DRAFT

The Scope of a National Framework for Conformity Assessment of Non-respiratory Personal Protective Technologies

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National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)

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CDC Workplace Safety and Health

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NPPTL Research to Practice through Partnerships

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LIST OF ACRONYMS

ANSI	American National Standards Institute
AQL	Acceptable Quality Levels
BHSRs	Basic Health and Safety Requirements
CASCO	ISO Conformity Assessment Standards Committee
CA	Conformity Assessment
CFR	Code of Federal Regulation
EPA	Environmental Protection Agency
EU	European Union
FAE AAC	NFPA Fire and Emergency Services Protective Clothing and Equipment
FDA	Food and Drug Administration
IEC	International Electrotechnical Commission
IOM	Institute of Medicine
ISO	International Organization for Standards
ISO/PAS	ISO Publicly Available Specification
MAUDE	Manufacturers and User Facility Device Experience
MSHA	Mine Safety and Health Administration
NAS	National Academy of Sciences
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NPPTL	National Personal Protective Technology Laboratory
NTTAA	National Technology Transfer and Advancement Act
OSHA	Occupational Safety & Health Administration
PCAWG	PPT Conformity Assessment Working Group
PPE	Personal Protective Equipment
PPT	Personal Protective Technologies
PROSAFE	Product Safety Enforcement Forum of Europe
SDoC	Supplier's Declaration of Conformity
SEI	Safety Equipment Institute
SES	Society for Standards Professionals
UNIDO	United Nations Industrial Development Organization

SUMMARY

When personal protective technologies (PPT) are needed to protect the health and safety of workers, those workers must have a means of knowing the product they are using will fulfill the basic health and safety requirements (BHSR) they are designed to achieve. Conformity assessment (CA), together with relevant performance-based technical standards and metrology, provides this assurance. Transparent and internationally recognized CA procedures also facilitate global trade.

In 2011 the Institute of Medicine (IOM) published a report on the CA of non-respiratory PPT. In December 2011, NIOSH created a PPT Conformity Assessment Working Group (PCAWG) to address the specific recommendations of that report. The PCAWG, made up of more than 30 public and private organizations, has prepared a comprehensive set of reports which guided the development of requirements for a national CA framework for non-respiratory PPT used in occupational settings. The NIOSH public meeting is an important next step in seeking broad-based input on the requirements.

Measures to ensure conformity must maximize workplace safety and health to the extent practicable, be performed by independent, impartial, and technically qualified entities when the risk of non-conformance is not low, and backed up by post-market corrective action that is dissuasive and proportionate to the risk addressed by the product. Requirements for pre-market CA should be similar across products intended for equivalent levels of hazard and inherent level of risk for the tasks associated with the hazard. Requirements for post-market surveillance and enforcement programs should also be similar across products intended for equivalent levels of risk.

These requirements represent an alignment of the current public-private sector approach to PPT CA in the U.S. They support and extend private sector involvement in standard setting, conformity assessment, and market surveillance activities. The government's role should be to define the requirements for CA and market surveillance while providing coordination, technical assistance, and enforcement roles for implementing the aligned approach. Voluntary consensus standards should continue to be the preferred approach for defining technical requirements. Third-party private sector bodies should provide the inspection, testing and certification services needed for CA and market surveillance when the risk of non-conformance warrants.

The approach should establish BHSRs for all non-respiratory PPT; classify requirements into a tiered set of three or more risk-based CA schemes; and assign products to each tier based on the hazard they are designed to protect against. Conformity will be assessed based on adherence to standards that assure BHSRs are met. Products designed to protect against medium to high hazards will require CA by third-party private sector bodies. Products designed to protect against high hazards will also be subject to proactive market surveillance performed by third-party private sector bodies, with federal oversight.

1. BACKGROUND

The purpose of this document is to describe the basis for a national conformity assessment (CA) framework for non-respiratory personal protective technologies (PPT) in the United States. The framework defines the necessary requirements and criteria for comprehensive and consistent processes for ensuring that non-respiratory PPT reduces risks to workers by assuring conformity to standards that meet basic health and safety requirements (BHSRs). The intent is to apply a framework to PPT including specialized clothing, equipment, technical methods, processes, techniques, tools, and materials. The framework excludes respiratory protective technologies.

The Institute of Medicine (IOM) was requested by NIOSH to develop a set of recommendations addressing the CA of non-respiratory personal protective technologies. In its 2011 report, *Certifying Personal Protective Technologies: Improving Worker Safety*, the IOM recommended that the CA system should have a total lifecycle approach including post-market testing, evaluation, and surveillance, as well as an effective recall system. Specifically, the IOM recommended NIOSH:

- develop and implement a comprehensive, tiered, risk-based framework for the classification and CA of PPT products,
- continue involvement in standard-setting processes,
- facilitate end user participation in voluntary consensus performance-based standards;
- become the primary clearinghouse for reliable information on non-respiratory PPT support standards development for protective ensembles,
- develop and maintain an online list of all PPT that meet third-party conformance assessment requirements, and
- establish an electronic PPT and occupational safety and health surveillance system (IOM, 2011).

The IOM indicated that the goal of the system should be to reduce or eliminate risks to the worker to the extent practicable. The IOM further recommended that the CA framework take into account the risk to health and safety to workers as well as pragmatic factors such as burden, cost, product complexity, the globalization of PPT production and deployment, and barriers to innovation.

The PPT CA Working Group (PCAWG) was established by NIOSH in December 2011 with the purpose of preparing a set of requirements that would result in criteria for a national framework including comprehensive and consistent processes to address CA of non-respiratory PPT. The PCAWG members are identified in Appendix A1. The framework and processes define the components necessary to determine CA requirements for non-respiratory PPT across industry sectors. Further, the framework and processes provide the

basis to determine the appropriate role for NIOSH, including the option to either contribute to the development of a voluntary standard(s) which meet BHSR and/or establish an oversight function.

The organization and workflow for the PCAWG is shown in Figure 1.

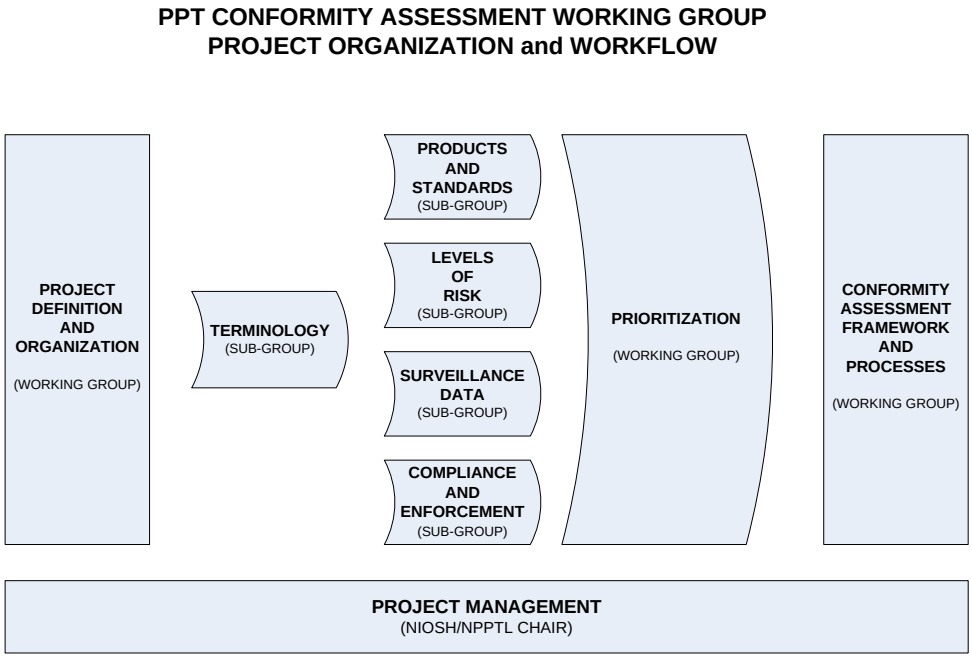

Figure 1. PPT CA Working Group Project Organization and Workflow

The five initial subgroups have completed their activities (see Appendix A2) and issued subgroup reports on the findings for their assigned tasks. The PCAWG Summary Report is available at Docket 237a. The findings include:

Terminology Subgroup

1. A list of terms with definitions to provide a consistent vocabulary for all PCAWG activities was developed.

Products and Standards Subgroup

1. PPE performance standards do not contain CA requirements.
2. With few exceptions, there are no nationally applied CA requirements for PPE.
3. A verified and searchable PPE standards database, including OSHA regulations, was developed as a prototype for potential use by stakeholders interested in PPE performance standards.
4. The value of a national PPE standards database and approaches to maintain an updated database need to be defined.

