Summary Report

Personal Protective Equipment Conformity Assessment Working Group

July 25, 2013

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ACRONYM GLOSSARY

ABLES—Adult Blood Level and Surveillance

AHETF—Agricultural Handler Exposure Task Force

ANSI—American National Standards Institute

ASTM—American Society for Testing and Materials

BSI—British Standards Institution

CA—conformity assessment

CB—certification body

CBD—chemical and biological defense

CBRN—chemical, biological, radiological and nuclear defense

C&E—compliance and enforcement

CEN—European Committee for Standardization

CPSC—Consumer Products Safety Commission

CTP—Compliance Testing Program

DARD—Defense Accountability, Reutilization and Disposal

DoD—Department of Defense

DOJ—Department of Justice

DSR—Division of Safety Research

EHR—Electronic Health Records

EPA—Environmental Protection Agency

FACE—Fatality Assessment and Control Evaluation

FAT/CAT—Fatalities and Catastrophes

FDA—Food and Drug Administration

FFFIPP—Fire Fighting Fatality Investigation and Prevention Program

FIT—Follow-up Inspection and Testing

HC—Hearing Conservation

IAFC—International Association of Fire Chiefs

IDS—incident data source

IEC—International Electrotechnical Commission

IOM—Institute of Medicine

IRB—institutional review board

ISEA—International Safety Equipment Association

ISO—International Organization for Standardization

JEAU—Joint Equipment Assessment Unit

JPEO—Joint Program Executive Office

MAUDE—Manufacturers and Users Facility Device Experience Database

MSHA—Mine Safety and Health Administration

NBC—nuclear, biological, chemical

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

NPPTL—National Personal Protective Technology Laboratory

NSC—National Safety Council

NTAA—National Technology Transfer and Advancement Act

OMB—Office of Management and Budget

OPP—Office of Pesticide Programs

OSHA—Occupational Safety and Health Administration

OSHCON—National Association of Occupational Safety and Health Consultation Programs

OSHSPA—Occupational Safety and Health State Plan Association

PASS—Products and Standards Subgroup

PCAWG—Personal Protection Equipment Conformity Assessment Working Group

PCE—protective clothing and ensembles

PPE—personal protective equipment

PPT—personal protective technologies

RP—respiratory protection

SEI—Safety Equipment Institute

SIC—standard industry code

UL—Underwriter Laboratories

Summary Report for PPE Conformity Assessment Working Group

Background

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

> A comprehensive conformity assessment program which enhances the confidence that the PPT health and safety products used in American workplaces have been appropriately tested to demonstrate compliance with state of the art performance standards and are manufactured in quality facilities does not exist. Several private organizations, such as the Safety Equipment Institute (SEI) and Underwriters Laboratory (UL), provide third party certification services for PPT; however, in most cases testing and certification are voluntary so most users rely on manufacturers' declaration of conformity to demonstrate that products meet quality and performance requirements of a recognized consensus or federal standard.

Establishment and Purpose of Working Group

In response to recommendations made by the National Academies [and its Institute of Medicine (IOM)], the PPT Conformity Assessment Working Group (PCAWG) was established in 2011 by NPPTL[1]. The purpose of the PCAWG is to prepare a national framework establishing criteria, including comprehensive and consistent processes, to address conformity assessment (CA) of non-respiratory PPE. The framework and processes define the components necessary to determine CA requirements for non-respiratory PPE across industry sectors.

Organization and Goals of Subgroups

[1] Certifying Personal Protective Technologies: Improving Worker Safety, Committee on the Certification of Personal Protective Technologies, Institute of Medicine, Cohen, et al. 2010, The National Academies Press.

The PCAWG is chaired by NPPTL and includes members from NIOSH, other federal agencies and stakeholder representatives. Consultants support PCAWG activities and participate in meetings but do not serve as members. The areas of expertise represented through consultants include statistical support, risk management, PPE, and NIOSH sector and cross-sector representation and expertise.

The organization and workflow for the PCAWG are shown below.

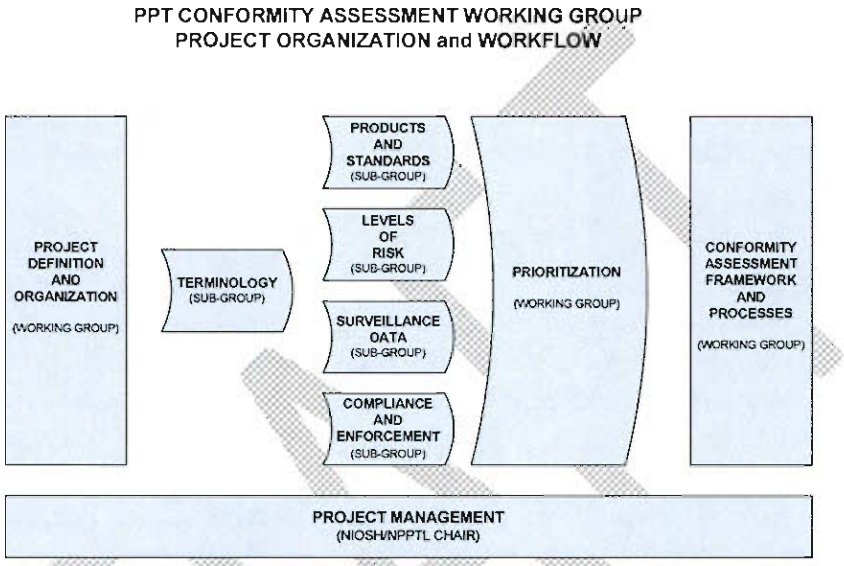

Figure 1. PCAWG Project Organization and Workflow

Summary of Subgroup Activities and Findings

A summary of the main findings and activities of key subgroups is presented below. In addition to these points, final reports of each subgroup are provided in the appendix of this document.

Terminology

- There is a need to identify standard terms and definitions for conformity assessment.

- A list of terms and definitions was identified.

Products and Standards Subgroup(PASS)

- PPE performance standards do not contain CA requirements.
- With few exceptions, there are no nationally applied CA requirements for PPE.
- A verified database of United States PPE standards including OSHA regulations was needed and developed.

- A searchable PPE standards database was developed as a prototype for potential use by stakeholders interested in PPE performance standards.
- The value of a national PPE standards database and approaches to maintain an updated database need to be defined.
- The International Organization for Standardization (ISO) published more than 28 CA standards that could be applied in the US to PPE CA.

Risk Subgroup

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

Surveillance Subgroup

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

Compliance and Enforcement Subgroup

- An assessment of state and federal compliance programs indicated that PPE is not an integral component of these programs.

- With few exceptions, there is no universal program to verify PPE manufacturer's claims of conformance to claimed product standards.
- Data relating PPE non-conformance to claimed standards with enforcement actions (e.g. violations, fines, etc.) are not in OSHA and MSHA databases.
- The NIOSH respiratory protective device (RPD) approval program, the European Union (EU) PPE directive, and EU CA program were benchmarked to assess best practices.
- The EU PPE Directive and associated programs are currently under revision to address needed improvements (e.g. post market surveillance) .
- The EU PPE program has substantial CA components.
- The EU model is a good reference for CA requirements that could be adapted to non-RPD in the United States.

Appendices

Appendix A: Risk Subgroup Report

Purpose

This section details the risk assessment process developed by the Risk Subgroup of PCAWG during 2011-13. Included in this report is an outline of a sample risk assessment process for CA.

Sample Risk Assessment Procedure

Overview

Workers on the job are exposed to a variety of occupational risks, and the PPE they wear is intended to aid in the mitigation of these risks. However, the charge of the Risk Subgroup was to look specifically at risk as it relates to CA of PPE. Therefore, within the context of this document, the Risk Subgroup has developed a sample Risk Assessment Procedure with an appropriately narrow scope: "What is the risk to the user of (non-respiratory) PPE failing to meet a given performance standard?" In order to gain an understanding of this risk, it is important to frame the question within the scope of the performance standard. The procedure below accomplishes this by: 1) determining the relative risk to the worker wearing PPE that complies to a given performance standard; 2) determining the relative risk to the worker if the PPE failed to meet that standard; 3) framing the risk estimation within the appropriate scope and limits set by the performance standard; and 4) documenting the risk assessment procedure in a consistent, thoughtful manner.

The following steps are taken after the PPE type has been identified and documented in accordance with the products and standards database (developed by the PCAWG Products and Standards Subgroup).

Step 1: Document the PPE type, intended use of PPE, and required standard.

Step 2: Identify user population/usage scenarios.

Step 3: Identify failure modes and performance requirements addressed by the standard.

Step 4: Identify several typical, illustrative hazards for PPE users.

Step 5: Estimate risk of injury/illness while using PPE that meets performance standard.

Step 6: Estimate initial risk of injury/illness while using non-compliant PPE.

Step 7: Verify relative efficacy of performance standard vs. the potential contribution of CA activities.

Step 8: Identify current CA activities and estimate their overall effectiveness.

Step 9: Document and follow through.

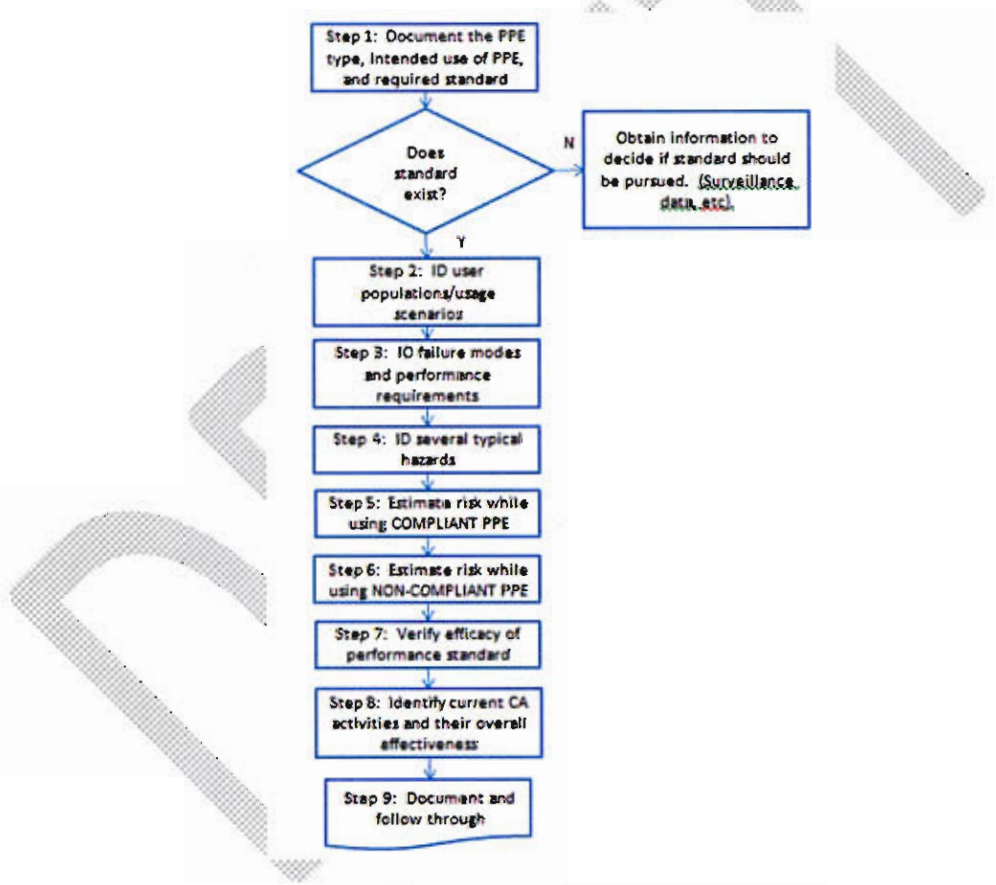

Figure 2. Risk Assessment for CA in Flowchart Format

Step 1: Document the PPE type, intended use of PPE, and required standard

Each CA risk assessment must link a type of PPE to a specific performance standard in order to answer the question "What is the risk to the user of a type of PPE failing to meet a given performance

standard?" The following questions, at a minimum, must be documented in order to proceed with the risk assessment. If no specific performance standard exists, then this should be documented, as further analysis would not be possible?

- What is the performance standard in question?
- Which type(s) of PPE is covered by the standard?
- What is the documented scope of the performance standard? Limitations?
- What are specific performance requirements?

Step 2: Identify User Populations and Typical Usage Scenarios

To gain an understanding of the overall risk to the American worker, it is important to characterize who is using the PPE in question and in what context. If the PPE is typically used in scenarios outside of the scope of the performance standard, this fact should be documented. Also, a lack of information regarding PPE user populations and usage may be an indication that further research on the topic is needed.

If possible, the following basic information regarding user populations and typical usage scenarios should be collected. Where information is not available, this may be an indication that further study/estimates are needed.

- User Population:
  - How many workers use this type of PPE in the American workforce?
  - In which industries is the PPE commonly used?
- Usage Scenarios
  - For which tasks is this PPE typically used?
  - From which hazards is the PPE intended to protect the worker?

– Is there evidence that the PPE is typically misused? If so, to what extent is this a problem and what are the root causes?

Step 3: Identify Failure Modes and Performance Requirements Addressed by the Standard

A well-written performance standard should specify to what extent PPE should protect the worker and under what circumstances; these performance criteria should be documented in this step in the process. Furthermore, there may be multiple ways for the PPE to fail, and this should be recognized. For instance, ANSI z.89 not only specifies force of impact and penetration requirements for industrial helmets but also states a requirement for electrical protection. In this case the two modes of failure, failure to provide force of impact protection and failure to provide electrical protection, would be noted.

Step 4: Identify Several Typical, Illustrative Hazards for PPE Users

To complete subsequent steps in the process, several typical hazards for PPE users need to be defined. These definitions will aid in determining the risk level to the user while using PPE that is conforming to the performance standard vs. the risk to the user if the PPE failed to meet the performance standard. The typical usage scenarios identified in Step 2 should be used as a basis for determining these hazards. Moreover, each hazard should be characterized in terms of: 1) the source of the hazard, and 2) the outcome of the hazard.

In order to stay within the bounds of the performance criteria, the following should be kept in mind when identifying hazards for Step 4:

- Hazards and usage scenarios must be based on the stated constraints of the performance standard.
- Selection of usage scenarios and hazards should be representative of a variety of the industries in which the PPE is used.
- As much as possible, test criteria should dictate the hazards identified. For instance ANSI z.89 specifies impact protection in terms of ft/s and electrical protection in terms of volts.

Step 5: Estimate Risk of Injury/Illness While Using PPE Which Meets Performance Standard

For each hazard identified in Step 4, the relative risk to the worker while using ***conforming*** PPE should be determined using Table 1. In Step 5, the following basic question is to be answered for each hazard: "If the PPE conforms to the performance standard, what is the risk of injury/illness to the worker?"

Since Step 5 focuses on the performance standard, it is imperative to make the following assumptions:

- The PPE performed as designed (conformed to standard).
- The PPE was selected properly (within limitations of standard).
- The performance standard was intended to protect the worker against that hazard (proper selection and use).
- The severity of consequences from the hazard is for a typical case and not derived from extreme, unlikely scenarios.
- If there is verifiable evidence of injury/illness while using ***conforming*** PPE, it should be taken into account for this step.

The relative risk to the worker for each hazard is to be based on the following chart:

		Likelihood of Injury/Illness			
		Rare/Unlikely	Possible	Likely	Very Likely
Severity	Death or Permanent Disability	MEDIUM	MEDIUM	HIGH	HIGH
	Lost Workdays	LOW	MEDIUM	MEDIUM	HIGH
	Restricted Workdays	LOW	LOW	MEDIUM	MEDIUM
	First Aid Case	LOW	LOW	LOW	MEDIUM

Figure 3. Risk Matrix for PPE Conformity Assessment

Step 6: Estimate Initial Risk of Injury/Illness while Using Non-Compliant PPE

Step 6 helps to determine the relative contribution CA makes in protecting the worker from injury/illness. For each of the hazards identified in Step 4, the risk to workers if PPE does not conform to performance standard should be estimated.

Using the risk level chart provided in the previous step (Table 1), the following question should be asked for each hazard: "What is the risk of injury/illness to the worker if the PPE ***fails*** to meet the performance standard?" When determining the ***probability*** of the PPE failing, the following data should be taken into account if known:

- How many workers use this type of PPE?
- How many industries?
- Is there existing evidence of non-conforming PPE reaching the marketplace?
- Is there evidence of non-conforming PPE causing injury or illness?

- Would non-conforming PPE be obvious to the worker?

Step 7: Verify Relative Efficacy of Performance Standard vs. the Potential Contribution of CA Activities

One of the major objectives of this risk analysis is to differentiate the contribution of the performance standard to reducing risk vs. the potential contribution of CA activities. To accomplish this, a comparison of risk levels from Steps 5 and 6 should be made. In general, the following trends should be noted:

- If the risk to workers of ***conforming*** PPE does not go down (Steps 4 to 5), CA activities may be moot. In this instance, the root causes of the situation should be studied and appropriate action taken.
- If comparison of results from Steps 5 and 6 indicates that CA makes a large contribution to protecting the worker from injury/illness, this situation should be noted. In this case, relevant risk assessment data should be used in conjunction with other data like cost/benefit information, market influences, effectiveness of current CA activities, etc. to make a decision regarding optimal CA levels.
- A more thorough discussion of various scenarios and their interpretations is provided in Appendix C.

Step 8: Identify Current CA Activities and Estimate Their Overall Effectiveness

As noted in the preceding paragraph, current CA activities need to be considered when determining the appropriate CA scheme for a given type of PPE. When documenting these CA activities in Step 8, the following aspects should be considered[2]:

- Regulatory basis for CA

[2] Adapted from: TABLE S-2 Risk-Based Framework for Non-Respirator Personal Protective Technologies (PPT) Conformity Assessment from IOM Report

- Product testing (1st, 2nd, or 3rd party)
- Accredited testing labs (1st, 2nd, or 3rd party)
- Declaration of product compliance (1st, 2nd, or 3rd party)
- Conduct post-marketing testing, evaluation, surveillance (1st, 2nd, or 3rd party)
- Recall products (1st, 2nd, or 3rd party)
- Listing of certified products (government agency)
- Institute tracking label (3rd party)
- Provide oversight to the CA process (1st, 2nd, or 3rd party, government agency)

Step 9: Document and Follow Through

All information, logic and assumptions of analysis should be documented. Information gained in the risk analysis should be compiled with other available information including cost/benefit data, market influences, effectiveness of current CA activities, feasibility of enacting a change in CA activities, etc. In particular, any evidence that performance standards are not adequate or that a change in CA activities may be warranted should be carefully documented; all logic and assumptions should be thoroughly explained in order to stand up to later questions.

Discussion of Key Concepts

Limitations of the Risk Assessment Process

In the course of developing the sample risk assessment process for CA, it has become apparent that the process is limited by several factors including the following:

- As outlined, a great deal of data will need to be generated to conduct a thorough analysis.
- This type of risk analysis is qualitative and subjective.
- A risk model for CA ***cannot*** conclusively predict or verify the outcome of changing a CA scheme.
- Consistent and reliable feedback and surveillance data regarding failure of PPE in the field do not currently exist.

- Risk assessment is not the only basis for facilitating a discussion on optimal CA activities.
- Risk assessment should not be a sole basis for justifying a change in CA activities.

Advantages of the Sample Risk Assessment Process

Despite the limitations mentioned above, the risk assessment process for CA is a powerful tool in collecting information in a systematic, logical way. As such the process outlined above can help:

- Identify significant gaps between CA activities and risk that the PPE would fail to meet performance standards.
- Identify when the risk of non-conformance is eclipsed by the risk of an inadequate performance standard.
- Provide a straightforward process that can facilitate thoughtful group discussion and decision making.
- Justify decisions to make changes in CA activities.
- Provide a basis of consistency in analysis between various PPE types. Furthermore, this consistent analysis can aid prioritization of research activities and help determine which performance standards merit a different CA scheme.

Conclusions and Recommendations of Risk Subgroup

- The Risk Subgroup verified that there are no requirements for US risk assessment activity to match PPE types with appropriate CA requirements.
- A substantial level of expert judgment is required to establish qualitative risk levels due to lack of readily available data to assist with risk assessment of PPE.
- Standards developers do not currently use quantitative risk assessment tools to guide updates of PPE performance, reliability, and quality requirements.
- As is evidenced by a European Commission directive, risk assessment guidelines could be established to link PPE types to CA requirements.

