Recall Products | Listing of Certified Products[b] | Institute Tracking Label | Provide Oversight to the Conformity Assessment Process |
| Low | First party | Voluntary | First party | Voluntary | First party | | | First party |
| Medium | Third party | Third party | Third party | Third party | Third party | Federal govt. agency | | Third party |
| High | Third party | Third party | Third party | Third party | Third party | Federal govt. agency | Third party | Federal govt. agency |

NOTE: The term *third party* is used to denote that the responsibility could be carried out by either private-sector organizations or federal government agencies that are independent of the product manufacturer.
Govt. = government.
[a]Risk is based on the potential for illness and injury that would result from failure of the PPT product.
[b]Listing could provide links to lists of certified products from third-party private-sector and government certifying organizations and agencies.

adequate. Therefore, for PPT products for low-risk use, the role of federal agencies in the conformity assessment process would be to specify the standards to which the product must conform and require first-party declaration by the manufacturer that the product meets the standards.

### PPT with Medium Degree of Potential Risk

For products that present a medium risk of injury, illness, or death to the user in the event of product failure, third-party testing and declaration of conformity assessment would be required. The role of federal agencies in the conformity assessment process would be to do the following:

- Specify the required standards; and
- Require third-party testing and certification by accredited entities.

The committee recommends in Chapter 6 that the National Personal Protective Technology Laboratory (NPPTL) develop and maintain an online resource (available through a website and/or other sources) that provides access to lists of all certified products in this category (and for high-risk use). Such a resource could help end users identify the correct product for the specific task and allow for easy identification of products that do not meet required standards. Links could be provided to listings of certified products from third-party private-sector certifying organizations as well as to similar databases in other agencies such as the Coast Guard's Maritime Information Exchange—Approved Equipment (USCG, 2010). Such a site would not only help end users select the correct PPT product, but it would also help spot problems and potentially prevent substandard products from reaching end users.

### PPT with High Degree of Potential Risk

For products that present a high risk of illness, injury, or death to the user in the event of product failure, third-party testing and declaration of conformity assessment would be required. The conformity assessment process should include the specification of design and performance standards, periodic (unannounced) inspection of production facilities, evaluation of quality control techniques and standards in the manufacturing plants, product audits, post-marketing evaluations and surveillance, and

enforcement. The role of federal agencies in the conformity assessment process for these products would be to do the following:

- Specify the required standards;
- Require third-party testing and certification by accredited entities; and
- Provide oversight to any technical issue that may arise and assist the certifying organization in the enforcement of the conformity assessment process for non-respiratory PPT.

For products with high degree of risk in the event of product failure, additional requirements would include the use of tracking labels that could lead to faster recall or compliance enforcement in the event of product failure. As in the case of products in the medium degree of risk category, NPPTL should provide a resource that provides access to lists of all certified products in this class (as described above).

The committee recognizes that the proposed tiered approach to risk classification must be considered on an individual product basis and also take into account the specific task in which the PPT will be used. For instance, the degree of risk to the user's hearing loss when using hearing protection in an automobile repair facility may be comparatively lower than the risk to another worker using hearing protective equipment on the airport runway. So, hearing protection PPT may call for two or more risk tiers. On the other hand, firefighters are subjected to a high degree of risk due to product failure when engaged in firefighting and hence their protective clothing may have only one tier or class of risk. Thus, the committee emphasizes that it is important to carefully evaluate the specific PPT product in conjunction with its use in a specific task and accordingly assign it to the appropriate risk category. Finally, the host of pragmatic factors presented earlier should be weighed in along with the health and safety factors in determining the appropriate level of conformity assessment for that PPT product. Given the complexity and time required to develop such a detailed classification scheme, the committee did not engage in that task and proposes it as a recommendation in Chapter 6.

The committee recognizes that many conformity assessment processes already in place can fit into this framework. What will be important will be to make decisions that provide workers across all occupations who face risks of similar severity to be able to use protective equipment that is adequately tested and, where necessary, that there is third-party confirmation that the product is safe and effective for use.

Classifications of PPT should be revisited periodically as evidence and knowledge gained through health surveillance systems and analyses of the results of conformity assessment processes are accumulated over time.

## REFERENCES

INCOSE (International Council on Systems Engineering). 2010. *What is systems engineering?* http://www.incose.org/practice/whatissystemseng.aspx (accessed August 2, 2010).

USCG (U.S. Coast Guard). 2010. *United States Coast Guard Approved Equipment Listing* (http://cgmix.uscg.mil/equipment/equipmentsearch.aspx (accessed July 20, 2010).

# 6

# Findings and Recommendations

## A COMPREHENSIVE RISK-BASED FRAMEWORK FOR PPT CONFORMITY ASSESSMENT

In considering conformity assessment for personal protective technologies (PPT) used in the workplace, the committee recognized the broad array of PPT products and the wide range of job tasks that people perform while using this equipment. Within the same basic type of PPT, for example gloves, there are wide variations in requirements that must be met to protect workers—protecting construction workers from lacerations when handling sheet metal, healthcare workers handling chemotherapy agents, firefighters facing flames and hot surfaces, and agricultural workers applying pesticides. The lives or health of many members of the U.S. workforce depend on the proper selection and reliable performance of various types of PPT. Reliable conformance of these products to appropriate performance standards is critical.

Current U.S. approaches to occupational PPT are fragmented, often by job sector. Little has been done to classify PPT products based on a comprehensive risk-based framework, which can then be used to identify gaps, prioritize resources, determine and direct conformity assessment efforts, and ensure consistent conformity assessment approaches for comparable products, with the goal of improving worker safety and health. In Chapter 5, the committee began the process toward a comprehensive framework by outlining the guiding principles and a risk-based approach that is needed to categorize PPT, and then outlining options for conformity assessment that could be associated with each category of PPT. Data on the occupational health risks of a specific job due to haz-

ardous exposures in the workplace can be estimated based on knowledge about the exposure; this information can be used to categorize PPT.

Throughout the report the committee documents a wide range of approaches to PPT conformity assessment and the varied nature of government agency involvement in these processes. The role of federal agencies ranged from an all-encompassing role in each phase of conformity assessment (e.g., respirators) to more specific roles such as standardized labeling (e.g., Noise Reduction Rating labels for hearing protection devices). Other roles for federal agencies include accrediting testing laboratories or specifying accreditation organizations. For some products, the government agency acts as the certifying organization. A unique government role in a voluntary third-party conformity assessment program is evidenced by the Bulletproof Vest Partnership Program, through which the Department of Justice provides a financial incentive through matching grants to law enforcement agencies to purchase compliant body armor. Government agencies also play key roles in the research needed to support standards development and conformity assessment processes, including the development and assessment of potential test methods. Health surveillance also can be facilitated through the work of federal, state, or local agencies.