5. The International Organization for Standardization (ISO) published more than 28 CA standards that could be applied in the US to PPE CA.

Risk Subgroup

1. There is no national requirement for US risk assessment activities to link PPE types with appropriate CA requirements.
2. Standards developers do not currently use quantitative risk assessment tools to guide updates of PPE performance, reliability, and quality requirements.
3. A substantial level of expert judgment is required to establish quantitative risk levels due to the lack of readily available data to assist with risk assessment of PPE.
4. As is evidenced by the European Union (EU) PPE directive, risk assessment guidelines could be established to link PPE types to CA requirements.
5. A sample risk assessment procedure was developed.

Surveillance Subgroup

1. There are no universal data collection programs relating PPE conformance to standards with injuries, illnesses, and fatalities.
2. No PPE surveillance programs link non-conformance or adverse health and safety outcomes to fraudulent and counterfeit PPE marketed in the US.
3. Comprehensive surveillance programs need to be defined and funded to provide appropriate data and collection methods.
4. A national program to purchase PPE from the open market and test and evaluate its conformance to claimed standards would be a key component to a comprehensive surveillance strategy.

Compliance and Enforcement Subgroup

1. An assessment of state and federal compliance programs indicated that PPE is not an integral component of these programs.
2. With few exceptions, there is no universal program to verify PPE manufacturer's claims of conformance to claimed product standards.
3. Data relating PPE non-conformance to claimed standards with enforcement actions (e.g. violations, fines, etc.) are not in Occupational Safety & Health Administration (OSHA) and Mine Safety & Health Administration (MSHA) databases.
4. The NIOSH respirator approval program, the EU PPE directive, and the EU CA program were benchmarked to assess best practices.
5. The EU PPE Directive and associated programs are currently under revision to address needed improvements (e.g. post market surveillance).
6. The EU PPE program has substantial CA components.
7. The EU approach is a good reference for CA requirements that could be adapted to non-respiratory PPE CA in the United States.

NIOSH is now performing its **PRIORITIZATION** activity where it will use the results from the initial five subgroups and public input to:

1. Identify the scope of the framework including CA requirements to be achieved as part of the framework (i.e. performance standards, quality assurance

requirements, declaration of conformity, obligations to maintain compliance, consequences of noncompliance)
2. Identify potential roles and responsibilities for public and private parties

This initial prioritization has resulted in the development of a comprehensive set of requirements for this framework. NIOSH is seeking public input to finalize its definition and scope of the framework and the roles and responsibilities of involved parties.

The proposed requirements are informed by existing CA programs in the U.S. as well as by international standards and best practices. The U.S. programs include the American National Standards Institute's (ANSI's) programs and standards, as well as the application of those standards by, for example the National Fire Protection Association (NFPA). The international CA standards were published by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Many of those standards are reflected in ANSI's accreditation standards and programs. The PCAWG also studied the European Union's CA system to explore how all the ISO CA standards could be implemented in one comprehensive system. Because the U.S. does not currently have a comprehensive national system of CA that fulfills the ISO standards, the framework also references the European Union as an example of an approach to implementing the ISO standards at the national level.

1.1 Conformity Assessment

The basic processes of a comprehensive conformity assessment system are:

1. **Selecting information about the product**, which involves (1) identifying the specific and/or general requirements for products such as standard(s) or other document(s) to which conformity is to be assessed, and (2) selecting examples of the product to be assessed using statistical sampling techniques, if applicable.

2. **Gathering evidence of conformity**, which includes testing to determine specified characteristics of the product; inspection of physical features of the product (e.g., visual examination of a physical item, measurement or testing of physical items, examination of design drawings or other specification documents), and auditing of supplier's quality and/or environmental systems and records relating to the product.

3. **Reviewing the evidence and attesting to conformity**, which includes the Supplier's Declaration of Conformity (SDoC), third-party certificate of conformity, and marks of conformity.

4. **Conducting market surveillance**, which includes both proactive and reactive actions. It also includes both pre-market surveillance (gathering evidence of conformity at the point of production or in the supply chain to the marketplace) and post-market surveillance (gathering evidence of conformity in the marketplace, and/or at the place of use).

5. **Taking enforcement and corrective actions**, which include official warnings, customer alerts, sales bans, sales suspensions, product withdrawals and recalls, fines, and incarceration.

6. **Using mechanisms to ensure that all service providers are competent**, this includes accreditation, auditing, and peer evaluation.

The interrelationship of these processes is illustrated in **Figure 2.**

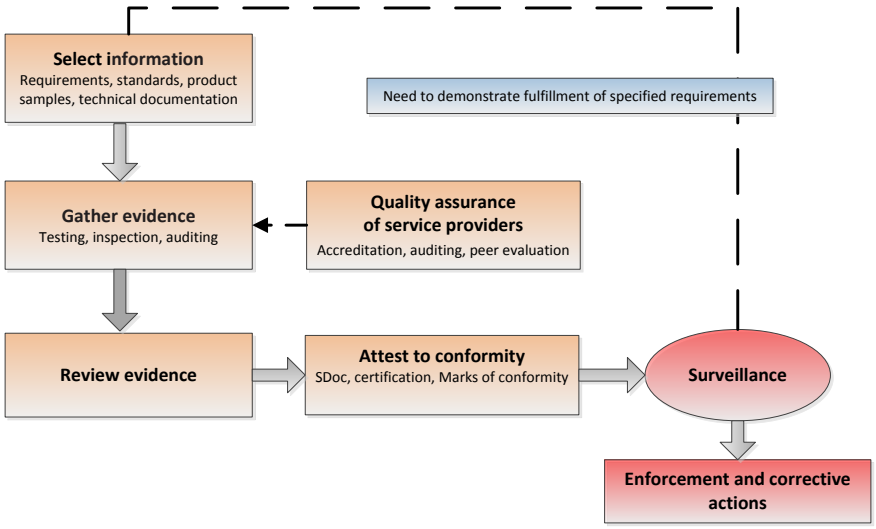

Figure 2. Functional Approach to Conformity Assessment

Source: Adapted from ISO- United Nations Industrial Development Organization (UNIDO) (2013:30, Figure 4).

1.2 Conformity Assessment in the Quality Infrastructure

Conformity assessment is the demonstration that specified requirements for a product, process, system, person, or body are fulfilled (ISO/IEC 17000). These requirements are found in suppliers' or purchasers' specifications; national, regional, or international standards; and/or governmental regulations. "Suppliers" as used in this document refers to the entities and organizations that control the quality of the product or service that they introduce into the supply chain. Methods for demonstrating conformity include testing, inspection, suppliers' declarations of conformity and certification.

CA is fundamental for all modern economies. Consumers benefit from CA because it gives them a basis for selecting products or services by ensuring BHSRs are met. Suppliers and service providers benefit by avoiding the costs of product failures in the market and obtaining access to foreign markets. CA is thus a means both for achieving public health and safety policy goals and for removing trade barriers.