Appendix B: Surveillance Subgroup Report

Purpose

This purpose of this section is to detail activities undertaken by the Surveillance Subgroup of the PCAWG during 2011-13. Included in this section are descriptions of: 1) the available data sources and case studies investigated by the subgroup, 2) possible collaboration with the NIOSH Electronic Health Records Working Group, and 3) possible approaches for NIOSH surveillance of PPE.

Available Data Sources and Case Studies

Overview

These surveillance activities were undertaken to aid in: 1) documenting and assessing data source needs and available data sources which identify PPE marked to a standard that does not meet the performance requirements, and 2) evaluating 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.

Available data sources investigated

NIOSH State-Based Surveillance Program

The NIOSH state-based Surveillance Program does not collect information about the type of PPE used in reported occupational illness cases. However, some states collect information on respirator use and other states such as New York also ask about other, non-respirator PPE. The Adult Blood Lead Epidemiology & Surveillance (ABLES) state-based surveillance program of laboratory-reported adult blood lead levels, was also investigated as a possible source of surveillance data for PPE. However, NIOSH does not receive information about PPE used by adults with elevated blood lead levels under this program. Rather, the program objective of ABLES is to build state capacity to initiate, expand or improve adult blood lead surveillance programs which can accurately measure trends in adult blood lead levels and effectively intervene to prevent lead overexposures.

Fatality Assessment and Control Evaluation (FACE) Program

The Fatality Investigations Team in the NIOSH Division of Safety Research does not collect any information that would assist in the CA of non-respirator PPE.

Firefighting Fatality Investigation and Prevention Program (FFFIPP)

The Division of Safety Research conducts the NIOSH Fire Fighter Fatality Investigation and Prevention Program (FFFIPP), which conducts investigations of firefighter line-of-duty deaths to formulate recommendations for preventing future deaths and injuries. In incidents suggestive of potential performance problems with respirators or personal protective clothing, investigators will request that the equipment or clothing be sent to the NIOSH National Personal Protective Technology Laboratory for evaluation. Currently, PPE conformity is evaluated only for self-contained breathing apparatus (SCBA), but not for other types of firefighter PPE. If the SCBA is certified to NFPA 1981, the Air Flow Performance Test from the appropriate edition of the NFPA standard is also conducted. NIOSH (in a limited capacity) already does some CA activities for non-NIOSH standards.

However, evaluators of new protective clothing will conduct a visual inspection of the gear and report whether or not the gear was marked to a particular standard. Testing is not planned for the gear, because the testing is generally destructive. The NPPTL Protective Clothing and Ensembles (PCE) Team evaluation process calls for notifying the body issuing the standard. The reports generated by this new process will serve as a good start for a database for firefighter non-respirator PPE.

Department of Justice

The Department of Justice/Office of Justice Programs, National Institute of Justice (NIJ)/Office of Science and Technology, Operational Technologies Division tests body armor, ballistic helmets, riot helmets and riot helmet face shields, bomb suits, ballistic resistant protective materials, and protective gloves as part of the National Law Enforcement and Corrections Technology Center (NLECTC) voluntary equipment

testing program to determine compliance with the NIJ standards. This program is the Compliance Testing Program (CTP). The NLECTC disseminates those test results and other pertinent information to the law enforcement and corrections communities. The Follow-Up Inspection and Testing (FIT) program compares the construction of newly made armor with samples previously tested under the CTP.[3] In response to documented variations, manufacturers worked with the CTP to implement quality control improvements at several manufacturing locations to prevent additional variations.

Another example of a new program for certification of PPE including surveillance requirements is for law enforcement officers through the NIJ. It covers chemical, biological, radiological and nuclear personal protective equipment (CBRNPPE). For their new standards on CBRNPPE for Law Enforcement and for Bomb Suits for Public Safety, NIJ utilized an approach that separates the technical requirements of the standard and the certification process requirements into two documents. Each document references the other so that there is a definite connection between the two indicating that the program is incomplete without both documents. The Certification Program Requirements standard includes all requirements for certification organizations and specific process and procedure requirements related to certification that are not covered by ISO/IEC Guide 65.

The NIJ Certification Program Requirements Standard for CBRNPPE requires that the certification body (CB) operate a surveillance program for compliant models to determine continued compliance, and that all such models shall undergo surveillance. At a minimum, the surveillance program includes inspection and audits and testing to the performance requirements annually.

The NIJ standard also requires the CB to have procedures for dealing with reports (or indications) from any source, including surveillance, regarding certified products which are noncompliant, are unfit for

[3]Ballistic Resistance of Body Armor, NIJ Standard 0101.06.

intended purpose, have failed in use, or involve a safety issue. The CB must also notify the NIJ and provide specific details.

National Institute of Standards and Technology

The National Institute of Standards and Technology (NIST) conducts a wide range of research on understanding the exposure of firefighters and uses that science to improve PPE standards. The results of this research are not a database. Oftentimes the research is initiated by specific fire incidents or a collection of incidents. For example, NIOSH brought to NIST attention several incidents where firefighters' Personal Alert Safety System (PASS) devices did not appear to function properly. Initial speculation was that the incidents were caused by either water in the electronics or thermal behavior of the batteries. NIST researchers started to collect data under realistic thermal exposures and discovered that the incidents were caused by high-temperature softening of the adhesive on the alarm-noise generating disk that tied the piezoelectric crystal to the brass disk. They shared this information with NIOSH and the National Fire Protection Association (NFPA) Electronic Safety Equipment Committee. They also provided a revised test method to the NFPA committee to evaluate high-temperature functionality. Technical reports document some of their data on the thermal performance of PASS devices.

Another example is some current work on the self-contained breathing apparatus lens. NIOSH Morgantown also brought this to NIST attention; NIST researchers collected data and provided NFPA with a revised test methodology. The results of the research are documented in publicly available journals and technical reports. Although NIST often includes commonly available equipment in their research, the institute does not typically identify the performance of a specific brand or manufacturer.

NIOSH Division of Safety Research Emergency Department Surveillance

The Division of Safety Research (DSR) conducts surveillance of nonfatal occupational injuries and illnesses treated in U.S. hospital emergency departments. The DSR emergency department surveillance program rarely includes information regarding PPE. When PPE is contained in the database, the records do not provide the information that can be used for CA.

Occupational Safety and Health Administration inspection Data and Voluntary Protection Program Participants' Association

NPPTL contracted with the RAND Corporation to explore the value that inspection data collected by the Occupational Safety and Health Administration (OSHA) could add to the NPPTL surveillance efforts. The RAND study did not look at all forms of PPE but was limited to analyses of a) toxic substance exposures and the related violations of the respiratory protection (RP) standard and b) noise exposures and the related violations of the Hearing Conservation (HC) program standard. Except for the auto repair industry, the analyses are limited to the manufacturing sector. The inspections cover 1999-2006. The report reviewed the potential benefits and drawbacks of OSHA data as a surveillance tool. The purpose of the study was not to be comprehensive in its coverage of issues or complete in its analysis of particular issues. Instead, it tried, first, to demonstrate the value of the data for comparing conditions in different industries. Second, it tried to illustrate the uses of a number of different data elements in the OSHA data. Special attention was devoted to the information on the particular RP and HC standards that were cited. More specifically, the report presented analyses at three levels: for all manufacturing, for the 2-digit standard industry code (SIC) industries within manufacturing, and for foundries (SIC 332) and auto repair establishments (SIC 753). For each of these, the following types of information were presented:

(a) Numbers of inspections and establishments with violations of the RP and HC standards

(b) Variations in the occurrence of these violations among establishments in different size categories and with and without unions

(c) Violations of particular provisions of the HC and RP standards, especially those concerning protective equipment

(d) Information on levels of toxic and noise exposures that accompany the violations.

Since the PCAWG is interested only in non-respiratory PPE, only the data dealing with HC violations were reviewed. RAND found data do not indicate whether the HP failed to meet a performance standard.

American Society of Safety Engineers, National Safety Council, and the International Safety Equipment Association

Data relative to injuries resulting from PPE conformity issues are not readily available at the American Society of Safety Engineers, National Safety Council (NSC), or OSHA Voluntary Protection Program Participants' Association. The NSC appears to have the largest database of injury data, but it primarily collects information on types of injuries, demographics, probability of occurrence, severity, body part, etc., and not on injuries that have occurred as the result of a particular PPE conformity issue.

The International Safety Equipment Association (ISEA) was contacted for input regarding the objectives of the Surveillance Subgroup. The ISEA commented that member companies would not be open to sharing information about product failures in the field or pertaining to the use of their products in a situation that involved an injury, illness or fatality.

US Army Joint Program Executive Office

The Joint Program Executive Office (JPEO) is the lead for integrated technical and business processes supporting the surveillance, assessment and reuse of chemical and biological defense (CBD) equipment. JPEO offers skilled capabilities in the shelf life management of chemical, biological, radiological and nuclear-defense (CBRN-D) assets that supports the JPEO-CBD in Total Life-Cycle Systems Management.

JPEO acts as the single point of contact for surveillance, accountability and disposal of CBRN-D equipment throughout the Department of Defense (DoD) as defined by the JPEO-CBD Charter. The service provided by JPEO supports the mission to sample, inspect, repair and assess CBRN-D assets. It has the following mission areas:

- Joint Shelf Life Testing and Set-Aside: Develop and maintain technical expertise in support of the DoD requirements for shelf life and surveillance programs which support total life cycle management of CBRN-D equipment.
- Joint Equipment Assessment Unit (JEAU): The JPEO conducts on-site cyclic assessments of wholesale and retail assets. It assists commanders at all levels of supply in determining the readiness of their assets. It monitors and reports the condition and degradation of CBRN-D equipment.
- Defense Accountability, Reutilization and Disposal (DARD): Provide efficient and cost effective collection, assessment and reutilization of serviceable CBRN-D clothing and textiles. The JPEO's DARD project will further ensure proper demilitarization of unserviceable CBRN-D equipment and maintain accurate accountability for all designated excess/unserviceable CBRN-D equipment.

The JPEO does not work with industrial PPE (only military),and includes mostly respiratory protection. There are groups at each installation led by the safety office that do their own investigations of problems with military PPE. The vast majority of problems encountered reportedly involve improper use or the wearer removing the PPE while it is still needed. There is no set protocol for safety people to notify management above them. All services do random inspection of chemical PPE to see if it is properly maintained. JPEO conducts five to eight audits per year. For each audit, they collect a statistical sample from a unit, conduct preventive maintenance, and conduct performance checks. They tell the

commanding officer what the status of the equipment is in his/her command and what deficiencies need to be corrected. The Army, Navy and Air Force each send a summary report of the audits with identifiers to their main commands once a year.

International data sources[4]

China[5]

Non-conforming PPE marked to a standard

In China, the AQSIQ (Administration of Quality Supervision, Inspection & Quarantine) issues PPE manufacture licenses to domestic PPE suppliers to ensure product quality is good. AQSIQ does two kinds of CA:

1) Each year PPE products are retested by AQSIQ to determine their compliance to standards. Products are collected from the PPE manufacturers' stock. If the PPE fails, the license may be withdrawn if corrective action is not effective. Every four years, a new license application is needed and AQSIQ will re-audit the plant.

2) The provincial and national AQSIQ agencies may conduct surveillance on a selected sample of products. AQSIQ may notify the supplier in advance to ensure samples of the selected products are available..

Investigation of PPE failures

There is no formal process of reporting PPE failures. When AQSIQ does find out about one, an investigation is conducted. AQSIQ had not conducted any investigation or research where PPE failure was identified as a cause of disease or injury.

Reporting fraudulent or counterfeit PPE in the market place

[4] Information contained in this section was obtained from email correspondence with contacts provided by the International Association of Fire Fighters and NIST.
[5] Contact: Julia Yao, 3M Corporate R & D, Beijing, People's Republic of China

Reports of possible fraudulent or counterfeit PPE can be entered on the AQSIQ Web site.

Brazil[6]

Non-conforming PPE marked to a standard

The official institution in Brazil responsible for providing determinations concerning PPE is the Ministry of Labour. PPE needs to be previously submitted for evaluation and approval by that ministry. The Department of Safety and Health of the Ministry of Labour has a General Coordination of Standardization and Programs which is responsible for the issuance of the Certificate of Approval (CA). That is a sector formed by a group of Labour inspectors who are responsible for analyzing all the documents that companies are obliged to send to the Coordination in order to obtain a CA. The companies that manufacture or import PPE and intend to commercialize those items as PPE have to follow the instructions of the Secretary of Labour Inspection Orders no. 121 and 126/2009.

Among the required documents, particular attention is drawn to the laboratory test reports, which are the documents that indicate whether the equipment is approved or reapproved after being submitted to a series of tests based on standards indicated by the Ministry of Labour, according to the protection the equipment is supposed to provide the user. After the evaluation of all of the documents, the Ministry of Labour issues a CA. This certificate contains a corresponding number that must be printed with each piece of PPE to be commercialized. The Ministry of Labour relies on its partnership with FUNDACENTRO, an institution which is part of the structure of that ministry that is authorized to run laboratory tests in a range of equipment. Moreover, the ministry has a cooperative agreement with INMETRO, the National Institute of Metrology, Quality and Technology, to do the following: 1) to coordinate the preparation of the technical regulations of quality and CA of personal protective equipment, which are submitted to advisory members of the Ministry of Labour; 2) to accredit,

[6] Contact: Sarah de Mattos Oliveira, Labour Inspector, Coordinator of Standardization and Registers, Ministry of Labor

according to minimum requirements, the institutions and laboratories that provide CA, with the approval of that ministry; and 3) to inspect, nationwide, directly or through delegated institutions, the compliance of the provisions related to CA of personal protective equipment that have regulation CA in force under SINMETRO. It is important to stress that SINMETRO is a Brazilian system which consists of public and private entities and performs activities concerning metrology, standardization, industrial quality and certification. INMETRO is also entitled to plan, develop and implement programs of CA of PPE under the Brazilian System SINMETRO.

Case studies or incident investigation

The Ministry of Labour does not have a formal report of any case studies or incident investigations.

Reporting fraudulent or counterfeit PPE in the market place

Concerning fraudulent or counterfeit PPE, the Ministry of Labour counts on the work of Labour Inspectors throughout the country. The inspectors identify fraudulent PPE during inspections and send the equipment to the General Coordination of Standardization and Programs. The Coordination sends a sample of the equipment to a laboratory, typically the laboratory of FUNDACENTRO, for testing. If the product is approved, the correspondent CA can be suspended or cancelled. The ministry can also act on anonymous reports.

New Zealand[7]

Non-conforming PPE marked to a standard

The New Zealand government does not have a data source for non-conforming PPE marked to a standard. When such equipment is identified, it is usually referred to the Ministry of Consumer Affairs.

[7] Contact: Keith Whale, National Adviser, New Zealand Fire Service, National HQ

This will normally result in a recall and in the item being removed from sale and banned from further importation.

Case studies or incident investigation

New Zealand does conduct incident investigations. There are a number of trigger points, which mean that an incident has to be made the subject of an accident Investigation. There are two levels of investigation, one for minor incidents and one for what are called "serious harm incidents." This latter process is used whenever the incident may have resulted in permanent disability or death. In the New Zealand Fire Service, the most serious incident may be the subject of a National Commander's inquiry, for example where an incident results in the death of a firefighter.

Reporting fraudulent or counterfeit PPE in the marketplace

The Ministry of Consumer Affairs is the appropriate channel for reporting fraudulent or counterfeit PPE.

Australia[8]

Non-conforming PPE marked to a standard

Australian PPE standards require certain marking and information to be on the product and the packaging. There is no government body that "approves" or certifies PPE products; the last of these government PPE approval systems was halted around 2002. It is up to the manufacturer to appropriately mark the PPE for use. There is no comprehensive data source that informs the potential user/purchaser of PPE about what is tested and meets the Australian/New Zealand (AS/NZS) standard and what does not. Some manufacturers use independent certification bodies (like BSI, SAI Global, Bureau Veritas, etc.) to certify that their product meets a specified standard. This is a commercial arrangement (normally a marketing angle) and is not mandated by the standards or the government (federal or state).

[8] Contact: Terry Gorman, Senior Occupational Hygienist, 3M Occupational Health & Environmental Safety Division

Manufacturers are free to sell their equipment without this independent certification and will supply appropriate "proof" (e.g., test report) to potential purchasers.

Case studies or incident investigation

The Australian OH&S Inspectorates (mostly state based in Australia) do inspections and assessments of the circumstances of incidents, incidents, etc., as they occur. This would include assessment of hazard control measures in place including those for PPE and the systems associated with these. A set of Australian standards is commonly used as the measure of PPE program performance to determine the compliance of the employer with the legal requirement to maintain a safe place of work. Assessment of equipment would normally include its suitability for the task and conformance to a standard (most commonly the relevant Australian standard for that PPE, but other reputable standards have been accepted). The depth and detail of this assessment varies depending on the specifics and the relative involvement of PPE in the issue. These are done case by case. No coordinated overarching evaluation of PPE performance and compliance is done. If an issue goes to court as a civil matter (i.e., the injured party sues the employer for damages), lawyers closely look at the PPE in use with respect to its suitability and compliance.

Reporting fraudulent or counterfeit PPE in the marketplace

There appears to be no clear avenue for reporting fraudulent or counterfeit PPE in Australia. Information provided to the Surveillance Subgroup noted only one investigation into suspect products. In that case a small local company which made organic vapor filters which could be fitted to the half facemasks of several other manufacturers, but did not test them as a combination to the relevant Australian standard and sold them as suitable. There is no defined system in place to actively seek reporting of suspect products.

United Kingdom (UK) [9]

Non-conforming PPE marked to a standard

The UK does not have a data source which identifies PPE as being sold improperly when it does not meet requirements. If this were to occur in the UK and EU, the users would not know unless the responsible authorities identified such illegal activity.

Case studies or incident investigation

The UK conducts incident investigations. The following is an example of a case study. At a recent fire, five firefighters suffered burns and the fire commissioner requested that the UK Regulatory Authority Health and Safety Executives, Health and Safety Laboratory conduct an investigation. The outcome is confidential to the London Fire Brigade and could not be provided to the Surveillance Subgroup. Some information from the investigation was provided to the committees of the UK's British Standards Institution (BSI) and the EU European Committee for Standardization (CEN) responsible for the standard covering this type of PPE. Based on this information, the committees are investigating the potential of revising the standard (i.e., the addition of wet testing of firefighters' PPE).

Reporting fraudulent or counterfeit PPE in the market place

A number of trade associations (i.e., the British Safety Federation) keep records of PPE identified as counterfeit or fraudulent. This is a huge task due to the variation and amount of PPE in use. One survey indicated that 80 percent of high-visibility surcoats, jackets and trim were counterfeit.

Israel[10]

Non-conforming PPE marked to a standard

[9] Contact: Dave Matthews FIIRSM, DipSM, GIFireE, OSHCR, Fire & Industrial (PPE) Ltd.
[10] Contact: Kenneth KalmanSamet, Shalon Chemical Industries

No available data sources identify PPE that do not meet standard performance requirements. The safety market standards adopted locally are the European (EN) standards. Conformance to these standards is verified by reviewing the test/certification reports of a certified European test body that tested and approved the PPE to the EN standard. Military nuclear, biological and chemical (NBC) PPE are sampled and tested on a yearly basis by the military, but the data are not available.

Case studies or incident investigation

No specific cases could be provided to the Surveillance Subgroup .

Reporting fraudulent or counterfeit PPE in the market place

Reporting of fraudulent/counterfeit PPE would be expected to come from users or from the official importers of the "real" products, to the Israel Institute for Occupational Safety and Hygiene.

Case Study Databases Reviewed

Near Miss Reporting System

The U.S. National Fire Fighter Near Miss Reporting System database is searchable based on event type, contributing factors (e.g., equipment, protocol, training). Since this data are self-reported, the information can be very limited. For example, there is a report that a firefighter fell on ice due to his leather books sliding on frozen surfaces. The reports focused mostly on the lessons learned and recommendations for prevention, such as, "There must be a routine check of the serviceability and sizing of all PPE. Our issued equipment can change size/fit as it ages and is exposed to different hazardous conditions." Per the International Association of Fire Chiefs (IAFC), each reported incident would have to be read to determine if it contained information relevant to PPE conformity surveillance. A spreadsheet was compiled from reports dated between 2005 and 2008 focusing on PPE. The spreadsheet contained fields describing whether full, partial or no PPE was worn, the equipment type (SCBA, helmet, eye/face protection, hood, coat, pants, gloves, boots, etc.), usage, equipment failure or

damage, injuries that occurred, information about the department, the event type, and the narrative (see above examples). The report provided a summary of descriptive statistics but did not indicate whether the PPE met or did not meet a specific standard.