The committee emphasizes that consistency in the level of rigor required for conformity assessment of PPT products used for tasks with comparable risks is a priority. Therefore, the first step is to establish a framework that will categorize similar products based on the level of risk (low, medium, or high) to the health or safety of the worker that could result from failure of the product (equivalent to not using PPT), while also considering feasibility, cost, and other pragmatic factors described in Chapter 5 (e.g., cost of conformance, impediments to innovation, competition, comfort, durability, globalization, risk to manufacturer's reputation due to poor product quality and/or product failure). Conformity assessment requirements would be detailed for each category of products in the framework. Efforts will be needed to identify the gaps and inconsistencies in current approaches for specific types of PPT, particularly for those in the medium- and high-risk categories. Regulations mandating that PPT products used in the workplace adhere to conformity assessment and certification processes will be critical to ensuring that more rigorous product testing and audit requirements are met. An increased role for third-party testing and conformity assessment is recommended for many types of PPT because of the value of independent assessments in increasing the rigor of the process. As noted throughout

this report, third-party testing and declaration of conformity assessment can and are being done largely by third-party private-sector organizations, which is consistent with the approach of the *National Technology Transfer and Advancement Act* (Public Law 104-113).

The recommendations provided in this chapter are focused on the role of the National Institute for Occupational Safety and Health (NIOSH), and specifically the National Personal Protective Technology Laboratory (NPPTL), as it is the only federal organization that is focused solely on PPT and therefore has a leadership role in addressing PPT issues. However, the actions that are recommended require coordination and cooperation with multiple federal agencies, private-sector corporations and organizations, workers, and other stakeholders. Box 6-1 summarizes the findings of the committee regarding non-respirator conformity assessment efforts.

**BOX 6-1**
**Findings on Conformity Assessment**

**Range of Conformity Assessment Efforts**

- Currently, conformity assessment efforts for non-respirator personal protective technologies (PPT) products involve a wide range of processes, some of which rely on manufacturers' attestation that the product meets the relevant voluntary consensus standards and others that require third-party independent testing and/or certifying that the product's performance meets the required criteria. Several approaches to third-party conformity assessment processes using either mandatory or voluntary consensus standards appear to be successful in assessing the effectiveness of PPT.
- The Food and Drug Administration and European Union use tiered, risk-based approaches to conformity assessment of PPT; opportunities exist to enhance these processes.
- Several mechanisms exist for accrediting private-sector laboratories and certifying organizations to conduct testing of PPT products. The accreditation process based on American National Standards Institute/International Organization for Standardization requirements is commonly used for accrediting these organizations.
- Product specifications and procurement practices that reference standards and conformity assessment mechanisms provide the basis for client- and customer-driven systems.

**Product Standards**

- Product standards that require validated test methods and include adequate pass/fail requirements are the basis for rigorous and thorough conformity assessment processes. End-user input is critical to the development of valid and useful standards.

*continued*

BOX 6-1 CONTINUED

Role of Government Agencies

- Involvement of federal government agencies in the conformity assessment process for PPT has been shown to be beneficial for worker health and safety, as evidenced by certification of respirators and body armor. The role of federal agencies varies considerably among conformity assessment processes. Although there are models of collaboration among government agencies (e.g., National Institute for Occupational Safety and Health, Environmental Protection Agency, and Department of Homeland Security), opportunities to improve these relationships exist.
- Government acquisition of products, structures, and services can demonstrate leadership and better serve the public by specifying PPT that meet performance standards through procurement procedures.

**Recommendation 1: Develop and Implement Risk-Based Conformity Assessment Processes for Non-Respirator PPT**

**The National Institute for Occupational Safety and Health (NIOSH) should work with other relevant government agencies, certifying and accrediting organizations, manufacturers, and end users to develop, implement, and support conformity assessment processes for non-respirator PPT. These conformity assessment processes should be commensurate with the level of risk of injury, illness, or death that could result from failure of the PPT to protect the user from workplace hazards.**

**NIOSH's National Personal Protective Technology Laboratory (NPPTL) should serve in a leadership role and convene other relevant government agencies, certifying and accrediting organizations, manufacturers, and end users to develop and implement a comprehensive, tiered risk-based framework for the classification and conformity assessment of PPT products for specific applications. This framework should be based on the degree of risk to the safety and health of the user and other factors affecting the feasibility of implementing the proposed conformity assessment processes. To develop this framework and implement the conformity assessment processes, the committee recommends that**

- **Components of the tiered PPT conformity assessment framework include the following categories and actions:**

  - **Low risk—manufacturer's attestation to meet relevant standards,**
  - **Medium risk—third-party testing and certification, and**
  - **High risk—third-party testing and certification with government involvement to provide oversight and to assist in enforcement;**
- **Current processes and innovative models (e.g., probabilistic models) should be explored, where adequate data exist, for assessing the level of risk and incorporating other feasibility factors into categorizing PPT;**
- **NIOSH NPPTL should work with other relevant federal agencies, manufacturers, organizations, and end users to identify current gaps and priorities in conformity assessment for medium- and high-risk PPT use, and to subsequently engage in developing and implementing the appropriate conformity assessment processes;**
- **NPPTL and other government agencies should have the appropriate level of engagement in the conformity assessment processes for non-respirator PPT depending on the risk level; and**
- **Government contracts should specify that PPT used in work to fulfill those contracts must meet the requisite level of conformity assessment based on the comprehensive risk-based PPT framework.**

## RESEARCH, SURVEILLANCE, AND COMMUNICATION

As outlined in its vision statement, NPPTL aims to be the leading provider of quality and timely PPT research, training, and evaluation. NPPTL is already substantively involved in many aspects of conformity assessment for non-respirator PPT, particularly through active involvement in voluntary standards development and development of test methods. Continued efforts in standards setting would be enhanced with NPPTL working with stakeholder organizations and other government agencies to encourage and promote end-user involvement in the development of voluntary consensus standards.