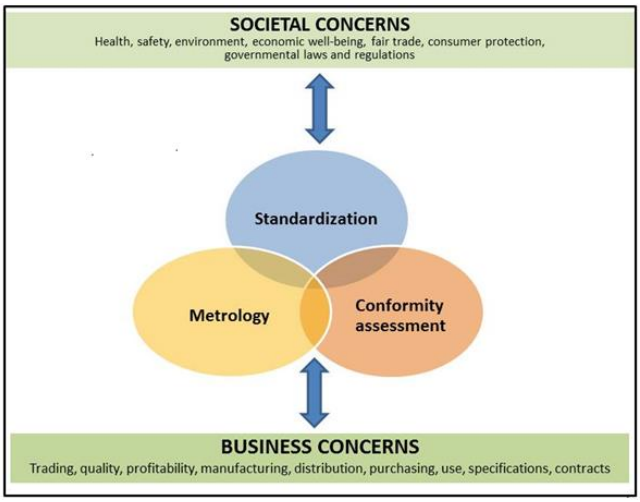

Figure 3. The Quality Infrastructure
Source: ISO-UNIDO (2010:6)

CA is one of the three interdependent pillars of a national quality infrastructure (see Figure 3). Together with metrology and standardization, CA satisfies the technical requirements of the multilateral trading system by increasing market access and ensuring adequate protection of consumers and of the environment (ISO-UNIDO, 2013:19, 29).

1.3 Current PPT Conformity Assessment in the United States

The United States does not have an existing comprehensive CA program for PPT. Current CA programs are product-based and designed primarily for products that protect workers against medium to high hazards (e.g., respiratory protection, body armor, and personal flotation devices). The NFPA, for example, has comprehensive standards for fire and emergency services PPT that include detailed CA requirements. NFPA applies the following CA requirements consistent with requirements generally applied for medium to high risk to all PPT standards listed in Appendix B. These include third-party certification (ISO/IEC 17065) by an accredited certification organization (ISO/IEC 17011), inspection, and testing (ISO/IEC 17025); annual recertification; manufacturer's quality assurance program (ISO-9001) and registered by registrar meeting ISO/IEC 17021; investigation of hazards

involving compliant products (ISO Guide 27); manufacturer's investigation of complaints and returns; and, manufacturer safety alert and product recall systems.

However, most PPT standards in the U.S. typically do not include CA requirements for products. Thus a supplier's declaration of conformity and no third-party verification or follow-up market surveillance is the norm. Appendix C summarizes CA programs for PPT that currently exist in the United States.

A well-established and comprehensive CA system in the United States is the CA approach in place for respirators led and managed by NIOSH, known in the nation as the "respirator certification activity". The NIOSH respirator certification activity includes most CA components described in the ISO CA standards (ISO, 2010). NIOSH is responsible for directing and conducting the respirator certification activity and its related laboratory, field, quality, and research functions. NIOSH has administered the respirator certification activity since 1972 (US Congress, 1970), and traces its respirator certification origins to circa 1910, the early years of the U.S. Bureau of Mines. NIOSH now has exclusive authority for testing and certifying respirators with the exception of certain mine emergency devices, which continue to be jointly certified by NIOSH and the Mine Safety and Health Administration (MSHA). In 1995, NIOSH published revised respirator certification requirements for particulate respirators and recodified the previous certification standards for the other respirator classes as Title 42 Code of Federal Regulations Part 84 (42CFR84).

Existing CA programs in the U.S. represent a wide diversity of approaches. For example, while most certification programs are conducted by private-sector bodies, the NIOSH respirator certification activity involves a public-sector certification body. In the absence of a comprehensive framework, the system as a whole has evolved to include a large number of organizational participants (ANSI, 2006).

2. BASIC CONFORMITY ASSESSMENT REQUIREMENTS

CA has become increasingly important to federal agencies. Federal agency programs have been and are increasingly leveraging CA programs and activities in support of regulatory, procurement and other mission objectives in order to meet their responsibilities with ever shrinking resources. The International Organization for Standards CA Standards (see Appendix D) serve as the basis for establishing CA requirements across the nation.

The purpose of CA is to ensure the safety of products placed on the market. For non-respiratory, occupational PPT, the current U.S. approach is a complex arrangement of mandated and voluntary consensus standards intended to provide guidance to suppliers and purchasers of these products. Some of these standards are in the U.S. Code of Federal Regulations (CFR); others are voluntary consensus standards that have been incorporated by reference;[1] still others are voluntary consensus standards whose application is also voluntary. Some of the mandated and incorporated standards include federal enforcement powers, but most do not (*Appendix* E provides a preliminary inventory of the standards that apply to PPT in the United States).

Identifying the appropriate balance of federal and consensus standards is important to the development of a comprehensive PPT CA framework. Voluntary consensus standards have numerous advantages over regulatory standards. In 1996, the U.S. Congress passed the National Technology Transfer and Advancement Act (Public Law 104-113), which requires all U.S. Federal agencies to use voluntary consensus standards to the extent possible. (IOM, 2011:26-27) Those that are incorporated by reference simplify and accelerate legislative work and lower cost to government in developing and enforcing regulations. They also can improve responsiveness of regulators to public health and safety concerns, can facilitate technological innovation and eliminate barriers to trade by referring to recognized national standards that have been harmonized internationally (SES, 2000).

To help fulfill their mandate to ensure public health and safety, federal agencies participate in voluntary consensus standard setting and are involved in third-party accreditation activities (ANSI, 2013). Federal agency oversight and the continued development and application of voluntary consensus standards are important components of a comprehensive system.

In the absence of a national comprehensive CA system in the United States standards development organizations may adopt their own CA requirements. (Appendix B provides an NFPA example). Industry could apply the appropriate CA elements required in that industry but the current diverse U.S. CA approaches do not provide a consistent model for the nation. One option is to follow best practice guidelines, in an effort to distinguish and separate standard setting from CA to establish the most effective framework.

[1] "Incorporation by reference" is a method of drafting a regulation in such a way that a detailed statement of the technical requirements is replaced in the text of the regulation by a reference to one or more standards, or parts of standards, produced by private or governmental organizations (SES, 2000).

2.1 Current Conformity Assessment Practices

In 1995, a report by the National Academy of Sciences (NAS) described the conformity assessment system in the United States as complex and decentralized (NAS, 1995:68-69). The National Technology Transfer and Advancement Act (NTTAA) enacted that year charged the National Institute of Standards and Technology (NIST) with "coordinating federal, state, and local conformity assessment efforts with private-sector activities to eliminate duplication and reduce the complexities of the processes" (IOM, 2011:26-27). In response, NIST published regulations entitled Guidance on Federal Conformity Assessment Activities (15CFR287) in 2000. However, little other progress has been made: the system remains complex and incomplete.

Federal regulations on respiratory PPT incorporate a hazard-based foundation for establishing conformity assessment quality control requirements for respiratory protective devices. Title 42 of the CFR[2] classifies respirator characteristics for certification purposes according to the potential effect of defects of those characteristics as follows:

- **Critical -** A defect that judgment and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator.

- **Major A -** A defect, other than critical, that is likely to result in failure to the degree that the respirator does not provide any respiratory protection, or a defect that reduces protection and is not detectable by the user.

- **Major B -** A defect, other than Major A or critical, that is likely to result in reduced respiratory protection and is detectable by the user.

- **Minor -** A defect that is not likely to materially reduce the usability of the respirator for its intended purpose, or a defect that is a departure from established standards and has little bearing on the effective use or operation of the respirator.

In addition to a manufacturing quality assurance system, NIOSH requires each item manufactured to be 100% inspected or tested for all defects classified as critical characteristics and all defective items to be rejected. Acceptable Quality Levels (AQLs) required by 42CFR84 based military standards are applied in the classification system.[3]

Federal agencies require certification by NIOSH to meet BHSRs in their particular regulated industries, or require, co-approval or "clearance" (e.g. co-approval with MSHA for respirators used in mining, co-approved by a private certification authority (Safety Equipment Institute) for respirators complying with NFPA standards for use primarily in emergency response scenarios, and cleared by the Food and Drug Administration if the product is intended to be used in the healthcare environment)

[2] Specifically, the Code of Federal Regulations, Title 42, Public Health, Part 84 — Approval of Respiratory Protective Devices [42 CFR 84].