Doug Landsittel, PhD (associate director, Data Center, Center for Research on Health Care) was contacted about his work with the near-miss firefighter data on whether he thought the database would be useful in CA surveillance. He stated that a problem with the database is that it contains self-reports, which could lead to criticism, and is not sufficient for determining PPE failures and the other information on PPE conformity.

Occupational Safety and Health Administration (OSHA) Fatalities and Catastrophes (FAT/CAT) reports

The OSHA FAT/CAT report descriptions did not contain information to determine if there was a PPE failure involved in the reports.

OSHA public "accident" data

OSHA public "accident" data files were investigated for incidents involving PPE. The records are somewhat general. It is difficult to determine if the PPE (e.g., hard hats and gloves) did not meet the performance requirements of the marked standard or the environmental conditions were outside the PPE design capabilities. The safety shoe database does provide some information on the weight of the object that fell on the employee's foot and from what height.

OSHA IMIS database

The OSHA IMIS database collects information from inspections carried out by compliance officers. Since 1991, it has included data from every state. IMIS data provided to researchers typically come in several different files:

(a) A "stem" file, with one observation per inspection, provides the identity of the facility inspected and its characteristics (industry, employment), the type of inspection and the number of violations cited.

(b) A "violation" file, with one observation per violation, provides the detailed provisions of any standards that were cited in an inspection, the severity of the violation, the number exposed to the violation, the length of time given for its abatement, and other matters.

(c) A "health" file, with one observation per sample, contains the results of samples obtained in the field on levels of toxic substances and physical agents and the number of employees who had similar exposures to the workers who were sampled.

(d) A "hazard" file contains the actual readings from the samples expressed as levels—whether expressed in milligrams, parts per million, dose (as for noise) or fibers per cubic centimeter—and as "severity," where the level is divided by the permissible exposure limit (PEL).

(e) An "accident" file, with one observation per injured worker, contains information from the accident investigations that are conducted. For federal OSHA, these are limited to cases where either a death or an accident leading to the hospitalization of 3 or more workers has occurred.

OSHA Data Initiative

The OSHA Data Initiative (ODI) collects work-related injury and illness data from employers within specific industry and employment size specifications. The data are used by OSHA to calculate establishment-specific injury and illness incidence rates. This searchable database contains a table with the name; address; industry; and associated total case rate (TCR; days away, restricted and transfer (DART) case rate; and the Days Away From Work (DAFWII) case rate for the establishments that

provided OSHA with valid data for calendar years 1996 through 2009. A search of the database using SIC was unsuccessful with regard to obtaining information on PPE conformity.

Workers' Compensation Data

There is a lack of detail in many reports. There is no field to describe PPE, and the reports vary in terms of detail depending on who completes the form. Data from large companies might not be included in the workers' compensation database since, in some states, large employers can be self-insured. Ted Courtney of Liberty Mutual also mentioned the limitations of compensation data and the fact that the narrative is limited to 125 words. In his experience he has not seen a lot of detail in reports about PPE usage. He noted that, in general, data quality is highly variable.

Mine Safety and Health Administration (MSHA) Data

The Mine Accident Injury and Illness Data Exploration Tools (MAIIDETS) application is maintained by Spokane Research Lab (SRL) under the project "Improving Surveillance Data Utilization Through GIS" within the lab's surveillance activity. It is an internet application available at http://maiidetsdev.cdc.gov/. The data contained within this Web site date from 1983 through 2002. This application is made available through the NIOSH Web site to enhance public access to mine workplace safety and health information. The MAIIDETS application utilizes the MSHA-published Web mine identification and accident, injury, and health data. The Accident, Injury, and Illness Data Set Wizard was not suitable for developing a database dealing with PPE failure. The database narrative information was searched by keyword (e.g., hardhat). The results were genera,l and no information was provided on whether the PPE conformed to a standard, failed under situations covered by the standard, etc.

Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience Database

The FDA Manufacturer and User Facility Device Experience Database (MAUDE) represents reports of adverse events involving medical devices. The data consist of voluntary reports since June 1993, user

facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements given in 21 CFR 803.19. The database does contain descriptions of PPE which malfunctioned. The descriptions are general and do not contain information on whether the PPE was designed to a particular standard.

FDA MedWatch: The FDA Safety Information and Adverse Event Reporting Program

The FDA MedWatch Program Safety Alerts for Human Medical Products (Drugs, Biologics, Medical Devices, Special Nutritionals, and Cosmetics) is used to report serious adverse events for human medical products, including potential and actual product use errors and product quality problems associated with the use of:

- FDA-regulated drugs,
- biologics (including human cells, tissues, and cellular and tissue-based products),
- medical devices (including in vitro diagnostics), and
- special nutritional products and cosmetics.

It is a voluntary program started in 1993 by the then FDA commissioner. It is not mandated by regulation. People can report an event on the Web, through the mail, by fax or phone. Sixty percent of all complaints are now received electronically on the Web.

Ten years ago, the FDA was getting 15,000 reports a year; now it is up to 40,000 a year. The current challenges are with promotion and marketing. Since there is insufficient funding for marketing purposes and only about 1.5 full-time employees devoted to promotion and marketing, most marketing is done electronically through social media and the Web. FDA spends approximately $300,000 a year in data entry. FDA representatives report they would like additional funding to enhance the ease of reporting, which they feel is key for people to use the system.

FDA Safety Reporting Portal

On May 24, 2010, the Food and Drug Administration and the National Institutes of Health launched a new Web site that, fully developed, will provide a mechanism for the reporting of pre- and post-market safety data to the federal government. Currently the Web site can be used to report safety problems related to foods, including animal feed and animal drugs, as well as adverse events occurring on human gene transfer trials. Consumers can also use the site to report problems with pet foods and pet treats.

In the future, the system may encompass other types of clinical trials and, eventually, safety problems arising from products regulated by a broad array of federal agencies. This is a first step toward a common electronic reporting system that will offer "one-stop shopping," allowing an individual to file a single report to multiple agencies that may have an interest in the event.

Pesticide Handlers' Cases

Several contacts were made to investigate PPE failures during the handing of pesticides. The Agricultural Handler Exposure Task Force (AHETF) is a consortium of 28 agricultural chemical companies that formed a joint data development task force in December 2001 to design and develop a database on exposure of agricultural workers during the mixing, loading and/or application of pesticides. While their data do not capture PPE failures, AHETF does get reports periodically about PPE problems.

In a study by the Pacific Northwest Agricultural Safety and Health Center using fluorescent tracers (FT), seam failure was found in nitrile suits.[11] No information was available on whether the suits should have conformed to a particular standard.

The U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) compiles an Incident Data Source (IDS) which defines an incident as any effect of a pesticide's use that is not

[11]Pacific Northwest Agricultural Safety And Health (PNASH) Center, Fluorescent Tracer Training*Hands on Learning for Pesticides:* http://www.youtube.com/watch?v=ZczZrd8tgBk&feature=related

expected or intended. The reports are obtained from registrants, private citizens, poison control centers, states, and other government and nongovernmental organizations. The IDS system is not fully automated. Once a query is performed in IDS (which gives information such as date, product, registration number and severity), individual incident reports can be retrieved from a secure limited access drive.

Anugrah Shaw, a professor with the University of Maryland Eastern Shore, was contacted regarding the current regulations for non-respirator PPE and stated that they are not performance based requirements. Garment requirements for pesticide operators are primarily based on type of garment (e.g., pant/shirt, coverall) and gloves and are often material based requirements. There are no data on performance. A CA standard for garments that is based on a performance specification standard is being developed through ASTM.[12]

Safety Equipment Institute and Underwriter Laboratories (UL) case studies

For accredited certification bodies (CB) such as the Safety Equipment Institute (SEI) and Underwriters Laboratories (UL), ISO Guide 65 requires, among other things, the CB have in place:

- Procedures for handling nonconformities and assuring the effectiveness of corrective and preventative actions taken,
- Requirements for the evaluation of any changes made to certified products to determine continued compliance with the product standard,
- Procedures for handling complaints, appeals and disputes,
- Procedures to be followed where situations are reported in which a compliant product is subsequently found to be hazardous,

[12]ASTM (Work Item: ASTM WK34503 - New Specification for Conformity Assessment of Protective Clothing Worn by Operators Applying Pesticides, http://www.astm.org/DATABASE.CART/WORKITEMS/WK34503.htm)

- Procedures to enable surveillance to be carried out in accordance with the applicable criteria to the relevant certification system, and
- Procedures for exercising proper control over use of its legally registered certification mark.

One example of an established surveillance program for PPE is in the fire and emergency services sector. All standards that are published under the NFPA's Fire and Emergency Services Protective Clothing and Equipment Project have explicit requirements for certification of PPE. Essentially, ISO Guide 65 accredited CBs must enforce extensive NFPA requirements for annual verification of product compliance through a follow-up inspection program including independent testing and audits at the manufacturing facilities. Additionally, the CB shall ensure the manufacturer has in place an approved safety alert and product recall system.

The SEI Web site has copies of recall and safety alert notifications for a variety of PPE. Recalls were initiated in some cases as a result of annual recertification testing uncovering non-conformances, complaints submitted to SEI, and manufacturers' internal quality controls.

UL similarly has a section titled "Public Notices" on its Web site. This section is used to communicate to the public information about unsafe products, counterfeit claims of certification, and unauthorized use of the UL mark.

Summary of Existing Databases and Possible Avenues of Future Collaboration for PPE Surveillance

Overall, based on the surveillance subgroup's research, there appear to be no existing databases which could be used for non-respirator PPE CA or identifying fraudulent or counterfeit PPE.

Collaboration with NIOSH Electronic Health Records Working Group

The possible collaboration with the NIOSH Electronic Health Records Working Group was discussed with Eileen Storey, Chief, Surveillance Branch, DRDS/NIOSH, about electronic health-care records. She indicated those records are spotty at best and do not currently contain any information which would be of use to the subcommittee. The group is working on incorporating industry and occupation data into the record, and is willing to collaborate with the PCAWG in the future.

Possible approaches for NIOSH PPE surveillance

The Surveillance Subgroup first developed a flowchart (Figure 1) of PPE surveillance steps.

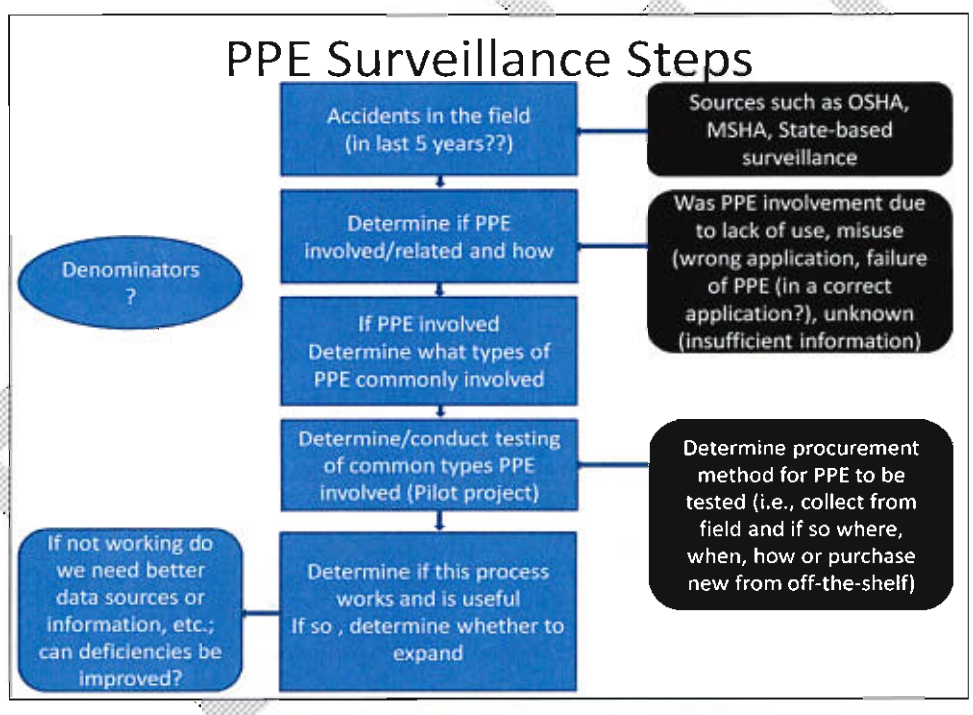

Figure 4. Flowchart of PPE Surveillance Steps

Several approaches could be employed to obtain data on PPE conformity and fraudulent PPE.

Product testing

Products would be tested against the appropriate standard(s). The products could be purchased new from distributors or obtained in the field (similar to the long-term field evaluation of self-contained self-

rescuers). In this scenario, new gear is exchanged for used gear. Using new products, this program would be similar to DOJ's program (described above), the previous NIOSH program, and the current audit program conducted on respirators by NPPTL. During the 1970s, NIOSH randomly purchased firefighter helmets, safety toe-wear and eye protection. Models were selected for testing from those advertised as meeting the requirements of the appropriate standard (e.g., ANSI Z89 for firefighter helmets, ANSI Z41.2 for safety toe-wear, and ANSI Z87 for eye goggles). In addition, a few models for which conformance to the requirements of the ANSI standards was not claimed were also ordered and tested when available. The number of specimens of each of those models tested ranged from twelve (six pairs) for shoes to sixty for firefighter helmets. The PPE was tested in-house by NIOSH and the results published as NIOSH-numbered documents.[13,14,15,16]

The new product testing program could be overseen either by NIOSH or an outside organization. The testing could be done in-house or under contract with outside laboratories. This would be resource intensive (purchasing products and testing them). The main advantage of this approach is that it would lead to an understanding of standard compliance. If the program was done in-house, another advantage would be that it would complement existing NPPTL research and standards development activities and lab capabilities. For example, NPPTL has evaluated new products against existing standards in several research projects.[17,18,19,20] However, the purpose of the testing was not for CA, but rather to assist in the

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[13]NIOSH Technical Information: A Report on the Performance of Firefighters' Helmets (DHEW (NIOSH) Publication Number 77-114). Cincinnati, OH. Centers for Disease Control/National Institute for Occupational Safety and Health. 1977.

[14]NIOSH Technical Information: Tests of Eyecup Goggles (DHEW (NIOSH) Publication Number 77-165). Cincinnati, OH. Centers for Disease Control/National Institute for Occupational Safety and Health. 1977.

[15]NIOSH Technical Information: A Report on the Performance of Women's Safety-Toe Footwear (DHEW (NIOSH) Publication Number 76-199). Cincinnati, OH. Centers for Disease Control/National Institute for Occupational Safety and Health. 1976.

[16]NIOSH Technical Information: A Report on the Performance of Men's Safety-Toe Footwear (DHEW (NIOSH) Publication Number 77-113). Cincinnati, OH. Centers for Disease Control/National Institute for Occupational Safety and Health. 1977.

[17]http://www.cdc.gov/niosh/nas/ppt/QUADCharts12/TRB_INH_927ZKRE_FY12_QC.html

[18]http://www.cdc.gov/niosh/nas/ppt/QUADCharts12/TRB_DRM_939ZUND_FY12_QC.html

[19]http://www.cdc.gov/niosh/nas/ppt/QUADCharts09/Z1NR_FY09_QC.htm

standards development process. The same laboratory equipment and methodology used in these research projects could be used to evaluate either new or used PPE for their conformance to a given standard.

User reporting

The second method would be to have users and wearers report problems and potentially fraudulent or counterfeit PPE (a passive reporting system). This could be a program similar to the FDA MedWatch using a Web page or mobile devices such as smartphones and iPads. Bryan Beamer developed a draft web page for surveillance data entry (Figure 2).

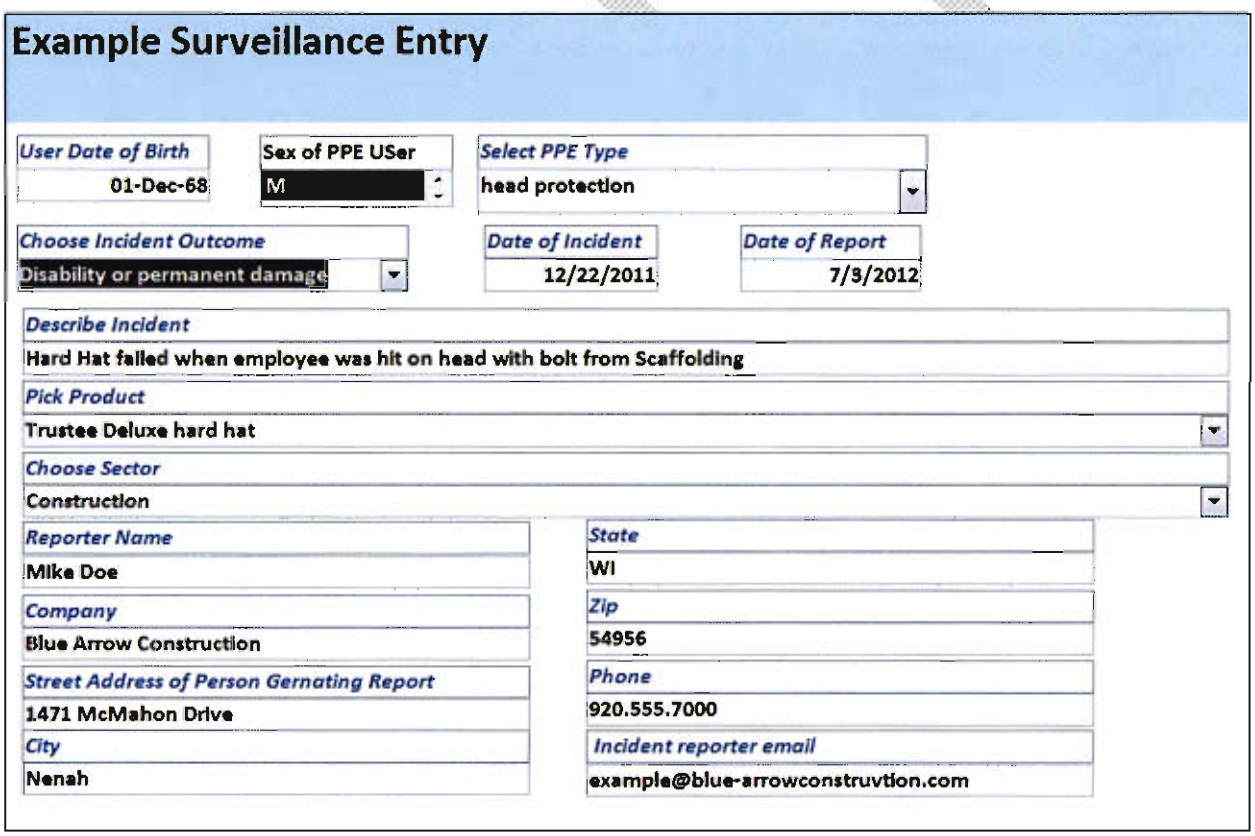


Figure 5. Sample Web Page for Surveillance Data Entry by Users

[20] http://blogs.cdc.gov/niosh-science-blog/2009/01/ppe-2/

The following would need to be addressed before a surveillance data entry Web page could go live:

- Define relevant questions—this defines data needed and structure of database.
- Determine what would be done with data.
- Obtain solid, reliable data for these topics from expert resources.

Lastly, the online interactive database would be implemented. Challenges to implementing this system include:

- Developing and publishing the database.
- Promoting use of the database—getting the word out that reporting site is available.
- Updating and maintaining database.
- How to obtain comprehensive information—how to word the questionnaire so that enough information is obtained to make the determination that a particular incident warrants follow-up. This will be challenging since a standard for eye protection, for example, covers a myriad of factors.
- Following up—who would do the follow-up (NIOSH, the certification body if any, the manufacturer).
- Reporting the results of the surveillance to the user community.
- Approvals—the system would most likely require approval by a NIOSH institutional review board (IRB) and the White House Office of Management and Budget (OMB) for the Paperwork Reduction Act. Obtaining these approvals can be time and resource intensive.
- Overhead—resources (management overhead) to maintain system.

Obtain PPE conformity information from other organizations' incident investigations

Another means to obtain data on PPE conformity and fraudulent PPE would be to have other organizations such as OSHA, MSHA, the NIOSH FACE and FFFIPP modify their reporting systems to collect pertinent information on PPE conformity. For example, additional fields could be added to the OSHA Health Sampling data entry program for compliance officers (Figure 3) dealing with PPE failures,

etc. In addition to the concerns already mentioned, this method would pose an additional burden on the inspectors to obtain comprehensive PPE information.