As a research agency, NPPTL is well suited to furthering its ongoing efforts to develop test methods and conduct research that contributes to the development of voluntary consensus standards and other conformity

assessment efforts for improving PPT. In particular, the committee emphasizes protective ensembles and believes that NPPTL should focus efforts on PPT interface and related issues that are important in ensuring the effective use of multiple types of PPT or integrated ensembles. A new area for exploration could be the development and evaluation of the effectiveness of integrated ensembles for healthcare worker infection control precautions.

Increased post-marketing testing, evaluation, and surveillance are key factors in enhancing PPT products for worker use. The limited availability of data on product effectiveness across the life cycle of PPT, and in particular on PPT use in the workplace (including use of PPT in emergency conditions), is currently hindering improvements in PPT and PPT conformity assessment processes. A surveillance network that draws on and expands current surveillance systems already in place (see Chapter 2) could provide information needed to identify workplace tasks where injuries, illnesses, or deaths are occurring because of noncompliant and/or poorly manufactured PPT, inadequately or incorrectly labeled PPT, the PPT not being provided by the employer, and/or any end-user performance issues associated with PPT (e.g., the incorrect use of PPT due to inadequate or improper training that could shed light on PPT training needs). This type of information will also support the development of an effective PPT recall system to prevent additional worker injury or illness when PPT performance problems are identified.

The fragmented nature of current PPT conformity assessment has resulted in multiple and diverse sources of information that employers, workers, and others need to consult in order to identify certified equipment or find independent information on non-respirator PPT. NPPTL currently administers its Certified Equipment List, which details the respirators and respirator components that meet certification criteria. This has been found to be valuable to end users and administrators responsible for selecting and providing respirator protection for workers. Similarly, the Responder Knowledge Base is a comprehensive resource for selecting emergency responder PPT. A single reputable source of information on all certified PPT is needed to provide end users, employers, and purchasers the ability to make informed PPT selections for a wide range of jobs and job tasks. This listing (available through a website and/or other sources) should include data on the product, relevant standards, the certification mark, date of certification, training requirements for safe use, and any product recalls and safety alerts about PPT. This expanded list of certified equipment could link to lists of certified equipment from accre-

dited third-party certifying organizations. Integrating information into this resource from the proposed surveillance system could provide additional information on PPT products. Box 6-2 summarizes the committee's findings on research, surveillance, and communication issues.

**BOX 6-2**
**Findings on Research, Surveillance, and Communication**

**NPPTL Expertise**

- The National Personal Protective Technology Laboratory (NPPTL) has unique expertise in personal protective technologies (PPT). There are opportunities for NPPTL to play an expanded role in standards setting and conformity assessment for non-respirator PPT, including research, surveillance, and communication.

**PPT for Healthcare Workers in an Influenza Pandemic**

- The unique strengths and expertise of the NPPTL, part of the National Institute for Occupational Safety and Health, could be better used to enhance PPT for healthcare workers through increased collaborations with the Food and Drug Administration.

**Limits on Current Data and Need for Enhanced Surveillance and Post-Marketing Evaluation Data**

- Assessing the impact of conformity assessment processes for specific PPT on worker safety and health is a challenge because of limited data collection systems and the difficulty in collecting data, especially in occupations where: (1) multiple safety measures are implemented; (2) exposures are intermittent or variable; or (3) risks are poorly characterized. Surveillance systems and follow-up data on field use of PPT are needed to determine where improvements are needed in standards and conformity assessment processes.

**Communication of PPT Conformity Assessment**

- Currently there is no comprehensive repository or database with government oversight that provides information to end users on certified non-respirator PPT. This information is needed so that end users can select PPT to meet the required standards for a specific work task.

**Recommendation 2: Enhance Research, Standards Development, and Communication**

**NIOSH NPPTL should continue and expand its role in PPT conformity assessment. Specifically, NPPTL should**

- **Continue its involvement in standards-setting processes and committees and facilitate end-user participation in voluntary consensus performance-based standards;**
- **Expand research efforts on non-respirator PPT (based on risk assessment and opportunities) to include further efforts to establish standards and to develop test methods;**
- **Develop and maintain an online resource (available through a website and other sources) that provides access to listings of all non-respirator PPT products that meet third-party conformity assessment requirements;**
- **Expand its role and become the primary clearinghouse for reliable information on non-respirator PPT;**
- **Fund research and support standards development necessary to test and certify protective ensembles, develop criteria for standardized interfaces, and flag non-conforming ensemble components; and**
- **Expand its efforts in influenza pandemic-related research and conformity assessment for infection control ensembles.**

**Recommendation 3: Establish a PPT and Occupational Safety and Health Surveillance System**

**NIOSH should work with the Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), third-party certifying organizations, and other relevant organizations to establish an electronic PPT and Occupational Safety and Health Surveillance System that includes data on PPT product effectiveness in the workplace. This system would involve the collection and analysis of data across the life cycle of PPT products (from design and production to worker use and maintenance) on the use of PPT, the failure of PPT, and adverse outcomes (injury, illness, fatality) that occur while wearing PPT in the workplace,**

**including information on the performance standards assessed and adherence to labeling requirements. These efforts should collect and analyze data on PPT product effectiveness in the field by collaborating with existing surveillance programs and expanding where needed to incorporate data collection on PPT use across industries including product recall information. The surveillance system should link to the expanded Certified Equipment List. Potential sources of collaboration include**

- **Other NIOSH surveillance and data collection systems, including the Fatality Assessment and Control Evaluation program, health hazard evaluations, and the Sentinel Event Notification System for Occupational Risk (SENSOR);**
- **CPSC's recall database, unsafe product reporting system, and the National Electronic Injury Surveillance System (NEISS);**
- **The FDA's surveillance and adverse event reporting databases, such as the Medical Product Safety Network (MedSun), the FDA Safety Information and Adverse Event Reporting Program (MedWatch), and the Manufacturer and User Facility Device Experience (MAUDE) database; and**
- **OSHA's injury and fatality investigations and surveys to collect information about injuries or illnesses potentially due to the failure of PPT.**

# 7

# Toward a Comprehensive Approach to Safe and Effective PPT for Workers

As noted throughout this report, there are currently a number of inconsistencies in the nature and rigor of the conformity assessment processes that personal protective technologies (PPT) are required to meet in the United States. To ensure that workers are using PPT that meets required standards, the committee has recommended that the National Institute for Occupational Safety and Health's (NIOSH's) National Personal Protective Technology Laboratory (NPPTL) work with other agencies, standards and certifying organizations, end users, and others to develop and implement a tiered risk-based approach that would categorize various types of PPT and apply consistent conformity assessment requirements. From the committee's perspective, this tiered approach has the advantage of addressing all types of non-respirator PPT and raising the quality of PPT conformity assessment. Although implementing this approach will be a major effort, it will incentivize non-respirator PPT developers and manufacturers to innovate and develop new products and technologies expeditiously to further enhance worker safety and health. This commitment to improve non-respirator PPT by strengthening the conformity assessment processes also necessitates an equally strong commitment to training and use of PPT. Equipment that successfully passes the conformity assessment process will not protect the worker if the selection and fit are incorrect, the PPT is not provided by the employer, or the PPT is used improperly.