[3] The AQLs for category *Major A* are 1.0 percent; for *Major B*, 2.5 percent; and for *Minor*, 4.0 percent.

2.2 The Role of Basic Health and Safety Requirements

The conformity assessment system should be developed to focus on achieving the BHSRs, using CA requirements proportional to the seriousness of the hazard necessitating particular safety requirements. To be effective, the CA system should incorporate voluntary consensus standards that reference the relevant BHSRs.

BHSRs provide a proactive, comprehensive alternative to product-based approaches that employ "incorporation by reference" clauses for this purpose. BHSRs describe the goals to be achieved by products, and leave decisions about the applicable technical standards and the technical approaches, for achieving those goals, to the private sector. This approach provides opportunities for voluntary consensus standards that are responsive to technological change and scientific progress to be more effectively developed. BHSRs can contribute to keeping workers safe and serve as the basis of an efficient, unambiguous CA and market surveillance system.

Alternatively, BHSRs were incorporated into the EU's CA system in the mid-1980s to provide legislative enforcement authority to the EU and its Member States while encouraging a robust system of voluntary consensus standard-setting procedures. Suppliers are legally required to meet the relevant BHSRs before placing products on the EU market. There is no legal requirement for specific technical standards to be fulfilled. The private sector is free to determine how the BHSRs will be fulfilled.

BHSRs help prevent technical barriers to trade, increase transparency in the PPT market (by helping consumers understand the risks the product is designed to protect against), and incorporate risk assessment into CA and post-market surveillance programs. As demonstrated by the EU example, BHSRs can provide the unifying, foundational element of a comprehensive CA system that relies on voluntary consensus standards. Their use can allow government authorities to apply consistent CA requirements across categories of PPT, based on risk levels. This process is illustrated in Figure 4.

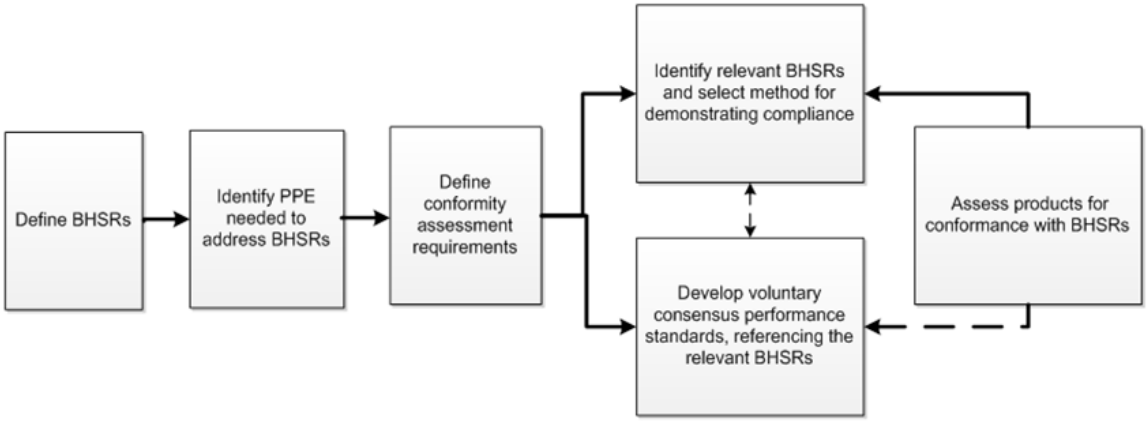

Figure 4. Relationships among basic health and safety requirements, standards, and conformity assessment

2.3 Defining Hazards and Risks

As the IOM's guidance suggests, PPT is a special case among commercial products because it is designed to have a protective function. Like socket protectors and fire extinguishers, PPT products do not necessarily have shortcomings that are dangerous in themselves (e.g., sharp edges that can injure a user). Whereas products such as pharmaceutical drugs and chemicals may themselves pose a risk to the consumer, the key risk factor for PPT is the hazard the PPT is designed to protect the user against.

2.4 Hazard-based product categories

The primary hazard presented by PPE is not the property of the product; it is the risk associated with failure or insufficient protective function. The risk arises because the product tempts users to change their behavior: they rely on the protective properties of the product. The approach to risk assessment for PPT CA, therefore, must "take into account injury scenarios in which the product does not provide the required protection." i.e. the hazards the person is exposed to that the equipment was supposed to provide protection against (PROSAFE, 2009:81).

A risk-based CA system classifies hazards such as extreme temperatures, fire, or mechanical vibration, and then places PPE into those classifications based on the hazard the PPT is designed to protect against. Risk determinations incorporated into voluntary consensus standards ease the risk assessment for the manufacturers by changing it from an open and broad analysis to a simpler one involving checking the fulfillment of the requirements in the standard.

The ISO system is not designed for a specific sector or category of products and does not specify which system should be used for specific levels of hazard/risk or for specific products or product categories. The EU system, based on the ISO's best practice guidelines, includes product-specific regulations that explicitly tie level of hazard to CA requirements. Legal CA requirements for PPE are covered by the EU's Personal Protective Equipment Directive 89/686/EEC.

To make good choices when selecting PPE, American consumers must know both the product specifications and the manufacturer's and supplier's qualifications. The complexity and uncertainty of the current system can lead to costly lawsuits for suppliers' noncompliance.

2.5 Current Market Surveillance Practices

Appendix F provides a summary of current PPT standards that incorporate market surveillance practices. The practices vary considerably among the standards and best practices among them and the EU practices should be considered as the PPT CA framework is developed.

3. REQUIREMENTS FOR THE DEFINITON AND IMPLEMENTATION OF THE FRAMEWORK

These requirements represent an alignment of current national and international public-private sector approaches as the framework is established. They provide a set of five general requirements for the system:

1. **The organization that manufactures/produces the PPT product, or controls its manufacture prior to placement on the market has the primary responsibility for its conformity with the stated requirements.** Even if this supplier obtains a certificate from an independent body stating that the product conforms to the relevant specification, if anything goes wrong, the supplier to whom the certification was rightfully granted remains responsible (ISO-UNIDO, 2010:46).

2. **Empowering legislation for the conformity assessment and market surveillance authority/ies must be in place.** The authorities must be formally identified, be competent, notified to the public in legislation, and be granted the necessary powers to perform their functions, e.g., powers to enter premises or conduct searches at borders, take samples, demand product safety files or other information, recall or confiscate and dispose of nonconforming goods, order a halt to production, delay or prevent market entry or, in extreme cases, close down premises.

3. **Transparency in identifying the authorities responsible for enforcing each technical regulation is essential.** Avoid turf wars over which government department is legally responsible for a particular field to minimize conflicts of interest and avoid duplication of responsibilities.

4. **Affected parties need to have the right to challenge decisions or actions taken by market surveillance authorities.** Any decision or action taken by an authority during market surveillance activities has to be open to legal challenge through the courts by the party(ies) affected by the decision/action.

5. **Regulatory interventions must be made at the appropriate risk-points within the product life cycle.** Some items of PPE such as self-contained breathing apparatus respirators are designed for repeated use, and the end user has a role to play in the safe use of the product. In such a case, depending on the situation, it might well be appropriate for surveillance to extend to the premises and operations of the end user (ISO, 2012:7-9).

The remaining sections of this chapter identify a draft list of more specifically defined requirements to be achieved in a PPT CA framework. A summary of the roles, responsibilities, authorizations and funding needed to begin a national dialogue for defining a comprehensive CA system for non-respiratory PPT in the United States is provided. As the ISO recommends, a CA and market surveillance system requires empowering legislation to provide federal authorities with the necessary powers. The following summary of requirements should be considered as the U.S. framework is designed and potential authorities identified.