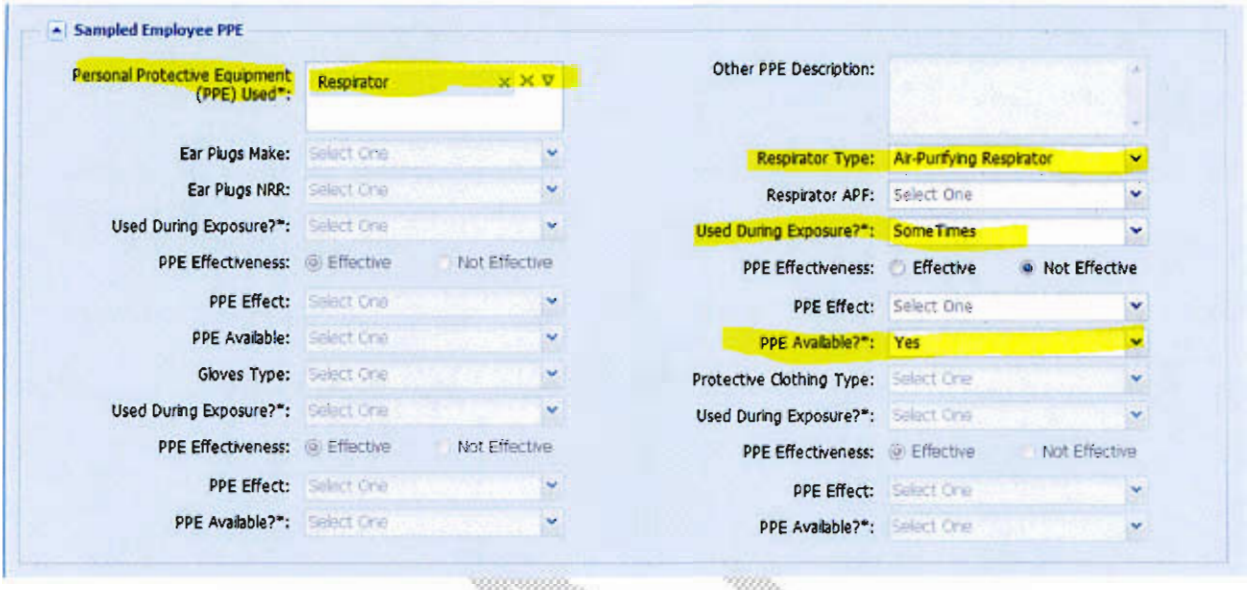


Figure 6. PPE Data Entry Screen in the OSHA Health Sampling Data Entry Program

FDA Safety Reporting Portal

One of the goals of the FDA in regards to the Safety Reporting Portal is to have it encompass other types of clinical trials and, eventually, safety problems arising from products regulated by a broad array of federal agencies. If this expansion occurs, NIOSH could work with the FDA to include data collection on non-respirator PPE.

Electronic Health Records

In addition to the industry and occupation information, PPE information including problems and failures could be added to the electronic health records. The main problem with this approach is it would create an additional burden on the person inputting the information into the records and that person may not have the technical expertise to complete the required data fields. In addition, the fields would need to be designed so that the information would be useful for the purposes of CA.

Innovative Surveillance Models

The following are examples of surveillance models which should be considered. With modifications, they may be applicable to the surveillance of PPE conformance.

FDA Sentinel Initiative

The initiative started in 2007. It comprises active, passive, active-passive and passive-active surveillance at every stage: product approval, manufacturing, post manufacturing , post approval, marketing, post-marketing and usage. At this time it does not replace all other efforts like MedWatch; it only adds to other efforts. Some subgroup members believe Med-Watch may be too passive for PPE surveillance. The initiative creates and maximizes the existing databases of manufacturers, public and private stakeholders with special emphasis on governance, data collection, analysis and dissemination for corrective action. This type of product surveillance may be more elaborate than what is needed for PPE surveillance, but it could be a guiding model for what can be done. The main advantage is that it combines both active and passive surveillance. This should allow the greatest amount of data to be collected. The disadvantages are the same as those described under the user Web based reporting system and having organizations collect the data as part of their investigations.

National Electronic Injury Surveillance System (NEISS)

The Consumer Products Safety Commission's (CPSC) NEISS is a national probability sample of hospitals in the U.S. and its territories. Patient information is collected from each NEISS hospital for every emergency visit involving an injury associated with consumer products. From this sample, the total number of product-related injuries treated in hospital emergency rooms nationwide can be estimated. This Web access to NEISS allows certain estimates to be retrieved online. These estimates can be focused by setting some or all of the following variables (and an example of each): date, product, sex, age, diagnosis, disposition, locale, body part.

Since 2000, when the CPSC expanded the system to collect data on all injuries, it has become an important public health research tool in the United States and around the world. It is used for product recall, public awareness campaigns and product safety standards. Currently the NEISS does not include PPE. A similar program could be set up for PPE, or the NEISS could be expanded to include PPE.

US Department of Agriculture (USDA)

The USDA surveillance programs were reviewed because USDA is responsible for monitoring food safety and recalls. The USDA methods seem too specific (e.g., Food Safety Inspection Service (FSIS) surveillance programs) to foods to be adapted to PPE.

Conclusions and Recommendations

After reviewing the available information, the Surveillance Subgroup has the following conclusions and recommendations for each of its six objectives:

- Objectives 1 and 2 (Identification of non-conforming PPE and the consequences of using such PPE) – No surveillance programs currently exist that adequately identify PPE marked to a standard that does not meet the performance requirements and whether that PPE was a contributing factor to any adverse consequences. A surveillance program can be either active (new or used samples are procured and tested) or passive (information is provided by PPE users or other stakeholders, etc.). If non-respiratory PPE surveillance is implemented, the surveillance subcommittee recommends that it utilize a combination of active and passive methods to facilitate collection of information on non-respiratory PPE conformance.
- Objective 3 (Interface and collaborate with NIOSH Electronic Health Records [EHR] Working Group) – The surveillance subcommittee recommends a continuation of the

collaboration with the NIOSHElectronic Health Records Working Group. The purpose of this collaboration is to:

a. Help garner support for the inclusion of industry and occupation information including PPE usage into EHR constructing a case for "meaningful use" of these data (the requirement for the EHR to provide complete and accurate information, better access to information through the EHR and sharing the EHR health information securely with patients and providers),

b. Adopt standards for capturing the above data capture,

c. Develop a pilot data collection system to test these standards in various health-care settings (e.g., clinics, hospitals) to determine ease of use, validity of collected data, acceptance by health-care workers, etc.

- Objectives 4 to 6 (Develop approaches that would result in 1) better assessment of PPE marked as meeting a standard but failing to meet the necessary performance requirements and inadequacies, 2) better reporting of incidents of PPE marked as meeting a standard but failing to meet the necessary performance requirement,; and 3) better reporting of fraudulent or counterfeit PPE in the marketplace) – The Surveillance Subgroup recommends that a pilot program be established to determine:
  a. The frequency of PPE failure in the workplace,
  b. If these failures (incidents) are a result of the PPE failing to meet an applicable standard, and
  c. the frequency of fraudulent/counterfeit PPE in the workplace.

This pilot program could be conducted using either new resources (e.g., establishing a Web site or hotline for reporting of fraudulent or counterfeit PPE) or existing resources (e.g.,

using the current PPE Concerns hot line). The fraudulent/counterfeit PPE surveillance program would need to be promoted extensively to obtain enough data to determine if there are problems with PPE failing to meet a performance standard or fraudulent/counterfeit PPE being used in the workplace. The program could be promoted through the use of the NIOSH and NPPTL Web sites, NIOSHeNews, and by other organizations with an interest in the subject such as the Safety Equipment Institute (SEI) and the American Industrial Hygiene Association, the American Conference of Governmental Industrial Hygienists and the American Society of Safety Engineers. The Surveillance Subgroup also recommends that NIOSH collaborate with other organizations which certify non-respiratory PPE such as SEI and the National Institute of Justice to share information on fraudulent/counterfeit PPE. The pilot study would provide information to determine if a larger surveillance project is warranted.

Appendix C: Products and Standards Subgroup (PASS) Report

Overview

The subgroup gathered national consensus standards information associated with various PPE types excluding NIOSH 42CFR84 requirements that are applicable to respiratory protective devices. The information was compiled in a number of spreadsheets or listings, and included in an MS ACCESS database to maximize access to the data. The prototype database was established to demonstrate the various ways in which information on PPE types and applicable standards could be sorted. The following section is a summary of the various spreadsheets and listings compiled to address these goals.

Summary of PASS Activities

The International Safety Equipment Association (ISEA) generously updated a database of PPE types and associated national consensus standards for the purposes of use by this subgroup. The information was contained in an Excel spreadsheet that identified PPE types and related national standards. The spreadsheet compiled PPE and standards for respirators, eyewear, gloves and protective headgear, which are the OSHA subgroupings for personal protective equipment. This initial spreadsheet was more fully developed by adding CA standards to the listing from all sources, public, and private sectors, including international ISO standards.

Another MS Excel spreadsheet covering CA standards specific to ANSI standards for various PPE types was developed. The objective of this spreadsheet was to capture whether the ANSI standards were primarily performance standards, or if they contained requirements addressing CA processes such as certification, testing, inspection, surveillance and quality assurance. For the standards which contained CA process validation information, these were broken down as self-assessment, supplier labeling and marking, third party assessment, or government assessment.

A third Excel spreadsheet covering CA in ASTM standards was completed. The objective of this spreadsheet was to capture whether the ASTM standards were primarily simple testing standards or if they contained information on CA processes. For the standards which contained process validation information, these were broken down as self-assessment, supplier labeling and marking, third party assessment, or government assessment.

An Excel spreadsheet also provided a listing of applicable DOL OSHA 29CFR1910 requirements listing citations to each regulation subpart and paragraph, and the national or international consensus

standard applicable to each PPE type. The information in this spreadsheet was reviewed and agreed upon by OSHA as being complete at the time of its development.

A list of third party certifiers and the tests that they certify to was also developed to support the subgroup goals.

With regard to goal 5 (document and identify PPE integration and interface issues), initially conformity standards which directly address integration and interface issues could not be identified. However, there was a set of standards which dealt with testing ensembles or groupings of PPE which are required to work in a specific environment. The bulk of these standards are from the National Fire Protection Association (NFPA) with a few DOJ standards.

The ultimate output of the team was an MS Access database which collected all of this information into a single location. This work was done in conjunction with the Risk and the Surveillance subgroups, as they needed the PASS outputs to be used as inputs for their activities. Once the database was established, the primary ownership of the product was assumed by the Risk sub-team and may well become the responsibility of the PCAWG itself as we move forward. Plans are underway for this database to be made available on a public Web site, but these are still in the developmental stages.

Overview of PPE Standards Database

Current Prototype Database

In order to expand the capabilities of these individual spreadsheets, a prototype database was designed in Microsoft Access. The prototype database has the following benefits over the original spreadsheets: through controlled input of records, the data are standardized; relationships between the data can be made; drop-down lists can be used for ease of data input; queries can be made to make searches for specific standards.

The current prototype database consists of the following tables, form and report:

Table 1: tbl_consensus_standards

Description: A table of both US and international performance standards pertaining to various non-respiratorPPE. This table currently has 702 entries.

Fields:

Field Name	Description of field	Notes regarding field
Organization	Standard setting organization	Drop-down list of organizations
PPE_type	Type of PPE	Drop-down list of PPE types
Designation	Determined by the standard setting organization, the designation is the number under which the standard is published.	
Year	Year of standard	
Title	Title of standard	
Link	Hyperlink to standard, if available	
Status	Status of standard, if known	
Certification	Information on certification requirements, if known	
Hazard_type	Type of hazard PPE protects against	Drop-down list
Industry	Industry that uses PPE	Drop-down list currently matches OSHA industries.
Notes_Comments	Any notes or comments from the original spreadsheets were put into this field.	
Referenced_standard_1	If the standard references another standard (like an OSHA regulation referencing a Performance Standard) it is noted here.	Drop-down list of all standards
Referenced_standard_2	If the standard references a 2nd standard, it is noted here.	Drop-down list of all standards
Standard_type	The type of standard (Conformity Assessment, Performance, Specification, etc.)	Drop-down list

Table 2: tbl_hazard_types

Description: Drop-down list of type of PPE for tbl_consensus_standards field, hazard_type.

hazard_category
biological
chemical
flame and thermal
human factor
physical
radiological

Table 3: tbl_ppe_type

Description: Drop-down list of PPE types for tbl_consensus_standards field, PPE_type. There are currently 67 types of PPE to choose from on the drop-down menu.

tbl_ppe_type	

tbl_ppe_type	
General - applies to all PPE	Lanyards
Auditory assessment	Medical gloves
Chemical protective clothing	Medical protective clothing
Chemical protective footwear	Medical protective footwear
Chemical protective gloves	Particulate protective clothing
Cold protective footwear	Physical protective clothing
Cold protective gloves	Physical protective footwear
Conductive footwear	Physical protective gloves
Connectors	Protective clothing, general
Ear muffs	Radiation protective clothing
Ear plugs	Radiation protective footwear
Electrical gloves	Radiation protective gloves
Electrical protective clothing	Riot helmet and face shield
Electrical protective footwear	Safety belts
Electrical worker helmets	Spectacles, face shields, goggles, welding helmets
Environmental protective clothing	Thermal protective clothing
Eye-protectors	Thermal protective footwear
Face masks	Thermal protective gloves
Fall arrest systems	Visibility warning clothing
Fall arresters	Welding gloves
Firefighting gloves	Welding helmets
Firefighting helmets	Welding helmets, hand shields
Firefighter footwear	Work gloves
Firefighter protective clothing	Work surfaces
Footwear, general	Anti-vibration gloves
Gloves, general	Respirators
Guide	High-visibility gloves
Harnesses	Climbing footwear
Headgear	Anti-vibration protective clothing
Headsets	Safety belts, harnesses, lanyards and lifelines
Hearing protectors	Positioning and travel restraints
Helmet	Rescue systems
Hoods	Coveralls
Industrial helmets	

Table 4:tbl_standard_type

Description: Drop-down list of type of types of standards for tbl_consensus_standards field, standard_type.

type_of_standard
Guide
Practice
Specification
Conformity Assessment
Test Method
Regulation

Table 5:tbl_standards_orgs

Description: Drop-down list of standard setting organizations for the tbl_consensus_standards field, organization.

acronym	*full_name*
AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
ANSI/ADA	American National Standards Institute/American Dental Association
ANSI/ASA	American National Standards Institute/Acoustical Society of America
ANSI/ASSE	American National Standards Institute/American Society of Sanitary Engineering
ANSI/ISEA	American National Standards Institute/International Safety Equipment Association
ASTM	ASTM International
ISO	International Organization for Standardization
NFPA	National Fire Protection Association
NIJ	National Institute of Justice
NSF	NSF International
SAE	Society of Automotive Engineers
US Govt	US Federal Specification
IEEE	Institute of Electrical and Electronics Engineers
ESDA	Electrostatic Discharge Association
UL	Underwriters Laboratories
OSHA	Occupational Safety and Health Administration

Interactive Form: Consensus Standards

Description: This form allows the user to search for consensus standards by one of six criteria:

1) Drop-down menu combination box by designation,
2) Drop-down menu combination box by standard setting organization,
3) Text search in the title of the standard,
4) Drop-down menu combination box by type of PPE,
5) Drop-down menu combination box by hazard type,
6) Drop-down menu combination box by standard type.

The user is able to search by any combination of fields that is useful. The form has two action buttons. The first initiates a search and generates a subsequent report (Consensus Standard Report). The second clears the form for a new search to be made.

Report: Consensus Standard Report

Description: This report provides the relevant data from the table "tbl_consensus_standards" based on the interactive form "Consensus Standards." Information reported back to the user includes PPE Type, Organization, Designation, Title, Year, Hazard Type, Industry, Standard Type, PPE Type and Reference Standards 1 and 2.

Proposed Online Database

Parties involved with the establishment of the aforementioned prototype database, including PCAWG and NPPTL, recommend the exploration of maintaining an online version of the database. Exploration activities include determining the potential users of the database, defining the purpose of the database, establishing the cost and benefit of such an online database, as well as soliciting comment from the public.

Conclusion

The data gathered and documented in Excel spreadsheets or listings, and incorporated into an Access database, are the primary outputs of the subgroup. The information gathered and presented in these documents clearly shows that with few exceptions there are no universal national CA requirements for PPE. It is noteworthy that a major exception of CA requirements is those for respiratory protective devices associated with 42 CFR 84 regulations. CA requirements for these products are very comprehensive. However, respirators were not included in the subgroup's objectives. If incentives and needs are identified by other subgroups supporting CA for PPE, then a national infrastructure is needed to support such a CA program, as it does not exist today.

Appendix D: Compliance and Enforcement (C&E) Subgroup Report

EXECUTIVE SUMMARY

As a benchmarking target, the EU offers a rich and evolving model of CA and market surveillance. The challenges EU officials have faced in building an effective system, across 27 Member States, to remove internal barriers to trade and the approach they have used to resolve those challenges is highly instructive. The EU system suggests the kinds of resources, procedures, and systems that may be needed in any effective CA system. Through recent and ongoing improvements, many "best practices" appear to be in place or are emerging. The evolution of the EU system underscores the value, in a CA system, of shared responsibilities and a collaborative public-private network of organizations and online information systems to foster communication, problem identification, informal technical assistance, and capacity building.

The European Union's system of CA is a comprehensive approach that features principle-based rather than rule-based product requirements, pre-market assessments as well as post-market controls, and both proactive and reactive market surveillance. Manufacturers must prove products conform to "Basic Health & Safety Requirements" covering horizontal risks before products can be placed on the EU market. There are no technical product requirements. "Harmonized standards" (which legally convey an assumption of conformity) and other European standards are developed by independent European standards organizations, in collaboration with the Member States.

The EU's pre-market CA requirements are risk-based. EU law divides all PPE into three categories, by level of risk, and establishes a set of CA procedures for each category.

The procedures for market surveillance of products that have been placed on the market is also governed by EU law. They are designed to be effective, proportionate to the economic scope of the PPE product, and dissuasive. Even when third party involvement is required, manufacturers are given a choice between quality assurance and product certification modules.

A key feature of the EU system is shared responsibility. Manufacturers are responsible for pre-market CA and are ultimately liable for product safety; other economic operators (importers, distributors) also have responsibilities. Conformity to basic requirements is documented with the Supplier's Declaration of Conformity, technical documentation, and a CE mark affixed to the product. For low-risk products, independent testing is not required. For medium to high-risk products, manufacturers must obtain

certificates of conformity from independent, third party CA bodies. High-risk products also require a quality control system with third party involvement.

Market surveillance is the responsibility of the Member States of the EU. Market Surveillance Authorities conduct proactive surveillance activities on high-risk products and respond to consumer complaints about products posing a danger to the user.

The EU's role is to set policy, coordinate CA and market surveillance authorities, provide TA, and control the borders in collaboration with the market surveillance authorities.

CA and market surveillance are also both supported by a network of private, independent coordinating bodies and an array of databases, online tools, rapid information systems and other features that encourage compliance with the procedures, provide technical assistance, and share best practices.

Introduction

The purpose of this report is to describe the European Union's (EU's) system of CA for personal protective equipment (PPE). This report is part of a larger effort being led by the National Institute for Occupational Safety and Health (NIOSH) in response to a recent Institute of Medicine recommendation that NIOSH develop and implement a risk-based CA process for non-respiratory PPE (Cohen et.al., 2010).

This report is based on a review of the literature. The documents reviewed include legislative and administrative documents, professional conference papers and proceedings, and information from the websites of stakeholder groups such as the standards organizations and independent safety organizations that form an integral part of the EU CA system. This material will be supplemented with information from key informant interviews for the final version of this report.

Key Features of the European PPE Market

- The EU has approximately 30% of the global PPE market.
- Three product groups make up 71% of the total PPE market (protective clothing, protective gloves, and safety footwear).
- The industry sectors with the highest demand for PPE are manufacturing, construction, mining, and health care.
- Approximately 4,000 companies in the EU are involved in manufacturing PPE.
- A large percentage of enterprises involved in the manufacturing of PPE (56%) are SMEs.
- There are few key players in the European PPE industry; some product market sectors (eye, hearing, and respiratory protection equipment) are highly concentrated.
- Price competition is intense; the margins at production are also low.