The rapid entry of certified products and technologies into the marketplace and workplace is critical, especially during events such as the recent novel H1N1 influenza pandemic. While federal agencies have processes in place for emergency authorizations to rapidly approve products for deployment in such situations, the proposed comprehensive ap-

proach to risk analysis and conformity assessment will eliminate the need to operate in a crisis mode that could inadvertently lead to the entry of unsafe products into the marketplace. Adopting a systems approach to conformity assessment for non-respirator PPT will complement the systems approach to PPT design and development recommended in a prior IOM report (IOM, 2008) and will also lead to an integrated system for certifying and regulating PPT.

What will it take to make this change happen? First, government agencies, employers, workers, and other stakeholders must recognize that improving the health and safety of workers is of critical importance and impacts both economic and national security. For example, the shortage of healthcare workers during an influenza pandemic (due to lack of effective PPT or other reasons) can negatively impact the nation's health, productivity, and security. Second, adequate resources and staffing will be required of relevant government agencies, labor and manufacturing organizations, standards-setting organizations, third-party testing laboratories and certifying organizations, and others engaged in ensuring the safety and effectiveness of PPT. Third, PPT end users must actively participate in the process by providing feedback based on experience in using PPT in work and emergency situations. Fourth, demand for certified products needs to be made evident. Professional organizations specific to various occupations (e.g., the Joint Commission) must reinforce the requisite conformity assessment processes for products used by workers in those fields. Government and private-sector contracts need to specify that PPT used in that work must meet performance criteria. Finally and most importantly, regulatory requirements will largely drive whether change occurs. Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA) regulations that stipulate requirements for third-party testing and certification, where applicable, can provide the impetus to drive the change that will result in a more consistent, comprehensive, and risk-based approach to PPT conformity assessment. The goal is ensuring and maintaining a safe and healthy workforce.

## REFERENCE

IOM (Institute of Medicine). 2008. *Preparing for an influenza pandemic: Personal protective equipment for healthcare workers.* Washington, DC: The National Academies Press.

# A

# Agendas of Public Meetings

**INSTITUTE OF MEDICINE**
Board on Health Sciences Policy

**COMMITTEE ON THE CERTIFICATION* OF PERSONAL PROTECTIVE TECHNOLOGIES**

*The National Academies*
*Keck Center*
*Room 109*
*500 Fifth Street, NW*
*Washington, DC*

**AGENDA**

**Open Session**
**Thursday, January 28, 2010**

**10:30 a.m.** **Welcome and Introductions**
*Howard J. Cohen,* Committee Chair

**Sponsor's Charge to the Committee and Background Information**

*Certification is defined broadly to encompass the entire conformity assessment process. The workshop and study are focused on non-respiratory personal protective technologies.

*Maryann D'Alessandro,* Associate Director for Science, NPPTL, NIOSH
*Les Boord*, Director, NPPTL, NIOSH

**Discussion**

**12:00 p.m.** **Lunch**

**1:00 p.m.** **Context for the Study**

1:00–1:45 Overview of Product Conformity Assessment and Examples of Various Approaches to Certification
*Gordon Gillerman,* NIST

Discussion

1:45–2:30 ASTM International—Certification Program
*Tim Brooke,* ASTM

Discussion

2:30–2:45 Break

2:45–3:30 Certification of Personal Flotation Devices
*Samuel E. Wehr,* Independent Consultant

Discussion

**3:30 p.m.** **Adjourn Open Session**

## COMMITTEE ON THE CERTIFICATION* OF PERSONAL PROTECTIVE TECHNOLOGIES

## WORKSHOP

*The National Academies*
*Keck Center*
*Room 100*
*500 Fifth Street, NW*
*Washington, DC*

**Tuesday, April 13, 2010**

**8:00 a.m.** **Welcome and Opening Remarks**
*Howard J. Cohen,* Committee Chair

**8:10 a.m.** **Overview and Terminology**
*Gordon Gillerman,* National Institute of Standards and Technology

**8:30 a.m.** **Session 1: Current Certification Efforts in PPT: Firefighter Ensembles**
Facilitator: *Roger L. Barker*

| | |
|---|---|
| 8:30–8:40 | Overview of the Process<br>*Roger L. Barker* |
| 8:40–8:50 | *Richard M. Duffy,* International Association of Fire Fighters |
| 8:50–9:00 | *Diane Haithcock,* Underwriters Laboratories |
| 9:00–9:10 | *Eric Beck,* MSA, Inc. |
| 9:10–9:30 | Discussion with the Committee |

**Questions:**

- Overview of the conformity assessment process for firefighter protective equipment: Who sets the standards? What products or materials are tested? Who does the testing? Who accredits the testing labs? Who provides the certification?
- Why was this process developed? What is or should be the role of government in the

certification process? What factors were considered in establishing the process as a third-party testing process?

- What is the typical time line? What is the typical fee structure? What is the duration of validity of the certification? What post-marketing surveillance activities are conducted? What production oversight procedures are in place? How are mislabeling or other false assertions of certification addressed?
- What are the incentives or barriers to assessing and asserting conformity?
- What are the challenges regarding innovation, interfaces among PPT components, etc.? What needs to be done to improve the conformity assessment process? What value is added by having a conformity assessment/certification process in place? Are data available on how certification of firefighter ensembles impacts firefighter safety and health?