3.1 Basic Requirements to be Achieved for a U.S. Conformity Assessment Framework for PPT

A CA framework should draw upon ISO standards and other recognized best practices, and be consistent with the current approaches of NFPA, ANSI, and other U.S. programs. The ISO standards set out requirements for CA procedures and the bodies that carry them out. International standards and other best practices are "intended to ensure that there are consistent and internationally harmonized practices among CA bodies and the bodies with which they work" (such as accreditation bodies) (ISO-UNIDO, 2010:18).

3.1.1 Requirements for Products and Standards

The PCAWG developed a products and standards database that identifies the federal and consensus performance standards in place in the Unites States for PPT; In addition, a risk model was established that should enable the information gaps in CA to be identified, where performance standards are inadequate, and what PPT should be in the high risk category. This process will enable high risk products to be prioritized.

Products and Standards

1. BHSRs for non-respiratory occupational PPT should be established to provide the foundation for a comprehensive and internally consistent PPT CA system.

2. Voluntary consensus standards should reference applicable BHSRs. The PCAWG established a database of U.S. PPE standards that can serve as a tool supporting a national PPT CA system.

3. Federal agencies should continue to support voluntary consensus standard setting for PPT.

4. A CA system should require the supplier as defined in general requirement 1 above to maintain a quality management system that includes conformity with specified product performance standards.

5. Federal agencies should develop a five year strategy to address priority areas of research interest based on risk and national interest in areas that address the BHSR gaps and the linking of appropriate consensus standards to confirm that the appropriate BHSRs are identified. The strategy should be updated regularly. The PCAWG recommended risk assessment approach could be used as a tool to support this effort.

3.1.2 Requirements for Conformity Assessment

Conformity assessment guidelines and authorities

1. Conformity assessment activities should be performed in accordance with ISO/IEC ISO Conformity Assessment Standards Committee (CASCO) standards in liaison with the ANSI.

2. A federal authority should be established to serve as the federal authority for non-respiratory occupational PPT CA.

3. The CA framework and processes should be consistent with international standards to facilitate global trade, i.e., each system will have a counterpart in the ISO or EU framework, or both.

4. Suppliers should be responsible for performing the necessary actions including tests to ensure conformity with the BHSRs, enlisting the services of independent, accredited third-party bodies where required.

Hazard-based conformity assessment requirements

1. CA for non-respiratory PPT should be based on BHSRs representing tiered, hazard based approaches to CA.

2. The system of product categories should be based on three or more hazard categories (e.g., high, medium, and low) founded on the BHSRs. Each hazard category should be assigned a CA scheme. Risk should be defined as the inherent risk of the task, i.e., the potential risk to the PPT user if no PPT is used. PPT should be classified based on the category of hazard they are designed to protect the user against.

3. Requirements should range from first-party assessment (for products designed to protect against low hazards) to independent, third-party assessment.

    a) For all products, the requirements should include (1) the supplier's product testing and internal production control to ensure products placed on the market conform to the relevant BHSRs, and (2) the supplier should maintain a technical file with all design and performance inspection and test data. The supplier or other entity influencing the production of the product or service should provide such data, upon request, to the purchaser or federal authority.

    b) For products designed to protect against medium and high hazards, the requirements should also include (1) a type-examination by an accredited third-party body, (2) certification by an accredited third-party body before placing the product on the market, (3) quality control to ensure compliance with the type-examination certificate, (4) inspection by the certification organization of all product labels, and (5) documentation of all design, performance inspection, and test data from the certification organization in the technical file maintained by the supplier.

    c) For products designed to protect against high hazards, the requirements should also include a quality assurance program and an assessment of the system by an accredited third-party body.

Third-party bodies

1. Inspection, testing, and audit activities for CA of products designed to protect against medium and high hazards should be conducted by independent third-party bodies. Third-party bodies may be public- or private-sector organizations.

2. Third-party certifying organizations should (1) be technically qualified, fully independent, and impartial, (2) have no monetary interest in the product's ultimate profitability, and (3) fulfill ANSI applicable accreditation requirements and ISO/IEC 17065 and 17011 standards.

3. All inspections, evaluations, and testing for certification should be conducted by third-party bodies accredited in accordance with ANSI specified ISO/IEC standards and guides.

4. Third-party testing laboratories should have the appropriate facilities, equipment, and instrument calibration program for conducting the tests, in accordance with ISO/IEC 17025. Laboratories should follow good practice regarding manuals, documentation, calibration, verification, testing, and staff qualifications and training.

Accreditation

1. Accreditation bodies should operate in accordance with ANSI requirements, including ISO/IEC 17011, CA— General requirements for accreditation bodies accrediting CA bodies.
2. Accreditation bodies should fulfill the requirements of peer evaluation, as specified in ISO/IEC 17040 and ISO/IEC 17065.

Certificates and marks of conformity

1. For products designed to protect against medium and high hazards, a statement of conformity should accompany the products stating all the applicable requirements and the product's conformity. The statement should be in accordance with ISO/IEC Guide 23, Methods of indicating conformity with standards for third-party certification systems.
2. An approach to conformity marking should be developed, with particular consideration for two options. One option would be to continue the current system with individual certifying marks for each third-party CA/certifying organization. A second option would be to introduce a single mark of conformity for all non-respiratory PPT.

3. Third-party certification marks should be legally registered and legally defended to protect the integrity of the mark.

4. The conformity label, symbol, or mark should be affixed to all products that meet certification requirements. For products designed to protect against medium and high hazards, the marks of conformity must clearly identify the certifying

authority/organization and fulfill ISO/IEC 17030, General requirements for third-party marks of conformity.

Certified product lists

1. All third-party bodies should be required to maintain a list of all products they have certified. Third-party bodies should submit these lists to the federal authority, which will maintain a comprehensive list of all certified occupational PPT on a publically available website. Third-party bodies should submit updates to the federal authority of their list on a regular basis.

2. The federal authority should establish a structured web portal for third-party bodies to submit lists of certified non-respiratory PPT that enables public access.

3.1.3 Market Surveillance

Market surveillance guidelines and authorities

1. Market surveillance activities of third-party bodies should be performed in accordance with ISO/IEC CASCO standards.

2. A federal authority for non-respiratory occupational PPT should be established.

3. The federal authority should work with federal enforcement authorities [e.g. MSHA for the mining environment, FDA for healthcare, and the Environmental Protection Agency (EPA) for pesticide use in agriculture] and interested parties in the various industries to develop long-term and annual market surveillance plans for proactive market surveillance of PPT.

4. Market surveillance activities should be performed by the federal authority or an accredited third-party market surveillance body.

5. The federal authority should create and maintain an online, publically accessible database of all registered third-party market surveillance bodies, including type of product expertise and type of market surveillance services qualified to perform.

6. Market surveillance activities should include selecting sample product at random from the supplier's production line, from the supplier's in-house stock, or from the open market.

7. Market surveillance activities should be performed by accredited third-party market surveillance bodies. Accreditation requirements for market surveillance are the same as those for CA (described above). The third-party body performing market surveillance can be different from the third-party certification organization.

8. The third-party market surveillance body should inspect the manufacturing facilities to verify the continued compliance of the manufacturing procedures.

Adverse Event Reporting System

1. The federal authority should collaborate with partners including the FDA to expand the FDA's MedWatch Safety Reporting Portal and MAUDE, existing data collection programs, to include reporting on unsafe non-respiratory PPT and PPT-related injuries and illnesses.

2. Where it is established that a hazard is involved with a certified product that is non-conforming, the third-party market surveillance body, in coordination with the federal authority, will determine the scope of the hazard, including products, model numbers, serial numbers, factory production facilities, production runs, and quantities involved.

3. Where a specific hazard is identified, the determination of the appropriate action for the supplier to undertake should take into consideration the severity of the hazard and its consequences to the safety and health of users.