The EU defines CA as the process of demonstrating that a PPE product, before it is placed on the market, meets specific requirements such as standards, regulations and other specifications. It typically includes

inspection, testing, certification, accreditation, and related procedures, and covers both the design and production phases of production. The essential objective of a CA procedure is to demonstrate to public authorities that products placed on the market conform to the requirements as expressed in the relevant legislation, particularly with regard to the health and safety of users.

Market surveillance is a separate process that consists of controls after the product has been placed into the market. The two systems are complementary and equally necessary to ensure the smooth functioning of the EU's internal market.

The EU is an economic and political union of 27 Member States.[21] Together with the Member States of the European Free Trade Association (EFTA), the EU's system of CA covers a population of over 490 million.[22] The European PPE market is large, diverse, international and—in some sectors—highly concentrated (European Commission, 2010). The European PPE industry benefits from European employers' and employees' high awareness of workplace safety, which creates a steady demand and from the EU regulatory framework, which reduces the cyclicality of demand and, through the introduction of high standards, shields European producers against competition from abroad. (European Commission: 2010).

The European CA and market surveillance systems are based on the following principles:

Principle-based rather than rule-based requirements. EU legislation specifies what must be achieved rather than how it should be achieved. Manufacturers must only demonstrate that products fulfill these legislative design and performance requirements. The application of technical standards is voluntary.

Balance between pre-market assessment and post-market control. The EU system goes beyond product certification to include procedures for both enforcement and accountability, through market surveillance.

[21] The number of Member States will increase to 28 on July 1, 2013, with the addition of Croatia. Current members are: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. There are also five candidate countries: Iceland, Macedonia, Montenegro, Serbia and Turkey.

[22] The four countries forming EFTA (that are not also EU members) are Iceland, Liechtenstein and Norway, and Switzerland.

Proactive as well as reactive market surveillance. Consumer complaints are to be investigated and action taken where appropriate. Market surveillance also includes inspection and testing of products that have been placed on the market.

Risk-based CA, surveillance and corrective actions. Requirements are designed to be proportional to risks, from the point of view of both the likelihood and the consequences of the product failing to conform to the requirements.

- **Good regulatory practice.** In selecting CA procedures, the European Commission conducts impact assessments, solicits stakeholder inputs, and conducts a Competitiveness Proofing assessments to ensure procedures are appropriate to the scale of production (Sacchetti, 2009).
- **Transparency**. Information about market surveillance activities is shared, including test results, risk assessments, accident information, corrective measures taken, and other information. The purpose is to help make the system efficient and to encourage accountability.
- **Collaboration**. The EU supports a wide range of efforts through communication, technical assistance, and joint action to help all stakeholders comply with the system.
- **Shared responsibility.** Manufacturers have primary responsibility for the safety of products and are held liable for product failures. Independent organizations develop standards, provide CA and market surveillance services, (authorized and coordinated by EU Member States), and coordinate various aspects of the system. The EU establishes the legal obligations of the various parties, provides financial support to the independent coordinating organizations, and oversees and monitors the system.

This shared responsibility is illustrated in ***Exhibit 1***. In contrast to the U.S. approach, which focuses on pre-market surveillance, the EU seeks a balance between pre-market assessment and post-market control (OECD, 2009; Sacchetti, 2009). Prior to placing a product on the market, the manufacturer

- determines which requirements apply to the product;
- designs, manufactures, and tests the product in accordance with requirements, including the required procedures for the assessment of the conformity (enlisting, when required, the assessment services of third parties),
- drafts the technical documentation of the product;
- takes all measures necessary so that the manufacturing process ensures compliance of the products; and
- upon positive assessment of the products, draws up a declaration of conformity and affixes the required conformity marking on the products (European Commission, 2000).

Importers and distributors also must know product regulations in detail to fulfill their new obligations and responsibilities and are obligated to import or distribute only compliant products. The following are the general obligations of importers and distributors (which are expected to be applicable to PPE in the near future):

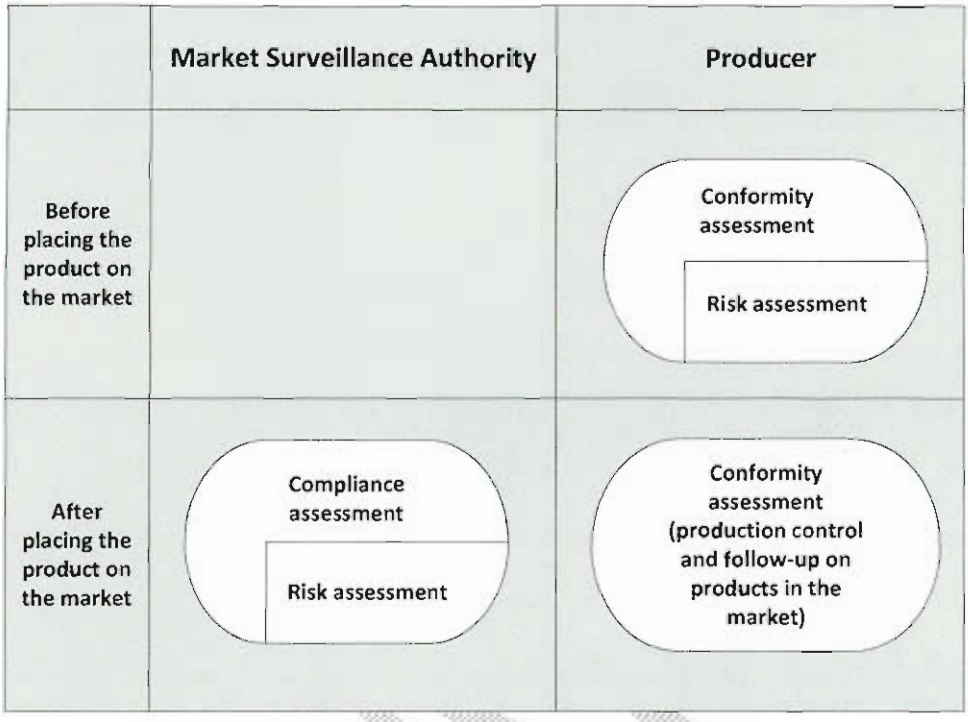
- verify the presence of conformity markings, technical documents, user instructions, and information about suppliers and clients (economic operators);
- take corrective measures for non-compliant products, including notifying authorities when a product on the market is non-compliant and poses a risk to consumer of end user; and
- cooperate with market surveillance authorities.

Independent CA bodies provide conformity assessment services and perform market surveillance activities. They must be authorized to perform these functions by national government authorities.

Member States are responsible for post-market control to ensure, through market surveillance, that products that have been placed on the market comply with basic requirements. Market surveillance activities are performed by independent organizations, often the same one responsible for third-party CA.

This report describes the organizations and requirements for each of these conformity assessment and market surveillance systems, beginning with the legislative context in the following chapter.

Exhibit 1. Responsibilities of Economic Operators and Market Surveillance Authorities Before and After Placing a Product on the EU Market



Source: Reproduced from PROSAFE (2009), Best Practice Techniques in Market Surveillance.

Legislative and regulatory framework

The EU operates in part through supranational institutions much like those of a federal system or confederation. The legislative institutions of the EU include the following:

- **The European Parliament:** Elected every 5 years by EU citizens, the European Parliament can amend or reject proposed legislation, but cannot initiate legislation. Like the U.S. Congress, the European Parliament does not select or control the top EU executive. PPE CA issues are typically addressed by the European Parliament's Internal Market and Consumer Protection (IMCO) Standing Committee.

- **The Council of the European Union:** A Council (also known as a "Council of Ministers") is composed of one national minister from each Member State. The national minister chosen to represent a Member State depends on the topic. There are currently 10 Council "configurations" (collectively known as the Council). Those involved most with CA issues are the Competitiveness Council (COCOM) and the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO).

The vast majority of European laws are adopted jointly by the European Parliament and the Council. The following are the executive institutions of the EU:

- **The European Commission:** This administrative body of about 23,000 civil servants is split into departments called Directorates-General (DGs) and Services. The European Commission is responsible for proposing legislation, implementing decisions and treaties, and conducting the day-to-day work of the EU. The DGs most involved with CA are the Directorate-General for Enterprise and Industry (DG ENTR) and the Directorate-General for Health and Consumers (DG-SANCO). The European Commission is led by a Cabinet of Commissioners, one from each DG.

- **The European Council**: Composed of the heads of the governments of the Member States, the European Council serves as the collective presidency of the EU.

A key feature of EU legislation is that it tends to be principle-based rather than rule-based. The former specifies what must be achieved (the principle), while the latter specifies how it must be done (the rules). Rule-based legislation is more common in the United States. Principle-based legislation in the EU takes the form of Directives.

The legislative framework for assuring the safety of PPE in the EU is based on two broad policy goals of the EU:

- removing technical barriers to trade caused by differing requirements across markets; and
- protecting the health and safety of consumers, including the workforce.

The EU takes into account the impact of conformance assessment measures on cost competitiveness, capacity to innovate, and international competitiveness, especially with respect to small- and medium-sized enterprises (SMEs). The EU approach to standard setting, testing, and certification requirements for PPE is based primarily on the harmonization of technical standards in each member country.

The EU's legislative framework for harmonizing CA has evolved significantly since its formation in 1993 and is still evolving. The rest of this chapter provides an overview of the key legislative framework for PPE CA in the EU. Details about specific procedures are provided in later sections of this report.

New Approach and Global Approach Directives

In 1985, the European Council adopted a new approach to technical harmonization and standards aimed at simplifying the removal of technical barriers to trade. The original policy on technical harmonization for PPE (and other products) involved detailed technical requirements, which frequently covered only one product or one element of a product. The adoption of such directives proved to be cumbersome and slow, and today these "old approach" directives no longer apply to PPE.[23] The Global Approach

[23] Old Approach directives still apply to products for which the nature of the risk requires extensive product-by-product or component-by-component legislation (e.g., chemicals, motor vehicles, pharmaceuticals and foodstuffs).

introduced by the Council Resolution of December 21, 1989 establishes a new policy for how manufacturers can demonstrate that their products meet the legally binding technical requirements in New Approach directives. Before the adoption of the Global Approach, it was common for countries to require mandatory testing and approval by government authorities before a product could be placed on the market (Australian Department of Industry, Science and Resources, 2001). The following are key features of the New and Global Approaches:

- **Principle-based requirements:** EU law (the directives) is limited to establishing "basic requirements" or performance levels to which a product must conform. Basic requirements refer to large families of products (e.g., PPE) and cover horizontal risks (e.g., ergonomics, protection against mechanical impact).

- **Standards are not mandatory:** Alternate paths are permitted for guaranteeing product quality. However, the producer has an obligation to prove that the products conform to the basic requirements.

- A **clear separation between EU legislation and European standardization:** The technical specifications required of products to comply with the directive are established by independent European standards agencies.

- **Harmonized standards:** Products manufactured in conformity with harmonized standards are presumed to be conformant to the basic requirements.

- **Requirements for CE Marking:** Common rules are established for affixing the CE Marking on products.

- **A common set of conformity assessment procedures ("modules"):** Procedures are based on the level of risk.

The method of determining conformity is intended to provide adequate assurance of conformity with essential requirements at the lowest possible cost. The CA modules include self-assessment by the manufacturer, type assessment by an independent body ("Notified Body"), quality assurance assessment by a Notified Body, and inspection of production items by a Notified Body. For the low risks, a supplier's declaration of conformity (SDoC) is sufficient; for the highest risks, third party assessment of products and quality management systems will be specified. Various combinations of modules can be included to give suppliers some choice while still maintaining the required level of assurance of conformity.

New Legislative Framework

The New Legislative Framework (NLF)[24] was adopted in 2008 as a complement to the New Approach model of legislation and represents a major step forward for market surveillance. The NLF contains two legal instruments that strengthen the CA system.

Regulation (EC) 765/2008 on Accreditation and Market Surveillance of the NLF sets out the minimum requirements for accreditation and market surveillance relating to the marketing of products. The Regulation took effect in 2010.[25]

Types of EU Legislation

Directives: Set out general rules to achieve a particular result but do not specify the means of achieving that result. Requires Member States to implement by making changes to their laws (through "transposition"). Aims at harmonizing EU law (removing contradictions and conflicts) across Member States.

Regulations: Self-executing. Do not have to be transposed into national law but confer rights or impose obligations on the Union citizen in the same way as national law. Aims at unifying EU law across Member States.

Decisions: Like a regulation, it is binding legislation with direct effect, but is focused more narrowly on a specific person or entity. http://ec.europa.eu/legislation/

Decision 768/2008/EC of the NLF establishes a common framework for the marketing of products by establishing more clear, transparent and coherent CA procedures. The Decision sets the policy blueprint for future Community legislation relating to products. Its provisions are expected to become effective for PPE once the PPE Directive is revised.

Personal Protective Equipment (PPE) Directive

PPE Directive 89/686/EEC has been in effect since 1995. The Directive applies to safety defects arising from the design, manufacture, or marketing of PPE. It is "Union harmonization legislation" designed to implement the New Approach Directive. It applies to protective equipment that is worn or held by the individual in order to protect him or herself against one or more health and safety hazards. It covers equipment for professional use at the workplace as well as for leisure or sports activities.[26]

The PPE Directive

- lays down basic requirements regarding safety,

[24] Formally called the New Internal Market Goods Package.

[25] There is some confusion about which of the provisions applies in which situations, and efforts are underway to resolve the confusion with a single market surveillance regulation. The Regulation stipulates that its provisions shall apply if there are no specific provisions with the same objective in EU harmonization legislation (such as the PPE Directive). The Commission is drafting a report on the implementation of Regulation (EC) 765/2008 to provide needed clarifications (Brown, 2011).

[26] It excludes equipment designed for use by the armed forces, police, self-defense or rescue operations on aircraft or ships; helmets and visors for users of 2 or 3-wheeled motor vehicles, and those designed for private use against adverse atmospheric conditions, damp, water, and heat (e.g., umbrellas or dishwashing gloves).

- divides PPE into three categories depending on the degree of risk,
- lays down risk-based requirements regarding conformance assessment procedures for the three categories of PPE, and
- sets out minimum safety requirements for the use of the PPE.

Fulfilling the Directive's requirements is the responsibility of the manufacturer. PPE can only be placed on the market if it has met all the Directive's requirements.[27] Foreign producers are also obliged to comply with quality standards, sizing, and packaging requirements set down by the Directive.

A recent study for the European Commission concludes that, although "it is difficult to isolate the impact of the Directive on the PPE market and EU economy as a whole," the Directive appears to have had positive effects. The Directive has led to the harmonization of standards and regulations on protective equipment, which removed barriers to trade related to the need to comply with the standards and regulations of different jurisdictions. The harmonization of standards, in turn, has meant that suppliers have had to face more direct competition from other producers within the EU, which put downward pressure on prices while shielding European producers against competition from low-cost, low-quality producers in other parts of the world. The study also noted there had been reduction in the number injuries and of working days lost as a result of these injuries since the PPE Directive came into force. However, available data are not disaggregated enough to be able to attribute trends in injuries directly to the PPE (European Commission DG Enterprise and Industry, 2010a).

The PPE Directive is currently being revised to bring its rules into alignment with Decision 768/2008/EC of the New Legislative Framework. The main elements to be addressed are accreditation, Notified Bodies, CE marking and CA, definitions and obligations, and market surveillance. The proposed amendments are designed to increase consistency between the products covered by the Directive and the health and safety risks associated with the use of these products. They are also designed to eliminate legal uncertainties and increase compliance with the Directive's provisions. In the revised PPE Directive,

- some products will be included and others will be excluded from the scope of the Directive,
- the risk categories under which some products are classified will likely change,
- some of the Basic Health and Safety Requirements that have proven impractical and difficult to enforce will be modified,

[27] Annex 1 of the PPE Directive provides a list of PPE that are not covered, which it labels as Category 0.

- alignments will be made with Regulation (EC) 765/2008 and Decision 768/2008/EC of the New Legislative Framework, and
- some CA requirements will likely be redefined (European Commission DG Enterprise and Industry, 2010a).

The expected amendments are described in more detail in this report. The expected changes to the CA requirements include the following:

- **Validity of EC type-examination certificates for Category 2 and 3 products:** Currently the CE marking for PPE products has no time limit. This means that if the standards of the Directive change, products that do not meet the new standards can nonetheless still be sold under the CE marking. The proposed changes would introduce time limits for examination certificates (5 years is proposed) and are intended to improve clarity and facilitate market surveillance.
- **Content of EC type-examination certificates:** The proposed change would codify the content of the EC type examination certificates either by including a standard content into the Directive or by asking the Notified Bodies to agree on a minimum content. The purpose is to make it easier for market surveillance authorities to identify products.
- **Quality control requirements:** The proposed changes would clarify the quality control requirements. The proposed amendments would also introduce the duty to send declarations of conformity to the market surveillance authorities.
- **EC declaration of conformity:** The proposed amendment is to create a requirement to provide a copy of the EC declaration of conformity (DoC) with the PPE. It is intended to facilitate market surveillance.
- **Introduction of a technical file requirement for Category 1:** To provide better clarity about stakeholders' responsibilities and to facilitate market surveillance.
- **Introduction of definition/responsibility of economic operators:** The proposed amendments would extend the requirements of the Directive to importers and distributors. It is intended to avoid legal uncertainties (European Commission DG Enterprise and Industry, 2010a).

One expected effect of the revised Directive will be to require CA by a Notified Body for most types of PPE (Thierbach, 2012). The European Commission may also change the nature of this legal act from a Directive to a Regulation. By eliminating the need to transpose the rules into national law (required for directives), this would speed up the application of the revised act.

As part of the revision process, the European Commission conducted an Impact Assessment of the proposed changes.

Impact Assessments

The European Commission's guidelines specify 6 key analytical steps that must be completed in any Impact Assessment:

1. identification of the problem,
2. definition of objectives,
3. development of policy options,
4. analysis of the impact of the options,
5. comparison of the options and identification of the preferred options, and
6. outlining policy monitoring and evaluation

In general, Impact Assessments are required for the most important Commission initiatives and those which will have the most far-reaching impacts (European Commission, 2009). This is the first time that an Impact Assessment Study has been carried out in the field of PPE (European Commission, 2013). The Impact Assessment Report recommends each of the proposed changes listed above (European Commission, 2010a).

Part of the Impact Assessment involved a Competitiveness Proofing, which focused on three dimensions of enterprise competitiveness:

- **Cost competitiveness:** the cost of doing business, which includes cost of intermediate inputs (including energy) and of factors of production (labor and capital);
- **Capacity to innovate:** the capacity of the business to produce more and/or higher quality products and services that meet better customers' preferences; and
- **International competitiveness:** the likely impact of the policy proposal on the European industries' market shares and comparative advantages (European Commission, 2012).[28]

Competitiveness Proofing

The aims of Competitiveness Proofing are to (1) further improve the analytical quality of impact assessment reports, and (2) facilitate the design of policies that take full account of competitiveness impacts, given their overall set of objectives (European Commission, 2012).

Specific attention is paid in Competitiveness Proofing to the impact of proposed amendments on small and medium-sized enterprises. Once Impact Assessments and Competitiveness Proofing reports are approved by the Impact Assessment Board, the European Commission formulates the text of the revised Directive/Regulation and submits the proposal to Council and Parliament (Thierbach, 2012).

European Standardization Regulation

A recent reform of the European Standardization system, Regulation (EC) No 1025/2012, is designed to enhance the transparency of the standardization process by facilitating representation and participation of SMEs in the process (European Commission, 2012c). The Regulation, which went into effect in January 2013, promotes greater involvement of consumer and societal organizations, including public authorities, in standardization activities, by establishing rules regarding

- the cooperation between European standardization organizations, national standardization bodies, Member States and the European Commission;

[28] Competitiveness Proofing has been required since 2010 for all important new policy proposals with significant effects on industry as part of the impact assessment process (European Commission, 2010b). In January 2012 a "Competitiveness Proofing Toolkit" was presented for use in the Impact Assessment procedures (European Commission, 2012a).

- the establishment of European standards and European standardization deliverables for products and for services in support of Union legislation and policies; and
- the financing of European standardization organizations by the Union (European Commission, 2012b).

Product Safety and Market Surveillance Package

A proposed new regulation, submitted to the European Parliament and Council by the European Commission in February 2013, would further amend the PPE and other harmonized sector Directives by establishing a single regulation on market surveillance. The EU's Single Market Act II of 2012 (COM, 2012) identified the Product Safety and Market Surveillance Package as priority initiative that would contribute to boosting growth and creating jobs. If passed, it is expected to go into effect in 2015 (European Commission, 2013a).