**9:30 a.m.** **Session 2: Current Conformity Assessment Efforts: Other Products**
Facilitator: *Melissa A. McDiarmid*

| | |
|---|---|
| 9:30–9:45 | Body Armor Safety Initiative<br>*Lance Miller,* National Law Enforcement and Corrections Technology Center |
| 9:45–10:00 | EPA Noise Reduction Rating Program<br>*Ken E. Feith,* Environmental Protection Agency |
| 10:00–10:15 | Consumer Product Safety<br>*J. Gibson Mullan,* U.S. Consumer Product Safety Commission |
| 10:15–10:30 | CBRN Ensembles for Law Enforcement<br>*Debra Stoe,* National Institute of Justice |
| 10:30–11:00 | Discussion with the Committee |

**Questions:**

- Overview of the certification/conformity assessment processes: Who sets standards? Who tests? Who accredits? Who provides the certification? What value is added by having a conformity assessment/certification process in place?
- What is the role of government in the process? How were decisions made regarding the role of government?
- What is the typical fee structure?
- What is the duration of validity of the certification? What production oversight procedures are in place? What post-marketing surveillance activities are conducted? How are mislabeling or other errors in assertions of conformity assessment addressed?
- What are the challenges regarding innovation? What are the incentives or barriers to assessing and asserting conformity? What needs to be done to improve the conformity assessment process? Are data available on how certification impacts worker or consumer safety?

**11:00 a.m.** **Session 3: Measuring the Impact of Certification on Worker Safety and Health**
Facilitator: *Barbara J. Burgel*

11:00–11:15 *Patricia A. Gleason,* Safety Equipment Institute
11:15–11:30 *Preston Anderson,* Sperian Fall Protection, Inc.
11:30–11:45 Discussion with the Committee

**Questions:**

- How do standards and conformity assessment/certification impact worker safety? What data are available?

- What value is added by having a certification/conformity assessment process in place?

**11:45 a.m.** **Lunch**

**12:30 p.m.** **Session 4: Incentives and Barriers to Conformity Assessment and Certification**
Facilitator: *James S. Johnson*

12:30–12:45 *Ginny Fitzner,* Directorate of Standards and Guidance, OSHA
*Kevin Robinson,* Nationally Recognized Testing Laboratories Program, OSHA
12:45–12:55 *Louise Kuhny,* Joint Commission (via phone)
12:55–1:05 *Robin T. Scott,* Sport Dimension, Inc.
1:05–1:15 *Daniel K. Shipp,* International Safety Equipment Association
1:15–1:45 Discussion with the Committee

**Questions:**

- What drives the need for conformity assessment/certification? For government? For manufacturers? For consumers? How is the balance determined between being overly prescriptive and not prescriptive enough?
- What issues do regulatory or accrediting organizations consider in stipulating the need for products to meet specific standards or certification requirements?
- What is the value of certification in terms of patient safety and worker safety? Does the Joint Commission provide feedback or incentive to healthcare facilities that choose to purchase certified equipment? Does the Joint Commission have any PPT standards related to healthcare worker safety?

- What are the relative costs of various certification mechanisms to the final product and what are the differences in manufacturing to meet different certification requirements globally?
- How does a manufacturer decide if it is worth investing in third-party testing or certification or if a new product is worth bringing to market if certification is required?

**1:45 p.m.** **Session 5: Risk-Based Approaches to Conformity Assessment**
Facilitator: *Anugrah Shaw*

| | |
|---|---|
| 1:45–2:00 | *Gordon Gillerman,* National Institute of Standards and Technology |
| 2:00–2:15 | *Markham C. Luke,* Center for Devices and Radiological Health, FDA |
| 2:15–2:45 | Discussion with the Committee |

**Questions:**

- What risk-based approaches have been used to develop current conformity assessment processes?
- Should the development of a conformity assessment process take into account the effectiveness of recalls in the product category or consider the likelihood that the user can effectively determine the quality and suitability of the product for the intended use?
- What current process is used at the FDA to assess the level of risk of a medical device and make determinations about the device class and whether the 510(k) process is required? Are medical device determinations predominantly based on risk to the patient or the healthcare worker or both? What are the current post-marketing surveillance efforts for device safety? Are any medical devices required to go through third-party testing prior to FDA clearance? How

are devices (e.g., gowns) regulated that are sold without having gone through the FDA medical device clearance process?

**2:45 p.m.** **Session 6: Case Study: Healthcare Worker Gloves**

Facilitator: *Alexander Isakov*

| | |
|---|---|
| 2:45–3:00 | *Terrell Cunningham,* Food and Drug Administration |
| 3:00–3:15 | *Michael S. Zedalis,* Ansell Healthcare, LLC |
| 3:15–3:30 | *David Hermann,* Aspen Healthcare Metrics |
| 3:30–3:45 | *Sharon Welbel,* Cook County Health and Hospitals System |
| 3:45–4:15 | Discussion with the Committee |

**Questions:**

- What is the current FDA process and what standards are required to be met for FDA 510(k) clearance?
- Should a more in-depth conformity assessment process be implemented for gloves used in health care? If so, what type of process? If not, why?
- Are there adequate performance standards in place to test various types of gloves to see if they would meet certification requirements? If not, what is needed?
- What are the reasons why third-party testing and certification efforts have not been developed to date?
- What incentives and barriers would there be for implementing a more in-depth certification/conformity assessment process?
- What risk-based approaches could be used to determine the type of conformity assessment processes needed for the various types of gloves?

- What factors go into the decision to purchase? Would a third-party certification process make a difference in purchasing decisions?

**4:15 p.m.** **Public Comment—Registered Speakers**
Moderator: Howard J. Cohen

**5:00 p.m.** **Adjourn**

# B

# Workshop Participants

Preston Anderson
Engineering Manager
Sperian Fall Protection, Inc.

Edward Bailor
Inspector (retired),
U.S. Capitol Police
InterAgency Board

Roger L. Barker
Professor
North Carolina State University

Eric Beck
Director of Marketing and Product Planning
MSA, Inc.

Rebecca Beck
Electrical Engineer
MSA, Inc.