4. The federal authority should create and maintain an online system for the federal authority to communicate non-conformances resulting in corrective actions and be given enforcement authority to require corrective actions in the event of product failure. These procedures should comply with the provisions of ISO Guide 27, Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.

Enforcement and corrective action

1. Where a report of a medium to high hazard involved with a product is received, the federal authority will investigate the validity of the report.

2. Where the supplier discovers, during the review of specific returns or complaints, that a product or product component can constitute a potential safety risk to end users and is possibly subject to a safety alert or product recall, the supplier will immediately contact the market surveillance authority and the third-party market surveillance body and provide all information about their review to assist the federal authority with the investigation.

3. Where the facts indicating a need for corrective action are conclusive and the supplier has exhausted all appeal rights, the third-party market surveillance body, in coordination with the federal authority should initiate corrective action immediately, provided there is a supplier to be held responsible for such action. Where corrective action is indicated, but there is no supplier to be held responsible, such as when the supplier is out of business or the supplier is bankrupt, the market surveillance body, in coordination with the federal authority, should immediately notify relevant

governmental and regulatory agencies and issue a notice to the user community about the hazard.

4. The federal authority and third-party bodies in collaboration with the supplier, should conduct an investigation to determine appropriate corrective action, following risk assessment guidelines developed for all non-respiratory PPT. The risk assessment should be transparent and subject to peer review.

5. Suppliers should establish and maintain a written corrective action system and preventive action process that addresses nonconformities in product performance as specified in the product performance standard and user complaints.

6. Suppliers should implement product recall, withdrawal and other corrective actions when directed by market surveillance organizations, or when high-risk products are found to be defective. Suppliers should provide corrective action in accordance with ISO 9001, Quality management systems — Requirements, for investigating written complaints and returned products or a similar process.

7. Procedures should be developed for the supplier to appeal decisions about corrective actions. These procedures should consider current processes such as those used by NIOSH for respirators, the Safety Equipment Institute (SEI) for NFPA certified products, and approaches described in ISO 17003.

Ongoing Monitoring and Evaluation

1. The market surveillance program should be independently evaluated from both effectiveness and a cost/benefit perspective on a regular basis.

2. Third-party market surveillance authorities should be required to provide data on performance output indicators such as number of inspections conducted, number of products investigated, number of measures taken against unsafe products, etc.

3.2 Funding needs

3.2.1 Conformity assessment

A comprehensive CA system as defined by these requirements will need resources to pay third-party CA bodies and to provide oversight and coordination to ensure the system is implemented fairly and consistently across product and hazard categories. To effectively support these functions of the CA system for non-respiratory PPT, Congressional funding should be provided to the federal authority for coordination, communication and oversight activities.

3.2.2 Market surveillance

A comprehensive risk-based market surveillance system as defined by these requirements will need resources to pay third-party market surveillance bodies and to provide oversight

and coordination to ensure the system is implemented fairly and consistently across product and hazard categories. Congressional funding is recommended to support planning, coordination, communication, oversight, and enforcement activities of the market surveillance system for non-respiratory PPT designed to protect against medium and high-risk hazards.

3.3 Conformity assessment responsibilities

3.3.1 Federal

The federal government's role should be to define the requirements for CA and market surveillance and provide coordination, technical assistance, and enforcement roles for implementing the programs.

3.3.2 Third-party

Third-party involvement in CA can include testing, inspection, and auditing as well as other activities such as studying design drawings and specifications. Third-party bodies must be independent of the person or organization that provides the PPT and of user interests in the product (ISO-UNIDO, 2010:52-55). They can be government laboratories or private-sector organizations.

3.3.3 Suppliers and other economic operators

Suppliers should remain responsible for the conformity of the products they place on the market to the relevant BHSRs.

3.4 Impact assessment

To ensure that the proposed system does not unduly burden suppliers or suppliers, purchasers/employers, or consumers/taxpayers who are affected by the costs of CA, an impact assessment should be conducted.

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APPENDICES

Appendix A1. PPT Conformity Assessment Working Group Membership

National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL)	
Members	**Organization**
BerryAnn, Roland, Deputy Director	NIOSH/NPPTL/OD
Book, David, Team Leader	NIOSH/NPPTL/SCSST
Coffey, Chris, Associate Director for Science	NIOSH/NPPTL/OD
D'Alessandro, Maryann, Director	NIOSH/NPPTL/OD
Metzler, Rich, Engineer	NIOSH/NPPTL/OD
Newcomb, Bill, Physical Scientist	NIOSH/NPPTL/PSD
Sporrer, John, Public Health Analyst	NIOSH/NPPTL/OD
Szalajda, Jon, Branch Chief	NIOSH/NPPTL/TRB

PCAWG Consultants, Members at large	
Members	**Organization**
Beamer, Bryan Robert PhD, PE, CSP	University of Wisconsin
Coyne, Judi, Health Communications Specialist	NIOSH/NPPTL/SCSST
Haskell, Bill, Physical Scientist	NIOSH/NPPTL/PSD
Krah, Jackie, Health Communications Specialist	NIOSH/NPPTL /SCSST
Landsittel, Doug, Statistical Consultant	University of Pittsburgh
Oke, Charles, Epidemiologist	NIOSH/NPPTL/SCSST
Parker, Jay, Physical Scientist	NIOSH/NPPTL/TRB
Perrotte, John, Computer Engineer	NIOSH/NPPTL/SCSST
Peterson, Kristina	RTI International
Rethi, Lynn	Consultant
Shaffer, Ron, Senior Scientist	NIOSH/NPPTL/OD

External Members	
Members	**Organization**
Carnahan, Lisa J., Computer Scientist Standards Services Group NIST	National Institute of Standards and Technology
Corrado, Steven D., Principal Engineer – Personal Protective Equipment	Underwriters Laboratories
Doney, Brent, Industrial Hygienist	NIOSH/Division of Respiratory Disease Studies
Duffy, Richard M., Assistant to the General President (retired)	International Association of Fire Fighters
Fiers, Rudy. Senior Safety Specialist	Occupational Safety and Health Administration
Gillerman, Gordon, Director	National Institute of Standards and Technology
Gleason, Patricia A., President	Safety Equipment Institute
Gulledge, Beverly, Regulation & Certification Manager	Scott Safety
Hamilton, Bill	OSHA - Standards and Guidance
Johnson, James S. Ph.D., CIH, QEP	JSJ and Associates
Kline, Joann M. JD, Regulatory Technical Leader	Kimberly-Clark Professional
Kojola, William, retired	AFL-CIO, Department of Occupational Safety & Health
Lovasic, Susan L., Principal Investigator	DuPont Protection Technologies
Love, Michael D., President	Gateway Safety Inc.
McDiarmid, Melissa A. M.D. M.P.H., D.A.B.T., Professor of Medicine, Director, Occupational Health Program	University of Maryland School of Medicine
Platner, James W., Assoc. Director/Toxicologist	The Center for Construction Research and Training
Rodríguez, Jr, J.A. CSP, SGE, Senior Manager, Environmental, Health & Safety	Raytheon Technical Services Company LLC
Seitz, Teresa A., Supervisory Environmental Health Specialist	NIOSH/DSHEFS
Shaw, Dr. Anugrah, Professor, Human Ecology/Operations	University of Maryland – Eastern Shore
Shipp, Daniel K., President	International Safety Equipment Association
Stull, Jeffrey O., President	International Personnel Protection, Inc.
Weber, Bob, Manager of Quality, Regulatory Affairs and Technical Services	3M Occupational Health & Environmental Safety/3M Company
Zeigler, James P.	J.P. Zeigler Co., LLC

Appendix A2. PPT Conformity Assessment Working Group Tasks

Chair (Maryann D'Alessandro)

Terminology Subgroup (Lead – John Sporrer/Bill Newcomb)

1. Determine the conformity assessment terminology to be used in the effort

Products and Standards Subgroup (Lead – Dave Book/Rich Metzler)

1. Develop an inventory of product and performance standards and available products;
2. Identify classes of PPE to which specific standards and requirements apply;
3. Perform an assessment of national and international conformity assessment processes;
4. Identify existing third party certifiers of PPE, their current accreditation, and the standards to which they test products;
5. Document and identify PPT integration and interface issues which need to be addressed in the PPE conformity assessment context. (e.g. proximity sensors in hardhats, permeation sensors in protective clothing).