Currently, market surveillance rules for PPE and other products are covered by three sets of legislation (Regulation [EC] 765/2008, the General Product Safety Directive and various pieces of product harmonized legislation such as the PPE Directive) (European Commission, 2013b: 60 and 2013c: 61). The proposed regulation would do the following:

- Ensure consistency in EU market surveillance activities by not distinguishing between consumer and non-consumer products or between harmonized and non-harmonized products.
- Streamline procedures for the notification by Member States of information about products presenting a risk and corrective measures taken. The same system of notifications would be used for all products.
- Strengthen controls at external borders.
- Promote the exchange of information relating to market surveillance in an easily accessible database. Market surveillance authorizes would not need to repeat tests and assessments already carried out in relation to a product by authorities in another Member State.
- Give market surveillance authorities the power to charge economic operators fees when they require corrective action to be taken in relation to a product or must monitor corrective action proposed by an operator.
- Improve the RAPEX system, simplifying notification criteria, providing more detailed information to increase the relevance and follow-up, and making time limits for sending notifications more realistic and workable.
- Establish a European Market Surveillance Forum to develop best practices for harmonized implementation across the EU.

- Develop a multi-annual plan for market surveillance to identify and pursue areas in which coordination by the European Commission would add value and bring real improvements.

Product Standards

Basic Health and Safety Requirements

The design and manufacture of PPE is subject to Basic Health and Safety Requirements (BHSRs) established by the PPE Directive.[29] Manufacturers must meet the relevant BHSRs before placing products on the market. The BHSRs "define the results to be attained, or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so" (European Commission' 2010c). Some BHSRs are general requirements that apply to all PPE; others are specific to classes or types of PPE or to particular risks. The list of BHSRs is provided in ***Appendix B***. The categories of requirements are provided in ***Exhibit 2***.

In line with the principles of the New Approach, the BHSRs are formulated to "enable the assessment of conformity with those requirements, in the absence of European harmonized standards or in case the manufacturer chooses not to apply [the harmonized standards]" (European Commission' 2010c, 42). By giving manufacturers the flexibility to choose the most suitable way to meet the requirements, the aim of the PPE Directive is to allow technical progress in materials and product design "since assessment of whether requirements have been met or not are based on the state of technical know-how at a given moment" (European Commission' 2010c, 42).

Standards

The primary objective of European standardization is to define voluntary technical or quality criteria with which manufacturers, production processes or services may comply (European Commission, 2013c). The European standardization process is a voluntary activity of building consensus through an independent, recognized standardization body. Compliance with technical standards is not compulsory. Manufacturers are only required to demonstrate that the product fulfills the BHSRs. In practice, however, European retailers and buyers often demand that products are in compliance with standards (European Commission, 2013d).

Manufacturers may choose to comply with various standards to demonstrate the fulfillment of the BHSRs, including

[29] In PPE Directive 89/686/EEC the term Basic Health and Safety Requirement is used. In other directives, the term is Essential Health and Safety Requirement (EHSR or ER).

- international standards adopted by an international standards organization;
- European standards adopted by one of the three independent European Standards Organizations (ESOs);
- Harmonized standards adopted by one of the three independent European Standards Organizations at the request of the European Commission; or
- National standards adopted by a national standardization body.

Exhibit 2. Types of Basic Health and Safety Requirements for PPE

General requirements for all PPE	1. Design principles 2. Innocuousness of PPE 3. Comfort and efficiency 4. User information
Classes or types of PPE	1. PPE incorporating adjustment systems 2. PPE "enclosing" the parts of the body to be protected 3. PPE for the face, eyes and respiratory tracts 4. PPE subject to ageing 5. PPE which may be caught up during use 6. PPE for use in explosive atmospheres 7. PPE intended for emergency use or rapid installation and/or removal 8. PPE for use in very dangerous situations 9. PPE incorporating components which can be adjusted or removed by the user 10. PPE for connection to another, external complementary device 11. PPE incorporating a fluid circulation system 12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety 13. PPE in the form of clothing capable of signaling the user's presence visually 14. "Multi-risk" PPE
Particular risks	1. Protection against mechanical impact 2. Protection against (static) compression of part of the body 3. Protection against physical injury (abrasion, perforation, cuts, bites) 4. Prevention of drowning (lifejackets, armbands and lifesaving suits) 5. Protection against the harmful effects of noise 6. Protection against heat and/or fire 7. Protection against cold 8. Protection against electric shock 9. Radiation protection 10. Protection against dangerous substances and infective agents 11. Safety devices for diving equipment

European and harmonized standards (collectively referred to as EN) describe in detail how a particular type of product should be tested and what performance is required. The tests are designed to assess the

products against the BHSRs for the risks of the particular activity for which the product is intended to be used (Doughty, 2012). The standards are posted on the European Commission's website.[30]

European and harmonized standards are developed on a consensus-based approach that is open to all stakeholders, including public authorities and economic operators, and **European organizations and associations representing SMEs and societal stakeholder interests.**[31] The European Commission encourages standards to be based on relevant international standards. Standards must take into account environmental impacts throughout the life cycle of products. The European Commission's Joint Research Centre (JRC) thus plays an active role in the European standardization system.

[30] http://www.newapproach.org/Directives/ProductFamilies.asp?89/686/EEC

[31] These include the European Office of Crafts, Trades and SMEs for Standardization (NORMAPME), European Association for the Co-ordination of Consumer Representation in Standardization (ANEC), European Environmental Citizens Organization for Standardization (ECOS), and European Trade Union Institute (ETUI).

European Standards Organizations (ESOs) for PPE

The European Standards Organization involved with developing standards for PPE are the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). There are currently about 350 EN, EN ISO, or amendment standards and 7 CENELEC standards covering PPE. Standards are still missing for some types of PPE (European Commission, 2013e). The work of the European Standards Organizations is financed in part by grants from the EU.[32]

CEN Technical Committees for PPE

CEN 79	Respiratory protective devices
CEN 85	Eye protective equipment
CEN 158	Head protection
CEN 159	Hearing protectors
CEN 160	Protection against falls from height including working belts
CEN 161	Foot and leg protectors
CEN 162	Protective clothing including hand and arm protection and lifejackets
CEN 122	Ergonomics

CEN/CENELEC Standards Development Process

European and harmonized standards for PPE are developed by CEN and CENELEC according to principles of national delegation whereby their members develop a European consensus. For example, CEN's National Members are the National Standards Bodies (NSBs) of the 27 European Union countries, Croatia, the Former Yugoslav Republic of Macedonia, and Turkey plus three countries of the European Free Trade Association (Iceland, Norway, and Switzerland). There is one member per country.

Content of EC Mandates

- Justification and indication of the framework of the European and regulatory policy (e.g., legislation such as a New Approach directive).
- Reference to and clarification of the requirements, providing a clear and precise indication of the relationship between its content and the Basic requirements covered.
- Involvement of the parties concerned, the stress explicitly the specific collaboration and involvement of certain interested parties, such as environmental bodies or consumer associations.
- Completion dates, establish a timeline for adoption of a standard by the ESO
- "Standard" clauses such as the standstill for national activities and the close cooperation among ESOs.

The process of developing a new European standard can be initiated by public agencies, non-governmental organizations or private persons, including the Vertical and Horizontal coordinating bodies of Notified Bodies (described in Chapter 7). Most European Standards have been drawn up in Technical Committees. A CEN Technical Committee is a technical decision making body that manages the preparation of the CEN standardization process. Committee

[32] CEN standardization system costs approx. 800 million Euro per year. 80% of the costs are carried by industry.

members are national delegations designated by the CEN members. The process takes an average of 36 months (but is possible in 16 months) (European Committee for Standardization' 2013). Once adopted, ENs are transposed into national standards.[33] The steps in the process are described in ***Exhibit 3.***

Harmonized Standards

Of the four types of standards, harmonized standards are the only ones that provide a presumption of conformity with the corresponding BHSRs. A harmonized standard is a European standard developed based on a request (or "mandate") from the European Commission to a recognized European Standards Organization (e.g., CEN or CENELEC). The request provides guidelines, which the standards must respect to meet the basic requirements or other provisions of relevant European Union harmonization legislation. CEN has developed guidelines, including a checklist, for drafting and verifying mandated European standards for PPE (European Committee for Standardization, [2007]). About 26% of European standards have been developed following specific mandates from the European Commission (European Commission, 2011).

The use of these standards remains voluntary, but compliance with harmonized standards provides a presumption of conformity with the corresponding requirements of harmonization legislation. Manufacturers, other economic operators (importers, authorized representatives, distributors) and CA bodies can use harmonized standards to demonstrate that products, services, or processes comply with relevant EU legislation. Most harmonized product standards are based on international standards (Rajamäki, 2002).

The standardization requests that have been issued by the European Commission and accepted by the ESOs are available in the EC's database of mandates.[34] The content of the mandates is covered in EC law (European Commission' 2009a).

Exhibit 3. Steps in the Development of an EN

Step	Description

[33] CEN also facilitates CEN Workshop Agreements (CWAs), which are less formal documents. A CWA can satisfy market demands for a more flexible and timelier alternative to the traditional European Standard.

[34] http://ec.europa.eu/enterprise/standards_policy/mandates/database/index.cfm?fuseaction=titSearch.main&CFID=S843496&CFTOKEN=2de220420c55c3a4-1C7563AS-B074-45CC-3A961DA00862A3B7&jsessionid=f5122f601404b59cd02d593938641e505556TR

1.	**Proposal to develop an EN**	Any interested party can introduce a proposal for new work in CEN. Most standardization work is proposed through the National Standards Bodies of one or more of the EU Member States.
2.	**Acceptance of the proposal**	Once a project to develop an EN is accepted by the relevant CEN Technical Committee (TC), the member countries put all national activity within the scope of the project on hold. This means that they do not initiate new projects, nor revise existing standards at national level. This obligation is called "standstill" and allows efforts to be focused on the development of the EN.
3.	**Drafting**	The EN is developed by experts within a Technical Body. The Technical Body prepares a technical report with recommendations about issues to be covered in the standards
4.	**CEN Enquiry: Public comment**	Once the draft of an EN is prepared, it is released for public comment, a process known in CEN as the "CEN Enquiry." During this public commenting stage, everyone who has an interest (e.g., manufacturers, public authorities, consumers, etc.) may comment on the draft. These views are collated by the CEN national members and analyzed by the CEN Technical Body.
5.	**Adoption by weighted vote**	Taking into account the comments resulting from the CEN Enquiry, a final version is drafted, which is then submitted to the CEN national members for a formal vote, weighted by population size.
6.	**Publication of the EN**	After its publication, a European Standard must be given the status of national standard in all CEN member countries, which also have the obligation to withdraw any national standards that would conflict with it. This guarantees that a manufacturer has easier access to the market of all these European countries when applying European Standards and applies whether the manufacturer is based in the CEN territory or not.
7.	**Review of the EN**	To ensure that a European Standard is still current, it is reviewed at least within five years from its publication. This review results in the confirmation, modification, revision or withdrawal of the EN.

Source: European Committee for Standardization (2013)

The European Commission drafts mandate through a process of consultation with stakeholders (social partners, consumers, SMEs, relevant industry associations, etc.). Draft mandates are submitted to a Committee on Standards (European Commission, 2012d). They are then submitted to the Member States in the Standing Committees of the standards organization.

To create the capacity to confer this presumption of conformity, the references of harmonized standards must be published in the *Official Journal of the European Union*. Once approved and published in the journal, all diverging national standards must be withdrawn, according to internal rules of the European Standards Organizations. The official list of harmonized standards for PPE are posted on the European Commission's website[35] and are listed in ***Appendix C*** of this report.

Role of International Standards

CEN and the International Organization for Standardization (ISO) coordinate standards development on the basis of the "Vienna Agreement" of 1991.[36] About 30% of the ENs in the CEN collection are identical to ISO standards (European Committee for Standardization, 2013). The European Standards

[35] http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/personal-protective-equipment/index_en.htm

[36] Officially, the *Agreement on Technicol Cooperotion Between ISO ond CEN*.

Organizations are also involved in a regular and ongoing dialogue and exchange of information with the American National Standards Institute (ANSI). At their meeting in Dublin in February 2013, they agreed they will "intensify their collaboration with a view to aligning their standards related issues arising from the implementation of the proposed Trade Agreement between the European Union and the United States...The Transatlantic Trade and Investment Partnership (TTIP) will aim to remove barriers to trade between the EU/EEA and the USA, and therefore it will be important to reduce any remaining differences between American and European standards in a number of sectors, and also to encourage a common approach, preferably at global level" (CEN-CENELEC, 2013[1].

Pre-Market Certifying of ConformITY

Manufacturers and other economic operators must verify and declare compliance with BHSRs for PPE before placing goods on the market. This is done with a combination of several risk-based tools. The assessment of conformity is carried out either by the manufacturer or by a third-party CA body, depending on risk level.

Notified Bodies

Where the PPE Directive requires third-party CA activities, these are undertaken in the EU by a "Notified Body." A Notified Body is a European-based organization that has been appointed by a Member State's national notifying authority to perform certification, inspection, or testing for the DoC of products. National notifying authorities "notify" the European Commission of the organizations designated to perform CA services.

Member States are responsible for ensuring that the Notified Bodies are competent and fulfill the requirements for Notified Body as defined in the PPE Directive. To be eligible as a Notified Body, an organization must be a legal entity established in the territory of the Member State concerned and under its jurisdiction. Notified Bodies must be technically qualified, fully independent, impartial, and have a high level of professional indemnity insurance (European Commission, 2010c). In addition, some non-EU CA Bodies (CABs) may also conduct investigations, certifications, and laboratory tests under Mutual Recognition Agreements. All Notified Bodies are subject to routine surveillance at regular intervals by the competent authorities of the Member States to verify their qualifications.

A Notified Body may not be the manufacturer, designer, or supplier of the PPE under assessment. The Notified Body may accept measurement results from a manufacturer's laboratory and can have part of their work carried out by another body/laboratory (through subcontracting) on the basis of established

and regularly monitored competence. However, the Notified Body remains responsible for all of its activities and issued documents.

Notified Bodies are designated for a defined range of CA procedures and types of products and risks. A manufacturer can choose any Notified Body in Europe that is designated for the type of product and required CA procedures. There are currently 112 European-based Notified Bodies in the field of PPE. The European Commission publishes a list of all Notified Bodies in the *Official Journal of the European Union* and on their website (NANDO Net).[37]

Prior to the development of the EU, public institutions typically provided product certification services that Notified Bodies now perform. Today, those public organizations have largely been privatized and consolidated under international ownership. Some now exist in a form of non-profit bodies; others are owned by a multinational body such as Underwriters Laboratory.

Accreditation and Auditing of Notified Bodies

National notifying authorities must demonstrate the technical competence of their Notified Bodies. Decision 768/2008/EC encourages demonstration through accreditation and promotes a high, uniform level of performance of Notified Bodies through strengthened supervision by Member States. Accreditation is a third-party attestation of the Notified Body's competence to carry out specific CA tasks. It serves as an impartial means of assessing and conveying the technical competence, impartiality, and professional integrity of CA bodies (European Commission, 2008).

The use of accreditation differs across Member States and across sectors, but is expected to become required under the revised PPE Directive/Requirement. Some Member States have made accreditation for notification purposes compulsory, and there is evidence of an increasing use of this method.[38] Under the current PPE Directive, accreditation operates in all Member States, but lacks a common set of rules.

Accreditation institutions in the EU are national public bodies with a defined monopoly. Regulation (EC) 765/2008 of the New Legislative Framework, which is in effect for the PPE sector, sets out requirements for accreditation (including ISO/IEC 17011 requirements) and creates a legal framework for operating accreditation in Europe. Specific provisions of the regulation include the following:

[37] http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=6

[38] At the end of 2009, before the Regulation came into force, 1,118 of 2,249 Notified Bodies (49.7%) were accredited; as of June 2012, 2,196 of 3,106 Notified Bodies (70.7%) were accredited (European Commission, 2013f).

- Accreditation is carried out by one single national accreditation body (NAB) appointed by its Member State.
- Accreditation is performed as a public authority activity, completely separated from commercial assessment activities.
- National accreditation bodies operate free from commercial motivations and on a not-for-profit basis.
- Competition between accreditors and between accreditors and accredited CA bodies within the EU internal market is prevented.
- A set of requirements for NABs is established.
- The European Cooperation for Accreditation (EA) is established to oversee the European accreditation infrastructure for PPE, including peer evaluation of national accreditation bodies, and cross-border accreditation issues.
- Member States have an obligation to share information about their accreditation activities.

The National Accreditation Bodies have been established in all the Member States (they are listed on the European Commission's website[39]), although not all national accreditation bodies perform the full scope of activities (European Commission, 2013f).

To avoid the need for multiple accreditations, the European Commission has also adopted a policy document that explains how accreditation bodies should proceed for multi-site international CA bodies and subcontracting. The EA developed guidelines on how to put into practice these policy principles (European Commission, 2013f).

Peer Evaluation of National Accreditation Bodies

The EU also encourages peer evaluation to ensure continuous quality control of the European accreditation system. The EA is an association of national accreditation bodies in Europe that have been officially recognized by their national governments to assess and verify CA organizations (http://www.european-accreditation.org/home). The EA's 35 full members are accreditation bodies located in an EU or EFTA Member State, or in an EU candidate country. The EA also has 13 associate members. EA is financed by the European Commission to manage the official European accreditation infrastructure, including the operation and management of the peer evaluation system.

Through the EA, members can apply for peer-group evaluation. Members who pass evaluation may sign the multilateral agreement (MLA) for accreditation as a certification body, laboratory, or inspection

[39] http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=ab.main

body. The MLA establishes a uniform level of competence of the accredited body. Signers of the MLA recognize and promote the equivalence of each other's systems and certificates and reports.

A similar system peer review and auditing of testing laboratories is in place at the international level through the International Laboratory Accreditation Cooperation (https://www.ilac.org/) for laboratories and inspection accreditation. Peer review and auditing of accreditation bodies is also conducted through national membership in the International Accreditation Forum (IAF, http://www.iaf.nu/). The IAF focuses on management systems, products, services, personnel and other similar programs of CA. The EA coordinates with each of these institutions.

Risk-based Product Categories and Conformity Assessment Modules

The PPE Directive establishes the CA procedure to be followed by manufacturers before the PPE product is placed on the market. Manufacturers determine the risk category for pre-market assessment. The procedure depends on the severity of the risk concerned and covers the design and/or the production of the product. The Directive makes a distinction between three, risk-based (rather than product-based) categories of PPE.

Category I PPE

Category I PPE are simple design products designed to protect the user against gradual or unexceptional risks. It assumes the user himself can assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time (European Commission, 1989). PPE is intended to protect the wearer against

- mechanical action whose effects are superficial (e.g., gardening gloves, thimbles);
- cleaning materials of weak action and easily reversible effects (e.g., gloves affording protection against diluted detergent solutions);
- risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50 °C or to dangerous impacts (gloves, aprons for professional use);
- atmospheric agents of a neither exceptional nor extreme nature (e.g., headgear, seasonal clothing, footwear);
- minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (e.g., light anti-scalping helmets, gloves, light footwear); and
- sunlight (sunglasses).

Category II PPE

Category II PPE are intermediate design products designed to protect against medium risk, i.e., those risks not enumerated under Category I or Category III such as protectors for motorcyclists, high-visibility vests.

Category III PPE

Category III PPE are complex design products designed to protect against mortal danger or against dangers that may seriously and irreversibly harm health "the immediate effects of which the designer assumes the user cannot identify in sufficient time." Category III PPE is intended to protect the wearer against

- filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;
- respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;
- PPE providing only limited protection against chemical attack or against ionizing radiation;
- emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material;
- emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of −50 °C or less;
- PPE to protect against falls from a height; and
- PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work.

The specific types of PPE that fall into these categories is listed in ***Appendix D***. Some products fall into more than one category.

Pre-market CA procedures are designed to avoid unnecessary burdens for economic operators (especially SMEs) by providing a choice of appropriate CA procedure (Sacchetti, 2009). Even when third party involvement is mandatory, manufacturers are given a choice between quality assurance and product certification modules. The goal is to be proportionate and effective, taking into account the economic infrastructure of the PPE sector, including the complexity of the product, size of companies, and the scope of production (European Commission, 2013f). The EU selects CA procedures for

categories of PPE based on appropriateness to the type of product and the nature and level of risk involved.

Conformity Assessment Modules

The three-category system for PPE derives from a menu of eight CA modules.[40] The modules enable the conformance assessment procedure to be tailored from the least to the most stringent, in proportion to the level of risk involved and the level of safety required.