Roland Berry Ann
Deputy Director
National Personal Protective Technology Laboratory

Les Boord
Director
National Personal Protective Technology Laboratory

Janice Comer Bradley
Executive Vice President
Waste Equipment Technology Association

Tim Brooke
AVP Standards Development
ASTM International

Gavin Burdge
Industrial Hygienist
BMT Designers and Planners

Barbara J. Burgel
Occupational Health Nurse-Specialist
Community Health Systems
University of California–San Francisco

Howard J. Cohen
Professor of Occupational Safety and Health, Emeritus
University of New Haven

Terrell Cunningham
Nurse Consultant/Reviewer
Infection Control Devices Branch
Center for Devices and Radiological Health
Food and Drug Administration

Maryann D'Alessandro
Associate Director for Science
National Personal Protective Technology Laboratory

Dack Dalrymple
Principal
Dalrymple & Associates, LLC

Richard M. Duffy
Assistant to the General President
Occupational Health, Safety, and Medicine
International Association of Fire Fighters

Michael Easterbrook
Professor of Ophthalmology
University of Toronto

Christina Egan
Director
Biodefense Laboratory
Wadsworth Center
New York State Department of Health

Cristine Fargo
Manager, Standards and Membership Services
International Safety Equipment Association

Ken E. Feith
Senior Scientist
U.S. Environmental Protection Agency

Ginny Fitzner
Directorate of Standards and Guidance
Occupational Safety and Health Administration

Tim Gardner
Regulatory Manager
3M Occupational Health

Gordon Gillerman
Chief
Standards Services Division
National Institute of Standards and Technology

Patricia A. Gleason
President
Safety Equipment Institute

Larry Green
Engineer
Syntech, Intl.

Diane Haithcock
Section Manager III
Personal Protective Equipment
Conformity Assessment Services
Underwriters Laboratories

David Hermann
Vice President
Aspen Healthcare Metrics

Alexander Isakov
Executive Director
Office of Critical Event Preparedness and Response
Emory University

Sundaresan Jayaraman
Professor
Georgia Institute of Technology

James S. Johnson
Consultant
JSJ and Associates

F. Selcen Kilinc-Balci
Senior Service Fellow
National Personal Protective Technology Laboratory

Joann Kline
Regulatory Affairs Technical Leader
Kimberly-Clark Professional

Louise Kuhny
Senior Associate Director
Standards Interpretation
The Joint Commission

Catharyn T. Liverman
Study Director
Institute of Medicine

Markham C. Luke
Clinical Deputy Director
Office of Device Evaluation, Center for Devices and Radiological Health
Food and Drug Administration

Philip Mattson
Program Manager
Department of Homeland Security

Melissa A. McDiarmid
Professor of Medicine
Director, Occupational Health Program
University of Maryland School of Medicine

Lance Miller
Director
National Law Enforcement and Corrections Technology Center

J. Gibson Mullan
Director, Compliance and Field Operations
U.S. Consumer Product Safety Commission

Mary Ogg
Perioperative Nursing Specialist
AORN

Jamie Phillips
Conformity Assessment Coordinator
National Law Enforcement and Corrections Technology Center

Andrew M. Pope
Director, Board on Health Sciences Policy
Institute of Medicine

Kevin Robinson
Office of Technical Programs & Coordination Activities
Occupational Safety and Health Administration

Robin T. Scott
Consultant
Sport Dimension, Inc.

Ron Shaffer
Branch Chief
National Personal Protective Technology Laboratory

Anugrah Shaw
Professor
University of Maryland–Eastern Shore

Angie Shepherd
General Engineer
National Personal Protective Technology Laboratory

Daniel K. Shipp
President
International Safety Equipment Association

Natalia Stakhiv
Occupational Safety and Health Administration

Debra Stoe
Physical Scientist
National Institute of Justice
Department of Justice

Jonathan Szalajda
Chief
Policy and Standards Development Branch
National Personal Protective Technology Laboratory

Lisa Tomlinson
Sr. Director, Government Affairs
Association for Professionals in Infection Control and Epidemiology

Tanya Wanchek
Health Economist
Center for Economic and Policy Studies
University of Virginia

Robert Weber
Regulatory Affairs & Quality Manager
3M

Samuel E. Wehr
Standards & Regulations Manager
Mustang Survival Corporation

Sharon Welbel
John H. Stroger Jr. Hospital of Cook County

Michael S. Zedalis
Senior Vice President, Science & Technology
Ansell Healthcare, LLC

James Zeigler
Research Associate
DuPont Protection Technologies

# C

# Biographical Sketches of Committee Members

**Howard J. Cohen, M.P.H., Ph.D., CIH** (*Chair*), is professor emeritus at the University of New Haven, where he was professor and chair of the Occupational Safety and Health Department. He is an associate (adjunct) professor at Yale University's Department of Occupational and Environmental Medicine. He formerly was the manager of industrial hygiene at the Olin Corporation and editor in chief of the *American Industrial Hygiene Association* (AIHA) *Journal*. He is certified in the comprehensive practice of industrial hygiene by the American Board of Industrial Hygiene. Dr. Cohen is the former chair of the American National Standards Institute (ANSI) Z88.2 committee on respiratory protection and a current member of the editorial board of the *Journal of Occupational and Environmental Hygiene*. He is the past chair of the AIHA's respiratory protection committee, a past president of the Connecticut River Valley Chapter of the AIHA, and a past officer and treasurer of the American Board of Industrial Hygiene. Dr. Cohen served on the Institute of Medicine (IOM) Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic and on the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health. He is currently working as a consultant to the Veterans Administration's North Florida/South Georgia Center for Occupational Safety and Infectious Disease (on the Advisory Board and assisting on an upcoming clinical study of influenza). Dr. Cohen is also a consultant to a pharmaceutical company that has developed the first Food and Drug Administration/National Institute for Occupational Safety and Health-(NIOSH-)certified antiviral N95 surgical respirator. He is a graduate of Boston University, where he received a B.A. in Biology. Dr. Cohen re-

ceived his M.P.H. and Ph.D. in industrial health from the University of Michigan.

**Roger L. Barker, Ph.D.,** is the Burlington Distinguished Professor in the Department of Textile Engineering, Chemistry, and Science at North Carolina State University and director of the Center for Research on Textile Protection and Comfort. He has been engaged in research and standards development for protective clothing for more than 20 years and is internationally recognized for his work in the field of protective clothing systems. Dr. Barker has published many technical papers on the protective properties of textile materials and clothing and on testing methods used for evaluation. He is active in the National Fire Protection Association (NFPA), ASTM International, and the International Organization for Standardization (ISO) committees involved in the development of standards for measurement for personal protective equipment. Dr. Barker holds B.S. and M.S. degrees in physics from the University of Tennessee and a Ph.D. in textile and polymer science from Clemson University.