Risk Subgroup (Lead – Jon Szalajda/Bryan Beamer)

1. Determine appropriate levels of risk including the exploration and development of operations research methodologies (expert decision models) to assign risk levels;
2. Document the benefits of each level of conformity assessment;
3. Develop decision logic to determine appropriate levels of conformity assessment;
4. Develop a risk assessment process.

Surveillance Data Subgroup (Lead – Chris Coffey)

1. Document and assess data source needs and available data sources which identify PPE marked to a standard that does not meet the performance requirements. (e.g. FDA MedWatch and MAUDE Database, firefighter near-miss database, worker's compensation data, electronic health records);
2. Evaluate case studies and sources of incidents to determine if PPE failure was identified as a contributing factor to the adverse consequences including whether or not a product's claim of performance is valid;
3. Interface and collaborate with NIOSH Electronic Health Records Working Group to identify potential collaborative support.
4. Develop approaches that, if deployed, would result in better assessment of PPE failures and inadequacies;
5. Develop approaches that, if deployed, would result in better reporting of incidents of PPE failure;
6. Develop approaches that, if deployed, would result in better reporting of fraudulent or counterfeit PPE in the marketplace.

Compliance and Enforcement Subgroup (Lead – Roland Berry Ann)

1. Assess and document existing national compliance programs including requirements for conformity assessment and enforcement activities for the various classes of PPE and effectiveness where they exist;
2. Enumerate needs, gaps, and deficiencies in compliance programs and requirements for conformity assessment and enforcement authority guidelines for classes of PPE;
3. Identify approaches/recommendations for developing appropriate national compliance programs and requirements with prescribed mechanisms for effective enforcement to address deficiencies.

Appendix B. NFPA Fire and Emergency Services Protective Clothing and Equipment (FAE-AAC) [4]

Standard Designation	Standard Title	NFPA Committee
NFPA 1801	Standard on Thermal Imagers for the Fire Service	Electronic Safety Equipment (FAE-ELS)
NFPA 1982	Standard on Personal Alert Safety Systems (PASS)	Electronic Safety Equipment (FAE-ELS)
NFPA 1951	Standard on Protective Ensembles for Technical Rescue Incidents	Special Operations Protective Clothing and Equipment (FAE-SCE)
NFPA 1952	Standard on Surface Water Operations Protective Clothing and Equipment	Special Operations Protective Clothing and Equipment (FAE-SCE)
NFPA 1953	Standard on Protective Ensembles for Contaminated Water Diving	Special Operations Protective Clothing and Equipment (FAE-SCE)
NFPA 1975	Standard on Station/Work Uniforms for Emergency Services	Special Operations Protective Clothing and Equipment (FAE-SCE)
NFPA 1983	Standard on Life Safety Rope and Equipment for Emergency Services	Special Operations Protective Clothing and Equipment (FAE-SCE)
NFPA 1971	Standard on Protective Ensembles for Structural Fire Fighting and Proximity Fire Fighting	Structural and Proximity Fire Fighting Protective Clothing and Equipment (FAE-SPF)
NFPA 1977	Standard on Protective Clothing and Equipment for Wildland Fire Fighting	Wildland Fire Fighting Protective Clothing and Equipment (FAE-WFF)
NFPA 1991	Standard on Vapor-Protective Ensembles for Hazardous Materials Emergencies	Hazardous Materials Protective Clothing and Equipment (FAE-HAZ)
NFPA 1992	Standard on Liquid Splash-Protective Ensembles and Clothing for Hazardous Materials Emergencies	Hazardous Materials Protective Clothing and Equipment (FAE-HAZ)
NFPA 1994	Standard on Protective Ensembles for First Responders to CBRN Terrorism Incidents	Hazardous Materials Protective Clothing and Equipment (FAE-HAZ)
NFPA 1999	Standard on Protective Clothing for Emergency Medical Operations	Emergency Medical Services Protective Clothing and Equipment (FAE-EMS)

[4] * This list includes only those FAE-AAC standards that apply certification requirements (Chapter 4) to non-respiratory PPT. Standards such as those for respiratory protective devices (NFPA 1981, NFPA 1984), selection, care and maintenance standards (NFPA 1851, NFPA 1852), and air quality standards (NFPA 1989) are not included.

Appendix C. Current conformity assessment programs in the U.S.* [5]

	Respiratory protection				Other PPT				
	1 NIOSH	2 NIJ	3 NFPA	4 JPEO	5 NIJ	6 USCG	7 FDA	8 EPA	9 EPA
Product testing									
First party							●	●	
First party, with third-party oversight						●			
Third-party—Optional			●						
Third-party—Mandated	●	●			●				
Declaration of Conformity (attestation)									
First party only								●	
Third-party—Optional [c]		●	●		●				
Third-party—Mandated	●			●		●	●		
Certification renewal requirements		●				●		●	
Laboratory Accreditation									
Accreditation required? / services	●	●	●						
Accredited third-party		●	●			●			
Conformity marking									
Third-party mark	●								
Communication									
Certified/conforming product list	●	●							

Source: IOM (2011:85)

***KEY**

1. NIOSH: respirators
2. National Institute of Justice (NIJ): CBRN PPE for law enforcement
3. National Fire Protection Association (NFPA): Firefighter PPT
4. U.S. Army Joint Program Executive Office (JPEO): Military respiratory protection
5. National Institute of Justice (NIJ): Ballistic resistant Body Armor
6. U.S. Coast Guard (USCG): Personal Flotation Devices
7. Food and Drug Administration (FDA), Healthcare Workers PPT = "medical devices"
8. Environmental Protection Agency (EPA): Hearing Protection Devices
9. EPA: Protective clothing for pesticide operators

[5] The first five programs in the table (columns 1 through 5) are designed for products the EU would classify as Category III products (designed to protect against medium to high risks); of those five programs, four pertain to respirators. Three of the remaining programs apply to products the EU would classify as Category II products (designed to protect against medium risks).5 Only one program (the FDA's program for non-respiratory PPT) focuses on products the EU would classify as Category I products (designed to protect against low risks).

Appendix D. ISO Standards for Conformity Assessment[6]

Topic	Standard	Title
Requirements for third-party bodies		
Impartiality	ISO/PAS 17001	Conformity assessment -- Impartiality -- Principles and requirements
Code of good practice	ISO/IEC Guide 60	Conformity assessment -- Code of good practice
Accreditation bodies	ISO/IEC 17011	Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies
Inspection bodies	ISO/IEC 17020	Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
Audit and certification bodies	ISO/IEC 17021	Conformity assessment -- Requirements for bodies providing audit and certification of management systems
Audit and certification bodies	ISO/IEC TS 17021-3	Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 3: Competence requirements for auditing and certification of quality management systems
Testing and calibration laboratories	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
Peer assessment	ISO/IEC 17040	Conformity assessment -- General requirements for peer assessment of conformity assessment bodies and accreditation bodies
Proficiency testing	ISO/IEC 17043	Conformity assessment -- General requirements for proficiency testing
Certification bodies	ISO/IEC 17065	Conformity assessment -- Requirements for bodies certifying products, processes and services
Certification bodies	ISO/IEC 17024	Conformity assessment -- General requirements for bodies operating certification of persons
Conformity assessment systems		
Third-party body certification	ISO/IEC Guide 28	Conformity assessment -- Guidance on a third-party certification system for products
Product certification	ISO/IEC 17067	Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes
Conformity assessment procedures		
Vocabulary	ISO/IEC 17000	Conformity assessment -- Vocabulary and general principles
Management systems	ISO/PAS 17005	Conformity assessment -- Use of management systems -- Principles and requirements
Management systems	ISO/IEC Guide 53	Conformity assessment -- Guidance on the use of an organization's quality management system in product certification
Management systems	ISO/IEC TS 17023:2013	Conformity assessment -- Guidelines for determining the duration of management system certification audits
Audit reports	ISO/IEC TS 17022:2012	Conformity assessment -- Requirements and recommendations for content of a third-party audit report on management systems