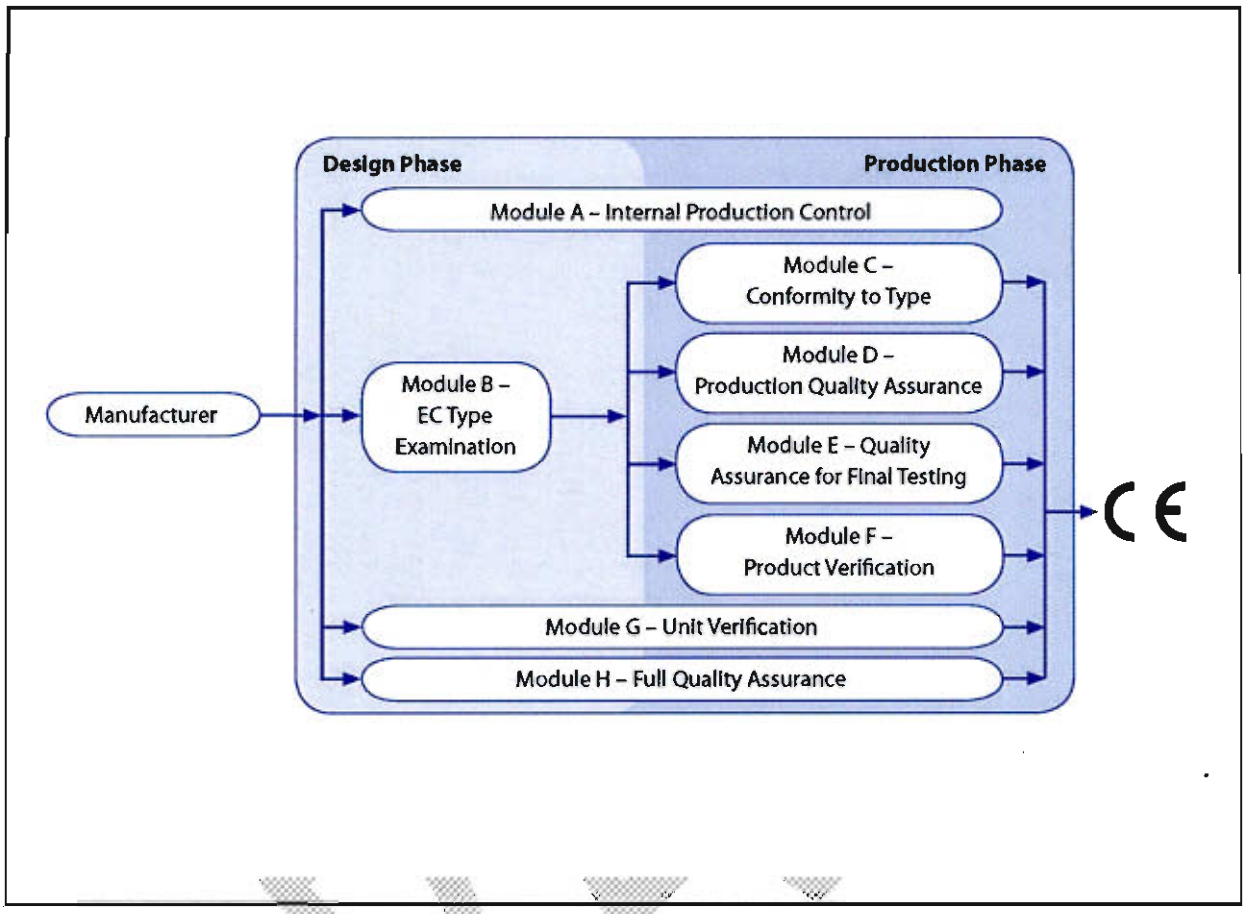
Modules range from manufacturer's declaration of conformity to full quality assurance certification (see ***Exhibit 4***). All procedures give equivalent results, i.e., the presumption of conformity. A full description of the modules is provided in ***Appendix E.*** A summary of the procedures is presented in ***Exhibit 5***. They are similar (though not identical) to the seven-type product certification system described in the ISO/IEC Guide 67.[41]

The correspondence between the modules and the three risk-based PPE Categories is defined in the PPE Directive. Category I products correspond with Module A; Category II products require Modules B and C; and Category III products require Modules B, C, and D (European Commission, 2000).

[40] Originally established in 1993 as part of the Global Approach to conformity assessment, the use of the modules as the basis for PPE and other harmonized products is reinforced by Decision 768/2008/EC of the NLF.

[41] The modules based on ISO EN standards. The quality assurance techniques (modules D, E, H and their variants) describe the elements a manufacturer must implement in his organization in order to demonstrate that the product fulfills the essential requirements of the applicable directive, and are derived from EN ISO 9000 and EN ISO 9001. Module A1 corresponds somewhat with ISO/IEC System 1b; Modules A2 plus B with System 1a; Module C with System 2; and so forth. Both systems call for increasing involvement of third parties in testing, oversight, verification, and surveillance across the modules.

Exhibit 4. Overview of Pre-Market Conformity Assessment Procedures



Source: European Commission (2000).

Exhibit 5. Conformity Assessment Requirements, by Module

Requirement	Module A	B	C	D	E	F	G	H
Manufacturer establishes technical documentation	X	X		X	X	X	X	X
Internal production control. Manufacturer ensures compliance of the manufactured products with the technical documentation and/or the applicable requirements of the legislative instrument.	X		X	X	X	X	X	X
Internal production control. Manufacturer ensures compliance of the manufactured products with the EC type-examination certificate			X	X[3]	X	X		
Conformity marking (CE marking)	X		X	X	X	X	X	X
Supplier's Declaration of Conformity (attestation)	X		X	X	X	X	X	X
Product testing (Supervised or conducted by a Notified Body)	X[1]		X[2]		X			
EC type-examination by a Notified Body		X				X		X[6]
Quality system, assessed by a Notified Body				X	X[4]			X
Surveillance by a Notified Body				X	X			X
Verification by a Notified Body						X[5]	X	
Design examination by a Notified Body								X

[1] Applies to two optional additions to Module A: A1, Supervised product testing of specific aspects of the product or A2, Supervised product checks at random intervals

[2] Applies to two optional additions to Module C: C1, Supervised product testing of specific aspects of the product or C2, Supervised product checks at random intervals. Follows Modules B.

[3] Module D includes optional D1, Quality assurance of the production process.

[4] Module E includes optional E1, Quality assurance of final product inspection and testing

[5] Module F includes optional F1, Conformity based on product verification

[6] Module H includes optional H1, Conformity based on full quality assurance plus design examination

Conformity Assessment Procedures for Category I PPE

All procedures for demonstrating compliance with regulatory requirements are considered as leading to the same level of conformity (see ***Exhibit 6***). The required procedures for Category I PPE products are

- a Supplier's Declaration of Conformity (SDoC)
- technical documentation, and
- CE mark.

Independent testing is not required for Category I products.

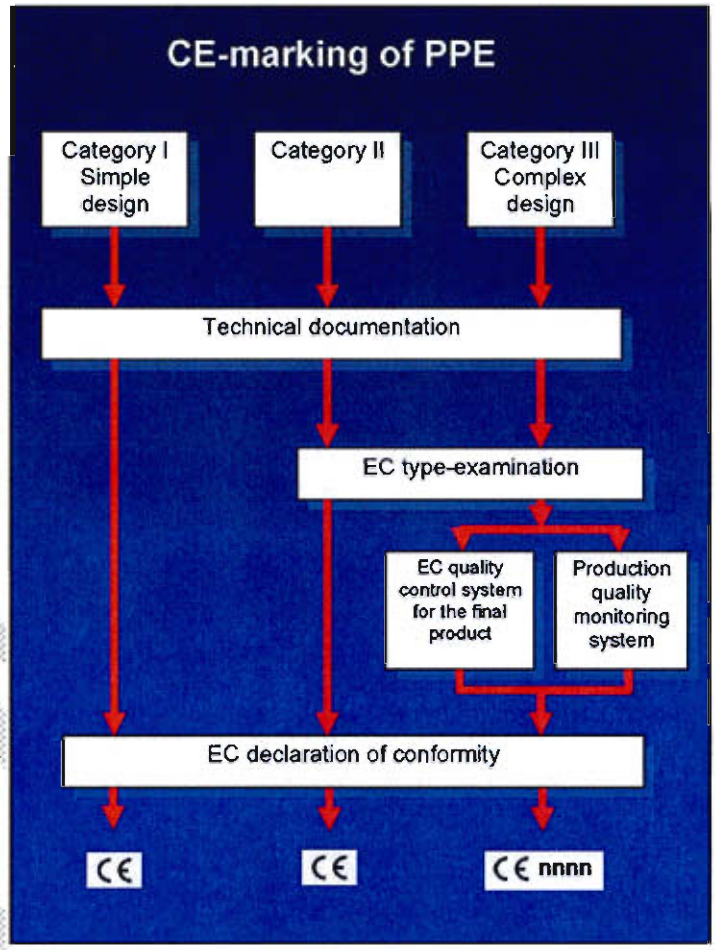
Conformity Assessment Procedures for Category II PPE

The required procedures for Category III PPE products are

- EC type-examination and EC certificate of conformity by a Notified Body (an authorized, independent inspection organization),
- SDoC attesting the PPE is identical to the product for which the EC declaration has been issued,
- technical documentation, and
- CE mark.

The production process is not independently assessed, but regular product samples are submitted for testing.

Exhibit 6. Pre-Market Conformity Assessment



Source: European Commission (2010c).

Conformity Assessment Procedures for Category III PPE

The required procedures for Category III PPE products are

- EC type-examination and EC certificate of conformity by a Notified Body;
- Quality Assurance procedures, either (a) an internal EC quality control for the final product supervised or conducted by Notified Body, which would conduct random checks at least annually, or (b) a system for ensuring EC quality of production by means of monitoring (e.g., ISO 9001);
- technical documentation; and
- CE mark that includes the Notified Body's 4-digit identification number.

Technical Documentation to be Supplied by the Manufacturer

Technical documentation is the technical file that provides information on the design, manufacture and operation of the product. A main purpose of drafting the technical documentation is to provide

supporting evidence of the conformity of the product in question. The content of the technical documentation is determined by the PPE Directive and is based on EN ISO 17050-2:2004.

All manufacturers must establish a technical file documenting the methods used by the manufacturer to ensure that the PPE complies with the basic requirements relating to it. For Category II and III PPE, technical documentation should also cover at least the following elements:

- general description of the product;
- design sketches, working blueprints, charts including assemblage blueprints and arrangement of parts, etc.;
- descriptions and explanations of blueprints;
- reference to the EU Directive(s), harmonized standards and other normative documents taken into account in the production of this type of goods;
- instruction for the use of the product, including safety instructions;
- copy of the SDoC;
- certificate or technical report of the Notified Body; and
- name and address of the manufacturer (representative) and the Notified Body.

Any changes made to the product must be documented in the technical file. Technical files must be stored for no less than 10 years after the last product is placed on the market and is recommended for the entire period of product service. Technical files must be presented on request to market surveillance authorities of the EU.

Supplier's Declaration of Conformity (SDoC)

If a product complies with all the requirements of the Directives, the manufacturer must complete the Supplier's Declaration of Conformity (SDoC). The SDoC indicates that the product meets all the necessary requirements of the Directive(s) applicable to the specific product. The model SDoC provided in the PPE Directive is reproduced in ***Appendix F***.

EC Type-examination Certificates

The PPE Directive requires that an EC type-examination be performed for Category II and III products. EC type-examination is a check on the design and documentation of a prototype or initial example of an

item of PPE to ensure it satisfies the basic requirements. The process is based on claims made about the product in the user information and is achieved by

- examining the design documentation (technical file) to ensure it satisfies all the relevant BHSRs and that the product is adequately described through the use of diagrams and lists giving the source of all materials; and

- carrying out a series of tests and examinations on the products to ensure they meet the claimed performance levels and have been produced in accordance with the manufacturer's technical file (this testing is from an agreed technical specification, usually a European standard) (Doughty, 2012).

An EC type-examination is carried out once, and test reports of the EC type-examination are added to the technical file (European Commission, 2012).

If the model passes the examination, the Notified Body grants an EC type-examination certificate called a Certificate of Compliance CE (or, CE Certificate of Conformity). For Category II products, this is effectively the end of the Notified Body's pre-market involvement and the certificate holder becomes responsible for ensuring that subsequent production remains the same as the model examined by the Notified Body.

Quality Assurance

Category III products are also subject to checks by a Notified Body to ensure the production versions of the PPE continue to comply with the initial sample previously approved by the EC type-examination. The Notified Body carrying out the production checks need not be the same as the one that carried out the original type approval.

Once the product has been placed on the market, manufacturers or their authorized representatives[42] may choose one of two methods for checking the conformity of ongoing production:

1. **EC quality control for the final product:** This involves the Notified Body obtaining a random sample of recently manufactured items of PPE which are then tested by methods used in the original EC type-examination to ensure continued compliance. These are referred to as Article 11A assessments.

2. **Quality monitoring system:** The Notified Body makes checks at the manufacturing site to ensure that the quality systems being used are capable of enabling consistent production of the

[42] An authorized representative is any natural or legal person established within the EU who has received a written mandate from a manufacturer to act on his behalf in relation to specific tasks. This can be an importer or distributor.

certified product. These are referred to as Article 11B assessments. (Doughty, 2012). The minimum requirements can be satisfied following EN ISO 9001:2000.

In both cases, a Notified Body carries out the check on the final product or monitors the production process. Checks have to be carried out periodically while that item of PPE remains in production, at least once a year.

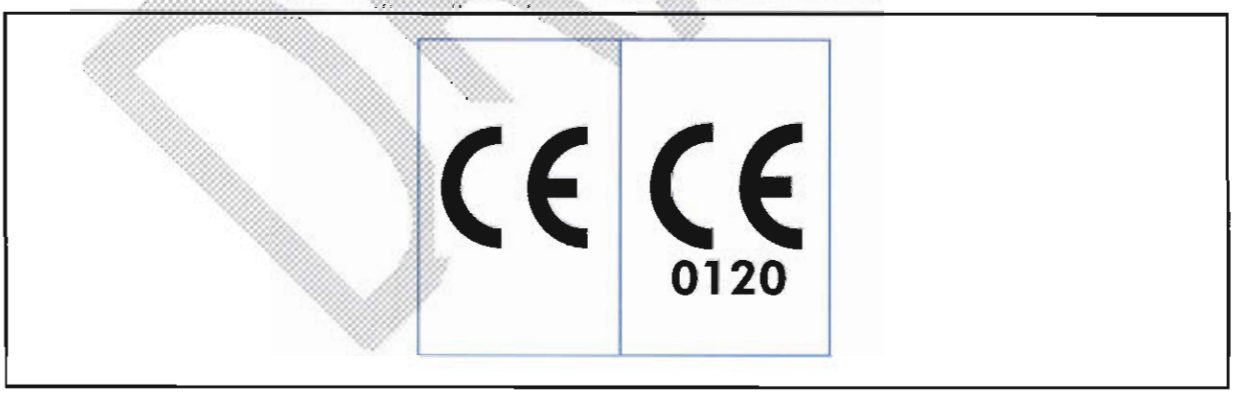
The Certificate of Compliance CE remains the property of the Notified Body. The Notified Body performing these pre-market quality checks can withdraw the certificate if there are sufficient grounds.

CE Marking

All products must be affixed with a CE marking[43] before being placed on the EU market. The CE marking indicates the product conforms with requirements and that the manufacturer has carried out all required conformity procedures established by the EU and related to the product. The CE mark must be applied by the manufacturer, authorized representative, or person responsible for placing the product on the market. It may be affixed in a third country if the PPE is manufactured there.

For Category I and II products, the "short CE mark" is affixed on the product. For Category III products, a Notified Body was involved in the production control phase, and the "Long CE mark" is affixed on the product (by the manufacturer) with the Notified Body's unique 4-digit identification number (***Exhibit 7***).

Exhibit 7. CE Marking, with and without Notified Body's Identification Number



[43] The term is from the French "Conformité Européenne."

Enforcement: Post-market Monitoring of COMPLIANCE

Market surveillance in the EU is the responsibility of the Member States. Member States are free to organize market surveillance to fit their own cultural, political, and legal system, so there is no single organizational model. Some organize market surveillance centrally while others follow a decentralized model organized by region or locality. As a result, several Member States use a single Market Surveillance Authority (MSA) for the PPE market while others have multiple MSAs (e.g., Germany has 16 and the United Kingdom has 14) (European Commission, 2013i).

Market Surveillance Resources

In a European Commission study of general EU market surveillance (MS) programs conducted in 2010, the authors identified key features of the MS programs in the EU. The study found that Member States varied widely in their market surveillance resources and procedures. The MSAs of three Member States had over 2,000 inspectors each while the MSAs of four other Member States had fewer than 10 each. Only four Member States had a unique qualification for their Market Surveillance Inspectors. There was also a large variation in the process MSAs used to obtain their samples for testing (purchased, seized or both) as well as differences in inspector productivity.[44]

Key points made in the report regarding market surveillance resources were as follows:

- **Resources:** Well-defined and assured budgets are necessary for good enforcement. Dedicated sampling and testing budgets allow for better long term planning and involvement in co-operation programs. Test purchasing of products is an important inspectional tool and is important in assessing the safety of equipment that is available for hire or rent. Carry-over of funding allows for strategic reserves to be created to enable appropriate reactive responses to emergency situations.
- **Inspectors:** The professionalism and competences of the inspectorate coupled with its ability to successfully recruit train and retain Inspectors with the necessary knowledge and relevant skills will determine to a great extent the effectiveness of the MSA. A distinct or unique qualification for MS Inspectors is a proven way to ensure that the required knowledge and skills are developed. Close links with educational establishments are important to ensure the identified training needs can be met (BSI Development Solutions, 2011).

[44] The average number of inspections per inspector per year ranges from 15 to 117.

Regulation (EC) 765/2008, which went into effect in 2010, establishes common minimum requirements for the national market surveillance authorities. Among these are requirements regarding Member States' capacity to perform market surveillance, including the following:

- Member States have an obligation to give their national Market Surveillance Authorities (MSAs) the powers, resources, and knowledge needed to perform enforcement activities.
- Member States submit their list of national MSAs, along with contact and other identifying information, to the European Commission, which publishes the lists on its website.[45]
- Member States have an obligation to organize cooperation between authorities within their national territory.
- Member States must have a national market surveillance program (NMSP):

  NMSPs must be updated annually and shared with the European Commission and other Member States and must be posted on national websites.

  NMSPs will also be posted on the European Commission's CIRCA website (an internal web portal for *European* institutions).

  NMSPs can be general or sector specific; the majority of the Member States have chosen to develop sector-specific NMSPs.

  Elements of a general NMSP are enumerated.[46]

  The European Commission is responsible for ensuring that the NMSPs are comprehensive and comparable across Member States.
- Member States must regularly evaluate their national market surveillance programs:

  They must send the results of the review to the European Commission and make them publicly available.

  Evaluations must be conducted every 4 years (the first reports are due in 2014).

  The purpose of the evaluations is to detect problems early, facilitate improvements, detect good practices, and share lessons learned (both good and bad).

Market Surveillance Procedures

The research report also addressed operational issues and had the following conclusions:

- **Performance measures**: An effective and efficient MSA needs to set clear and measurable overall performance targets; accurately monitor its performance and record and publicize its results. It also needs to monitor the performance of its staff both as individuals and teams.

[45] A combined list of market surveillance authorities for PPE is posted on PROSAFE's website at http://www.prosafe.org/default.asp?itemid=27
http://www.prosafe.org/default.asp?itemID=27&itemTitle=undefined#PPE

[46] The revised PPE Directive is likely to include a PPE-specific template (Sacchetti, 2011).

- **Inspection Planning:** MSAs need detailed and accurate information regarding the status of the economic operators that deal in the product sectors for which it is legal responsible. The required information includes a) location and contact details; b) category of products supplied; c) position in supply chain; d) type and effectiveness of management & quality systems; and e) Previous inspection and compliant history.
- **Inspection Methodology:** Economic operators are very concerned from a competitive viewpoint that they are all treated equally and that there is consistency of decisions and enforcement actions between individual Inspectors and between inspections in different regions of the country. Consumers are concerned that inspections are vigorous, free from outside influences, well targeted and effective in identifying dangerous products. MSA management needs to be able to manage the consistent delivery of effective market surveillance activities in a range of product sectors over time and geographical location.