**Janice Comer Bradley, M.A.,** is the executive vice president for the Waste Equipment Technology Association (WASTEC), where she represents manufacturers of equipment and technologies as well as service providers for the refuse and recycling industry. Prior to joining WASTEC, she was the vice president and technical director for the International Safety Equipment Association, where she managed the voluntary standards-setting and technical activities of 13 product groups representing suppliers of safety and health equipment. She works closely with federal regulatory agencies and outside standards bodies to influence activities that affect the manufacture, use, distribution, and conformity assessment of trash and recycling equipment, and she represents WASTEC on numerous committees, government panels, and association boards. Ms. Bradley has also spent a significant portion of her career in the higher education and healthcare industries as the director of environmental health and safety for Rockefeller University in New York City, the university health and safety officer for Brown University, and the safety specialist for the Department of Veterans Affairs Medical Center in Dayton, Ohio. Ms. Bradley is a safety professional certified by the American Society of Safety Engineers. She has been an adjunct professor at Georgetown University, teaching a graduate-level course in the M.B.A. program that introduces future business leaders to workplace safety and health issues. Ms. Bradley earned a B.S. from the University

of Dayton and a master's degree in environmental studies from Brown University.

**Barbara J. Burgel, R.N., Ph.D., FAAN,** is a certified occupational health nurse-specialist and clinical professor in the Department of Community Health Systems at the University of California–San Francisco (UCSF). She served on the board of directors for the American Board for Occupational Health Nurses. Her research focuses on evaluating the health and safety of low-wage workers. She has also acted as vice chair in the Department of Community Health Systems at UCSF. From 2000 to 2006, Dr. Burgel served as clinical director of the Community Occupational Health Project, funded by both the California Wellness Foundation and the California Endowment to provide education, outreach, and free weekly clinical services to low-wage immigrant workers in Alameda County. This faculty practice resulted in a major report on garment worker health and safety, three peer-reviewed publications, multiple presentations at national and international meetings, and extensive public press media coverage. She is currently pursuing a research project on taxi driver health and safety. Dr. Burgel has served in many professional organizations, including the American Nurses Association/California, American Association of Occupational Health Nurses, American Board for Occupational Health Nurses, International Commission on Occupational Health, and American Academy of Nursing. Dr. Burgel has also acted as a consultant for many governmental, industrial, and nonprofit groups, including NIOSH, the California State Health Department, LifeMasters, and Literacy for Environmental Justice. She received a B.S.N. from the University of Michigan before completing an M.S. in Nursing from UCSF. At that time she became a registered nurse practitioner in California and then a clinical instructor and professor. Dr. Burgel completed her Ph.D. at UCSF.

**Michael Easterbrook, M.D.,** is a professor of ophthalmology at the University of Toronto. He is presently on active staff at the Toronto Western Hospital, St. Michael's Hospital, Princess Margaret Hospital, and Mt. Sinai Hospital. For 25 years, Dr. Easterbrook was the eye surgeon for the Toronto Maple Leafs hockey team. For the past 10 years, he has been the consultant to the Toronto Raptors basketball team and most recently to the Toronto FC professional soccer club. Dr. Easterbrook has been active in preventing eye injuries in sport at both the amateur and professional levels. He is a medical consultant to the World Squash As-

sociation, Squash Canada, and Squash Ontario, and has consulted for the Canadian Badminton Association, American Amateur Racquetball Association, and Canadian Standards Association. He has written standards for prevention of eye injuries in sports, and lectures both nationally and internationally on his interests. Dr. Easterbrook graduated from the University of Toronto Medical School. He did a year of residency in neurology at Montreal General, followed by 3 years of ophthalmology in Toronto. A fellowship in uveitis and external disease was followed at the Proctor Institute at UCSF.

**Christina Egan, Ph.D.,** is director of the Biodefense Laboratory at the Wadsworth Center, New York State Department of Health. Dr. Egan's job duties include implementation of Laboratory Response Network protocols and policies as well as development of methods to counteract biothreats. Dr. Egan also participates in the New York State (NYS) Environmental Laboratory Approval Program and NYS Clinical Laboratory Approval Program by helping to develop surveys, guidelines, and checklists for laboratories interested in analyzing biothreat specimens and samples. In this capacity, she has performed onsite inspections and reviewed laboratory methods and protocols. She has participated on a number of federal and state committees to create standards for biothreat detection methods and has developed and provided training courses for first responders as well as clinical laboratorians. Dr. Egan serves on the Science and Technology Subcommittee of the national InterAgency Board for Equipment Standardization and Interoperability. She has received the designation of Certified Biological Safety Personnel through the National Registry of Certified Microbiologists. She is an assistant professor in the State University of New York School of Public Health, Department of Biomedical Sciences. Dr. Egan received a B.S. from Siena College prior to obtaining a Ph.D. in pharmacology from Albany Medical College.

**Alexander Isakov, M.D., M.P.H.,** is the founding director of the Emory University Office of Critical Event Preparedness and Response, which reports to the university president and serves as the center for Emory's enterprise-wide planning for and coordinated response to catastrophic events. He is an associate professor of emergency medicine, and directs Emory's Section of Prehospital and Disaster Medicine, whose faculty provides medical oversight for 9-1-1 ground and air ambulance responders in the City of Atlanta/Fulton County, Georgia. He also directs the

Grady Emergency Medical Services Bio-Safety Transport Program, which supports Emory University, the Centers for Disease Control and Prevention, and Hartsfield-Jackson International Airport for the transport of individuals who pose a serious communicable disease risk. Dr. Isakov practices clinically in the emergency departments of Grady Memorial Hospital, Atlanta's primary safety-net hospital and level 1 trauma center, and Emory University Hospital.

**Sundaresan Jayaraman, Ph.D.,** is the Kolon Professor in the School of Materials Science and Engineering and in the College of Management at the Georgia Institute of Technology in Atlanta. He and his research students have made significant contributions in enterprise architecture and modeling methodologies for information systems; engineering design of intelligent textile structures and processes; and design and development of knowledge-based systems for textiles and apparel. His group's research has resulted in the realization of the world's first Wearable Motherboard™ or Smart Shirt. He is currently engaged in studying the role of management and technology innovation in health care. He was involved in the design and development of TK!Solver, the first equation-solving program from Software Arts, Inc., Cambridge, Massachusetts. Dr. Jayaraman worked as a product manager at Software Arts, Inc., and at Lotus Development Corporation in Cambridge before joining Georgia Tech. Professor Jayaraman is a recipient of the 1989 Presidential Young Investigator Award from the National Science Foundation for his research in the area of computer-aided manufacturing and enterprise architecture. He has served on several Institute of Medicine (IOM) and National Research Council committees, including the Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic, the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health, and the Board on Manufacturing and Engineering Design. He received his B.Tech. and M.Tech. degrees from the University of Madras, India, and his Ph.D. from North Carolina State University.