[6] Source: ISO (2013B)

Topic	Standard	Title
Indications of conformity	ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems
Marks of conformity	ISO/IEC 17030:2003	Conformity assessment -- General requirements for third-party marks of conformity
Declaration of conformity	ISO/IEC 17050-1:2004	Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements
Supporting documentation	ISO/IEC 17050-2:2004	Conformity assessment -- Supplier's declaration of conformity -- Part 2: Supporting documentation
Mutual recognition of results	ISO/IEC Guide 68:2002	Arrangements for the recognition and acceptance of conformity assessment results
Information disclosure	ISO/PAS 17004:2005	Conformity assessment -- Disclosure of information -- Principles and requirements
Complaints and appeals	ISO/PAS 17003:2004	Conformity assessment -- Complaints and appeals -- Principles and requirements
Enforcement		
Corrective actions	ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
Conformity assessment standards		
Conformity assessment standards	ISO/IEC 17007:2009	Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment

Appendix E. Draft inventory of U.S. standards, by hazard and type of PPT covered

Hazard Type	PPE Type	Number of Standards	Total
Biohazards	Face masks	2	
	Medical protective clothing	1	3
Biological	Footwear, general	1	
	Chemical protective gloves	1	
	Medical gloves	35	
	Face masks	3	
	Medical protective clothing	26	
	Particulate protective clothing	4	70
Chemical	Chemical protective footwear	9	
	Chemical protective gloves	13	
	Thermal protective gloves	1	
	Escape respirators	1	
	Helmet	1	
	Hoods	1	
	Chemical, electrical, firefighter, medical, particulate, physical, radiation and other protective clothing	51	
	Chemical safety clothing	1	
	Pesticide application clothing	1	
	Protective clothing, general	7	86
Chemical reactions	Chemical protective clothing	1	
	Protective clothing, general	1	
	Spectacles, faceshields, goggles, welding helmets	1	3
Electrical hazards	Electrical worker helmets	1	1
Ergonomics	Eye-protectors	3	3
Flame and thermal	Cold protective footwear	3	
	Electrical protective footwear	12	
	Firefighter footwear	8	
	Footwear, general	1	
	Conductive footwear	4	
	Thermal protective footwear	2	
	Thermal protective gloves	4	
	Cold protective gloves	2	

Hazard Type	PPE Type	Number of Standards	Total
	Electrical gloves	5	
	Fire fighting gloves	12	
	Fire fighting gloves, gloves, general, physical protective gloves, thermal protective gloves, work gloves	1	
	Work gloves	1	
	Welding gloves	2	
	Electrical worker helmets	2	
	Electrical worker helmets, headgear, helmet, industrial helmets	4	
	Fire fighting helmets	8	
	Hoods	1	
	Welding helmets	3	
	Environmental protective clothing	23	
	Electrical protective clothing	11	
	Firefighter protective clothing	22	
	Protective clothing, general	3	
	Thermal protective clothing	36	
	Safety belts, harnesses, lanyards and lifelines	1	171
Flammability and fires	Welding helmets, handshields	1	
	Eye-protectors	2	
	Thermal protective clothing	2	
	Environmental protective clothing	1	6
Human factor	Gloves, general	2	
	Environmental protective clothing	7	
	Physical protective clothing	1	
	Protective clothing, general	2	12
Mechanical hazards	Eye-protectors	2	
	Footwear, general	1	
	Protective clothing, general	1	
	Riot helmet and face shield	1	
	Fall arrest systems	17	
	Lanyards	1	
	Positioning and travel restraint	1	
	Rescue systems	1	
	Safety belts, harnesses, lanyards and lifelines	8	

Hazard Type	PPE Type	Number of Standards	Total
	Work surfaces	2	35
Physical	Climbing footwear	1	
	Footwear, general	53	
	Physical protective footwear	4	
	Anti-vibration gloves	4	
	Chemical protective gloves	2	
	Electrical gloves	1	
	Gloves	10	
	Gloves, general, protective clothing, general	1	
	High visibility gloves	1	
	Physical protective gloves	3	
	Work gloves	21	
	Auditory assessment	4	
	Ear muffs	6	
	Ear muffs, ear plugs, hearing protectors	1	
	Ear plugs	7	
	Hearing conservation	1	
	Hearing protection program	1	
	Hearing protectors	10	
	Ballistic helmets	1	
	Headgear	2	
	Headgear, hearing protectors, industrial helmets	1	
	Headgear, helmet, industrial helmets	10	
	Headsets	12	
	Helmet	1	
	Industrial helmets	6	
	Law enforcement helmets	1	
	Riot helmet and face shield	1	
	Anti-vibration protective clothing	1	
	Coveralls	1	
	Physical protective clothing	39	
	Protective clothing testing	1	
	Protective clothing, general	9	
	Visibility warning clothing	7	
	Harnesses	1	

Hazard Type	PPE Type	Number of Standards	Total
	Ballistic resistant shields	1	
	Body Armor	1	
	Fall arrest systems	4	
	Lanyards	1	
	Personal body armor	1	175
Radiation	Eye-protectors	3	3
Radiological	Spectacles, faceshields, goggles, welding helmets	1	
	Hood	1	
	Medical gloves	1	
	Radiation protective clothing	20	
	Radiation protective footwear	3	26
Temperature	Radiation protective gloves	3	3
Toxics	Protective clothing, general	1	
	Protective clothing, general	1	2
	TOTAL		657

Appendix F. Current market surveillance requirements in the U.S.*

	Respiratory protection				Other				
	1 NIOSH	2 NIJ	3 NFPA	4 JPEO	5 NIJ	6 USCG	7 FDA	8 EPA	9 EPA
Pre-market surveillance									
Site audits of manufacturing site	•					•			
Good Manufacturing Practices							•		
Post-market testing & evaluation									
Product audits – samples purchased commercially	•	•						•	
Product audits – sampled from workplace	•			•	•		•		
Product audits – manufacturer sends sample from workplace						•			
Product audits following complaints (reactive)	•								
Product audits – other third-party audits			•						
Adverse Event reporting system – voluntary (passive)							•		
Adverse Event reporting system -- mandatory		•					•		
Corrective actions									
Revocation of certification	•						•		
Dissemination of revocation notifications		•			•				
Fines, recalls, imprisonment	•						•	•	
Corrective actions, unspecified			•			•			
Registries, surveillance		•					•		

Source: IOM, 2011

***KEY**

1. NIOSH: respirators
2. National Institute of Justice (NIJ): CBRN PPE for law enforcement
3. National Fire Protection Association (NFPA): Firefighter PPT
4. U.S. Army Joint Program Executive Office (JPEO): Military respiratory protection
5. National Institute of Justice (NIJ): Ballistic resistant Body Armor
6. U.S. Coast Guard (USCG): Personal Flotation Devices
7. Food and Drug Administration (FDA), Healthcare Workers PPT = "medical devices"
8. Environmental Protection Agency (EPA): Hearing Protection Devices
9. EPA: Protective clothing for pesticide operators

The first five programs in the table (columns 1 through 5) are designed for products the EU would classify as Category III products (designed to protect against medium and high risks); of those five programs, four pertain to respirators. Three of the remaining programs apply to products the EU would classify as Category II products (designed to protect against medium risks).1 Only one program (the FDA's program for non-respiratory PPT) focuses on products the EU would classify as Category I products (designed to protect against low risks).