**James S. Johnson, Ph.D., CIH, QEP,** is an industrial hygienist consultant who specializes in respiratory protection and personal protective equipment. He retired from the Lawrence Livermore National Laboratory (LLNL) in 2006 after 34 years of service in a variety of health and safety assignments. His position at LLNL from 2000 to 2006 was section leader of the Chemical and Biological Safety Section of the Safety Pro-

grams Division. Throughout his career at LLNL, Dr. Johnson has been involved with respiratory protection and personal protective equipment as the respiratory program administrator, research scientist, assistant department head, and division and section manager. Throughout his career he has also developed, organized, and presented a wide variety of industrial hygiene training programs and classes. The most recent was a 1-day seminar titled "Respiratory Protection for Aerosol Transmissible Diseases" presented at the Center for Occupational & Environmental Health, University of California–Berkeley, in July 2009. Dr. Johnson is an AIHA Fellow; a member of the NFPA Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment; a member of the NFPA Respiratory Protection Equipment Committee; a board member of the International Society for Respiratory Protection and Americas Section; chair of the AIHA/ANSI Z88 Secretariat for Respiratory Protection; and a member and vice chair of the AIHA Respirator Committee. He is also a member of the AIHA Protective Clothing and Equipment Committees and the Emergency Preparedness and Response Task Force. Dr. Johnson is a certified industrial hygienist. He serves as a member of the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health.

**Melissa A. McDiarmid, M.D., M.P.H.,** is professor of medicine and director of the School of Medicine's Occupational Health Program at the University of Maryland. She is board certified in internal medicine, occupational medicine, and toxicology. She maintains professional society affiliations as a Fellow of the Collegium Ramazzini, American College of Physicians, American College of Occupational and Environmental Medicine, and American College of Preventive Medicine. She is a member of the American Public Health Association and the Society of Occupational and Environmental Health. Dr. McDiarmid was director of the Office of Occupational Medicine for the U.S. Occupational Safety and Health Administration (OSHA) in Washington, DC, a position she held from 1991 until 1996. A principal career focus for Dr. McDiarmid has been that of environmental reproductive and developmental hazards. While at OSHA she guided the reproductive health effects aspects of several standards, including those for cadmium, butadiene, and methylene chloride. She is currently the cochair of the NIOSH/NORA (National Occupational Research Agenda) work group on reproductive health. Dr. McDiarmid has authored numerous journal articles and book chapters on occupational and environmental medicine topics related to

healthcare workers, medical surveillance and management, reproductive hazards, and occupational cancers. She received her B.A. in biological sciences from the University of Maryland–Baltimore County; her M.D. from the University of Maryland School of Medicine; and her M.P.H. from the Johns Hopkins School of Public Health, where she also completed fellowship training in Occupational Medicine. Dr. McDiarmid serves as a member of the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health.

**James W. Platner, Ph.D., CIH,** is the associate director of the CPWR Center for Construction Research and Training, which is the research and training institute of the Building and Construction Trades Department, AFL-CIO. He is a member of the ANSI A10 American National Standards Committee on Safety in Construction and Demolition Operations and the ANSI Z10 American National Standards Committee on Occupational Health and Safety Management Systems. He is a co-principal investigator of the NIOSH National Construction Research Center, and is actively engaged in issues related to personal protective technologies in construction. He has a B.S. in biophysics from Johns Hopkins University, an M.S. in radiation biology, and a Ph.D. in toxicology from the University of Rochester School of Medicine, and is a certified industrial hygienist (CIH) and a fellow of the American Industrial Hygiene Association.

**Anugrah Shaw, Ph.D.,** is a textile technologist and a professor at the University of Maryland–Eastern Shore (UMES) and has conducted research on protective clothing for pesticide applicators for more than 2 decades. Her research includes work related to standardization of test methods, development of performance specifications, and studies related to the development and evaluation of personal protective equipment for hot climates. Dr. Shaw was responsible for the creation of an extensive database that includes data for more than 130 fabrics that were evaluated at UMES. This database has been used to develop an online system for work and protective clothing. Dr. Shaw serves as the technical contact for ASTM and ISO standards and performance specifications for protective clothing for pesticide applicators, and as an ISO delegate for a subcommittee on protective clothing. She has presented at numerous national and international conferences, published in several refereed journals, and written a book chapter on the selection of personal protec-

tive equipment. She received her Ph.D. in textile technology from Texas Woman's University.

**Tanya Wanchek, Ph.D., J.D.,** is a health economist/lecturer at the University of Virginia, with a joint appointment at the Weldon Cooper Center for Public Service, Center for Economic and Policy Studies, and the School of Medicine, Department of Public Health Sciences. Her research focuses on occupational licensure, rural workforce development, childhood obesity, and mental health law. She teaches a course on healthcare economics for the M.P.H. program. She is also a faculty member of the Healthy Appalachia Institute at the University of Virginia's College at Wise. She obtained her Ph.D. in economics from the University of Washington and her J.D. from the University of Virginia School of Law.

**Samuel E. Wehr** serves as Mustang Survival's manager for Canadian, United States, and international standards for personal flotation devices (PFDs) and related regulations. He is serving as the chair of several Underwriters Laboratories Standards Technical Panel task groups, including the one dealing with development on a single consolidated North American standard for wearable PFDs. Until 2007, Mr. Wehr served as the Coast Guard's senior project engineer for the approval of PFDs or lifejackets and for rigid survival craft along with the development of standards and regulations for PFDs and survival craft. He represented the Coast Guard in the ISO for recreational boating PFDs and the International Maritime Organization (IMO) for lifesaving equipment for use on commercial vessels. He served as the correspondence group coordinator for IMO's project to improve personal lifesaving appliances. He worked for the Coast Guard on approval of lifesaving equipment beginning in 1977. His work included oversight of research and development projects dealing with all aspects of PFD performance, computer modeling of the in-water performance of PFDs, development of mannequins for evaluation of the rough-water performance of PFDs, and operational reliability of inflatable PFDs when used by recreational boaters. Mr. Wehr graduated from Pennsylvania State University in 1971 with a B.S. in engineering.