  The methodology should include a) inspection rules; b) documented inspection procedures; c) quality management systems; d) inspection handbooks; e) checks on products from third countries (at ports/airports/borders); f) supply chain inspections (at importer and distributor levels as well as main stream retail outlets); g) a documented procedure to underpin their sample planning and sampling procedures (BSI Development Solutions, 2011).

These issues are captured in Regulation (EC) 765/2008 by the following requirement:[47]

- Authorities must perform appropriate checks on an adequate scale, based on the risk assessment and on information from other Member States through their market surveillance actions and results (e.g., RAPEX notifications).

Border Controls

The EU market surveillance system is based on the principle that the earlier in the supply chain a non-conforming product is stopped, the easier and more efficient will be the remedies. Member States are obligated to have appropriate control mechanisms in place to verify that all products covered by EU legislation originating from third countries and entering the EU market comply with the requirements set out in EU legislation.[48] They must provide border control authorities with sufficient funding and policy guidance and must ensure that border controls are properly targeted and that trade facilitation is not adversely affected.

To promote cooperation between market surveillance and customs authorities, the EU requires Member States to

[47] A number of additional changes are being considered as part of the Product Safety and Market Surveillance Package, discussed in Chapter 2.

[48] Regulation (EC) No 765/2008 provides the regulatory framework.

- establish a single point of border control contact;
- establish written agreements between customs and market surveillance authorities to strengthen cooperation in the area of border controls; and
- provide cooperation between customs and market surveillance authorities (e.g., through information sharing and cooperation with market surveillance authorities of third countries).

Controls of products at external borders are facilitated under the EU's Customs Program, which aims to "achieve good administrative cooperation and proper communication between Customs and Market Surveillance Authorities" (European Commission, 2012g). The European Commission drafted guidelines to promote collaboration between customs and market surveillance authorities. The guidelines include practical tools for customs officers, i.e., information sheets and checklists for individual product groups (European Commission, 2012f). The European Commission also distributes RAPEX notifications considered as containing relevant information for customs officials and sponsors RAPEX training seminars for national market surveillance and customs authorities to strengthen knowledge of the RAPEX system and to improve enforcement capacity (Finnish Institute of Occupational Health, 2012, 19).

In addition, Decision 768/2008/EC requires border control authorities to ensure that technical documentation has been provided for products. In addition to the CE markings, SDoC, and user instructions, this documentation must include the manufacturer's and importer's name and address. The latter, which economic operators are required to provide, helps with traceability by ensuring products are identified and linked to both the manufacturer and importer (this requirement is expected to be reflected in the revised PPE Directive/Requirement).

Enforcement: Corrective actions and sanctions

EU Member States are free to choose the sanctions to be used when infringements take place.

Regulation (EC) 765/2008 requires the following:

- Authorities must perform appropriate checks on an adequate scale, based on the risk assessment and on information from other Member States through their market surveillance actions and results (e.g., RAPEX notifications).
- Authorities must establish adequate procedures to follow up complaints, monitor accidents, order corrective action, and verify its implementation.
- MSAs must provide for effective, proportionate, and dissuasive penalties for economic operators in case of infringements. Appropriate measures include corrective action, withdrawal, recall, or destruction.
- MSAs must exchange information with the European Commission and other Member States on serious risk cases via the Community Rapid Information System (RAPEX). Member States must have a single RAPEX Contact Point.
- Economic operators that do not cooperate with MSAs can be forced to via their "home authority."

The most common corrective measures reported through the RAPEX system are the bans of sales, withdrawal of a dangerous product from the market (or its recall from consumers); and import rejection by the customs authorities. Supplies can also be restricted, or destroyed (RAPEX, 2012). The EU New Approach Directive requires that the actions selected be based on an appropriate risk assessment.

New Approach directives also require that action be taken against

- persons who affix the CE marking to non-compliant products;
- the manufacturer (or other person) responsible for placing a non-compliant product on the market; and
- the Notified Body, if it was involved in the CA procedure that had, as a result, non-compliant products.

The sanctions must be effective, proportionate and dissuasive, and can consist of warnings or legal proceedings. (European Commission, 2000). Available sanctions for non-compliance include forfeiture or destruction of the dangerous goods, court fines, administrative fines, and prison sentences (sought through the courts).

EU law recommends that market surveillance authorities seek voluntary withdraws and recalls by economic operators before similar enforcement action is ordered. If no result can be achieved, the MSA must restrict or prohibit the placing on the market of the product and, if necessary, ensure that it is also withdrawn from the market. The MSA must document the grounds for the corrective action and notify the manufacturer. Unless the product presents a serious and immediate danger, the manufacturer should have an opportunity to be consulted in advance of the corrective action.

RAPEX

When products are considered to present a serious risk, Member States must immediately inform the European Commission of the measures taken by using the RAPEX rapid information system (GRAS-RAPEX). RAPEX (formally, the Community Rapid Information System) is a European rapid alert system for dangerous non-food products. It allows market surveillance authorities and the European Commission to share information about dangerous products found on the European market quickly and efficiently, so that appropriate action can be taken everywhere in the EU. Thirty countries currently participate in the system (including all the EU countries and three EFTA/EEA countries: Iceland, Liechtenstein and Norway).

Each participating member designates a RAPEX Contact Point for communications and notifications. When the national authorities (or a producer/distributor) take measures which prevent or restrict the marketing or use of a product posing serious risks to the public interest, the RAPEX Contact Point submits details about the product to the European Commission by means of a standard notification form, including

- product identification (name, brand, model, description, picture);
- risks posed by the product (type of risk, results of laboratory tests and risk assessment);
- measures adopted to prevent risks (type of measure, scope, duration, date of entry into force); and
- distribution channels of the notified product (manufacturer, exporter, importer, distributors and countries of destination).

This process is called notification. The European Commission examines the information with regard to its compliance with EU law and the RAPEX guidelines, and checks its completeness. The result of this process is called "validation" (e.g., a notification is not validated if another country has already notified measures against the same product and same risk).

Once validated, the European Commission circulates the notification to the RAPEX Contact Points in all countries participating in the system. RAPEX Contact Points then forward this information to their competent national authorities, who check whether the notified product is present within their market and, if necessary, take appropriate action. The results of these market surveillance activities, including additional information relevant for other national authorities, are then reported back to the European Commission through the RAPEX system. These feedback messages are called "reactions". A reaction normally contains information about the presence of the notified product in other Member States and the measures taken.

Producers and distributors, if they become aware that a product is dangerous, are required under EU law to immediately inform the competent authorities in their country, clearly identifying the product in question, the risk(s) it poses, and the information necessary to trace it. They must also inform the authorities of any measures taken to prevent further risk to consumers. The information is then submitted to RAPEX via the RAPEX Contact Point (RAPEX, 2012).

RAPEX statistics from 2011 (the most recent annual data available) show a very uneven distribution of notifications among Member States. The Market Surveillance Package, when it is adopted by the European Parliament, will require Member States' participation.

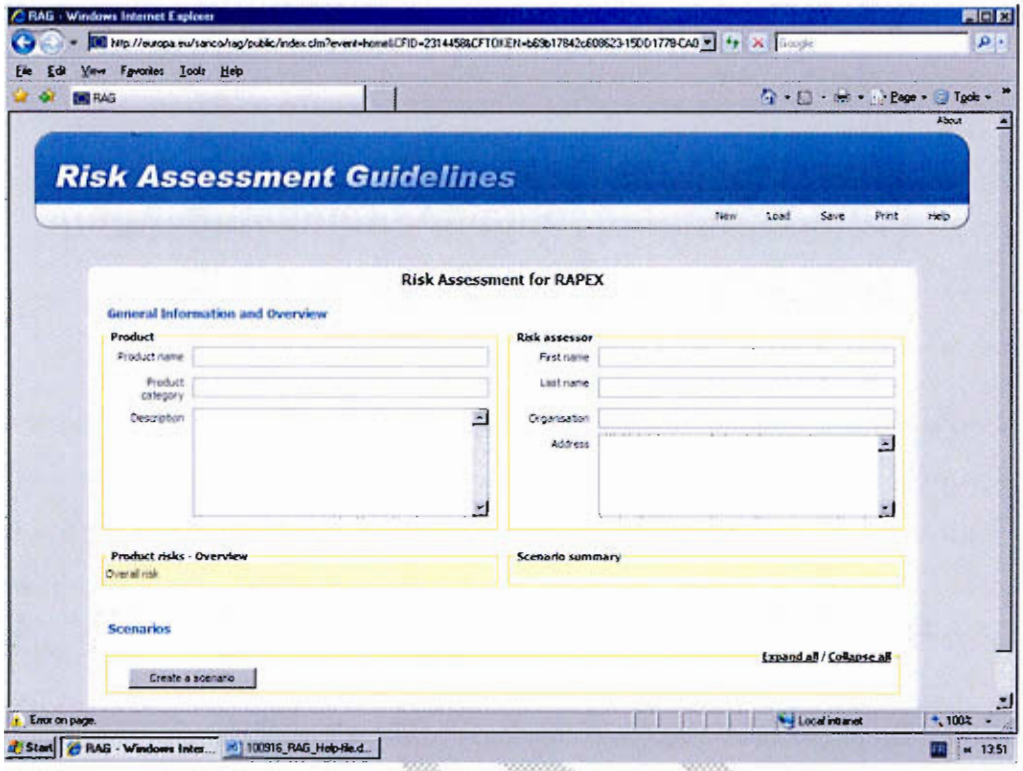
Risk Assessment

The European Commission has developed RAPEX risk assessment guidelines to help Member States identify the correct level of risk posed by specific products and to focus their notifications on those products posing the most serious risks. An online tool facilitates the preparation of risk assessments (see ***Exhibit 8***).[49] Details about the tool are provided in ***Appendix G***. The European Commission has also prepared guidelines for using the tool (European Commission, 2010d).

The RAPEX risk assessment method is increasingly being applied by market surveillance authorities in the EU. A recent Risk Assessment Task Force concluded that the RAPEX risk assessment methodology should be used for all non-food products, but recommended adding explicit references to the product essential requirements and to the relevant harmonized standards. The revised PPE Directive/Regulation is likely to incorporate RAPEX notification requirements (European Commission, 2012e).

[49] The tool is at http://europa.eu/sanco/rag.

Exhibit 8. Risk Assessment Guidelines



Safeguard Clause

The decision by a market surveillance authority to restrict or forbid the placing on the market of a CE marked product or to have a product withdrawn from the market usually invokes the safeguard clause procedure. The safeguard clause obliges all Member States to restrict or forbid the placing on the market of dangerous products, or to have them withdrawn from the market. The procedure is restricted to products that have been ascertained by the Member State to present a substantial risk. It is considered a last resort to prevent or remedy particular problems or threats.

Safeguard measures may be initiated by either European Commission independently or at the request of any Member State. The European Commission decides whether action is justified, and the measures to be taken, on a case-by-case basis following investigation and consultations with the market surveillance authorities and Member States (European Commission, 2013g).

Enforcement Indicators

Data on market surveillance activities at the EU level is somewhat limited. The mechanisms for sharing national level data with the European Commission consist of RAPEX notifications and "reactions," survey data, and Enforcement Indicators (BSI Development Solutions, 2011).

RAPEX publishes monthly and annual reports with statistics on the number and type of notifications received and the number of Member State "reactions" to the notifications. In its most recent annual report, in 2011, a total of 1,803 notifications were submitted through the RAPEX system.[50] The RAPEX statistics do not reflect all market surveillance corrective activities carried out in Member States (e.g., they do not cover products not sold outside of the Member State concerned).

Survey of Administrative Decisions Taken by Member States

The survey collects information on market surveillance including:

- Resources that assess Member States' enforcement capabilities such as:
  - the budget
  - the number of inspectors on enforcement activities
- Preventive and investigative activities such as:
  - the number of inspections
  - the number of laboratory tests
- Results of compliance checking such as:
  - the number of detected infringements and irregularities
  - the number of products identified as posing a serious risk
- Corrective measures such as:
  - product withdrawals from the market
  - product recalls from consumers
  - suspensions of products at the border (European Commission, 2013g)

In 2008 the European Commission established the annual Survey of Administrative Decisions Taken by Member States to collect more comprehensive information on enforcement and market surveillance activities. Member States provide data on market surveillance resources and results through an online questionnaire.

The European Commission also collects Enforcement Indicators from Member States. These include information on the number and type of measures national authorities in the EU take against products presenting a risk to health and safety of consumers. The accuracy and comparability of the information collected is limited because (a) not all measures taken by national authorities are required to be reported to the European Commission, (b) there is no reporting on the results of border controls, and (c) one measure can cover more than one product or one type of a product, so the number of products taken off the EU market is higher than the number of measures reported to the European Commission (European Commission, 2013g).

[50] Of those, 31 (2%) concerned PPE covered under general product safety legislation; the PPE Directive does not require RAPEX notifications.

Measures to encourage conformITY

Cooperation and exchange of information between authorities are key to the EU system of CA and market surveillance. A strong infrastructure is in place to foster these efforts, consisting primarily of independent organizations established to coordinate specific activities across Member States. The European Commission supports many of these organizations with funding for specific coordinating activities. In addition, the European Commission has invested significant resources to provide online coordinating and reporting mechanisms, enhance accountability through transparency, and promote high-quality and consistent CA and market surveillance systems through information campaigns, training, and practical guidelines.

Coordination Activities

CEN's Personal Protective Equipment (PPE) Sector Forum

The PPE Sector Forum coordinates European standardization in the PPE field. The forum is used to discuss horizontal issues for the benefit of all PPE standards. Members of the PPE Sector include the European Commission and EFTA, social partners,[51] PPE manufacturers associations,[52] and Notified Bodies for PPE.,

European Coordination of Notified Bodies in the Field of PPE

European Coordination of Notified Bodies in the Field of PPE, established in 1992, is an independent network of representatives from the Notified Bodies that meet on a regular basis to ensure that the standards and legislation are being applied uniformly across Europe (Brinks, 2012).[53] The organization provides a platform for discussing horizontal (general) as well as vertical (PPE-specific) topics, and for obtaining advice from other members, e.g., on the interpretation of type-examination procedures or quality control measures. It consists of a Horizontal Committee, an Ad Hoc Group, and several Vertical Groups. The organization receives funding from the European Commission and is supported by Decision

[51] These include European Association for the coordination of consumer representation in standardization (ANEC), the European Office of Craft, Trade and Small and Medium-sized Enterprises for Standardization (NORMAPME), the European Occupational Safety and Health Network (EUROSHNET), the Trade Union Technical Bureau (TUTB), and the Union of Industrial and Employers' Confederations of Europe (UNICE).

[52] European Safety Federation (ESF) and Federation of the European Sporting goods Industry (FESI)

[53] Council Decision 93/465/EEC contains a general obligation for Notified Bodies to participate, or ensure proper representation, in the co-ordination and co-operation activities of Notified Bodies at a European level.

768/2008/EC of the NLF, which encourages consistency in the application of the CA modules through coordination and cooperation mechanisms between Notified Bodies (Noetel, undated).

The organization's Technical Secretariat is responsible for coordinating the activities of the Committees and acts as the contact point for Notified Bodies for PPE in Europe. The Chairman of the Technical Secretariat represents the organization in relevant Working Groups of the Standing Committee at the EU Commission (e.g., the PPE Working Group, which functioned between 1995 and 2011), the PPE Administrative Cooperation (AdCo) group (a European group of experts for PPE market surveillance), and the PPE Sector Forum at the CEN (Finnish Institute of Occupational Health, 2010:14).

The Horizontal Committee of the organization is the forum in which representatives from the Notified Bodies, the Vertical Groups, and national coordination groups discuss general issues concerning the implementation of the PPE Directive's CA procedures and requirements. The Horizontal Committee has an Ad Hoc Group that deals specifically with issues concerning Article 11 of the PPE Directive (regarding product monitoring and quality system monitoring). To ensure transparency and allow for a full exchange of ideas among stakeholders, representatives from the EU Commission (DG Enterprise and DG Social Affairs), PPE AdCo, CEN/CENELEC, the EFTA secretariat, and European manufacturers' federations are invited to participate in the annual Horizontal Committee meetings as observers.

The organization's Vertical Groups discuss technical issues such as the testing and certification of individual types of PPE, the interpretation of standards, testing regulations used for certifying non-standardized products, etc. The Vertical Groups also organize round robin testing to ensure test results obtained by Notified Bodies are comparable (Finnish Institute of Occupational Health, 2010:16). The Vertical Groups meet at least once a year, depending on the priority of current issues. The Vertical Groups are listed in ***Exhibit 9.*** In addition to Notified Bodies, members of the Vertical Groups can include test houses which do not perform certification themselves and observers from different fields such as standardization or manufacturers' associations.

Recommendation for Use sheets (RfUs) summarize the discussion results of the committees and the recommended solutions to questions. RfUs can be issued by both Vertical and Horizontal Committees. Horizontal RfUs are submitted to the relevant Standing Committee of the EU Commission for

confirmation or approval. Vertical RfUs are confirmed by the Vertical Group and approved by the Horizontal Committee, then published on the European Commission's website.[54]

Some Member States require their Notified Bodies to be involved in these coordination activities and to participate in inter-laboratory testing to keep up their competence, but not all. As of 2010, only 50%–60% of the approximately 112 Notified Bodies in the PPE area attended the meetings or participated in the round robin testing.

Exhibit 9. Vertical Groups in the European Coordination of Notified Bodies

Vertical Group	PPE Type
1	Head Protection
2	Respiratory Protection
3	Eye and Face Protection
4	Hearing Protection
5	Protective Clothing, Hand and Arm Protection
7	Protective Clothing against Hand-held Chain Saws
8	Lifejackets
9	Protective Clothing for Motorcycle Riders
10	Foot and Leg Protection
11	Protection against Falls from a Height

Source: http://www.nbcoordinationppe.eu/home/

Administrative Cooperation Group for PPE (PPE AdCo)

PPE AdCo is an informal group of the national market surveillance authorities for the PPE sector.[55] It provides a forum for collaboration and exchange of information to encourage a consistent approach to surveillance activities, reduce the overlapping of national surveillance operations, diffuse good market surveillance practices and exchange views and solve practical problems. The European Commission is also represented in the group.

[54] Vertical RfUs are posted at http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/ppe-vertical-rfu_en.pdf. Horizontal RfUs are posted at http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/ppe_horizontal_rfu_en.pdf

[55] PPE AdCo is one of 20 AdCo groups in the EU. Each New Approach directive has an AdCo.

European Cooperation for Accreditation Committees

The EA's horizontal harmonization committee as well as its laboratory, certification and inspection committees work on furthering a common understanding of accreditation procedures and on supporting accreditation in the relevant regulated sectors (European Commission, 2013f).

Senior Officials Group—Market Surveillance Group (SOGS-MSG)

SOGS-MSG is an ad hoc group of Commission and Member States' experts that discusses market surveillance, accreditation and CA issues. It is a subgroup of the Senior Officials Group for Standardization and Conformity Assessment Policy (SOGS).

RAPEX Contact Points Groups

RAPEX Contact Points Groups include (a) at the EU level, the RAPEX Contact Points Network, a meeting forum involving the European Commission and persons responsible for managing RAPEX Contact Points in Member States which discusses and solves problems relating to notifications to RAPEX, (b) RAPEX Networks within Member States, (c) RAPEX Contact Points Working Groups, and (d) the European Commission's RAPEX Team.

European Commission's Expert Group on the Internal Market for Products

The European Commission's Expert Group on the Internal Market for Products is a forum for cooperation between the Member States' customs and market surveillance authorities.[56] The role of the group is to provide advice and expertise to the European Commission and its departments in relation to the preparation of legislative proposals and policy initiatives and the implementation of existing EU legislation, programs and policies, including coordination and cooperation with member countries and stakeholders in that regard. The first meeting took place on November 30, 2012 (http://ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2).

Measures to Promote Transparency

EC regulations include obligations for transparency of CA and market surveillance activities. Transparency puts pressure on less active Member States, and encourages them to think of the larger

[56] The application of the PPE Directive was until 2011 managed at a European level by a PPE Experts Working Group, chaired by the European Commission, and involving representatives of all stakeholders. Its purpose was to advise the Commission on any issue related to the transposition of Directive 89/686/EEC (PPE) and serve as a forum for collaboration and exchange of information. The PPE Experts Working Group no longer exists.

internal market rather than only their national market. The primary tools to encourage transparency are databases. In addition to RAPEX (described above), these include the following.

The NANDO Information System

Information about third party CA bodies is shared through the New Approach Notified and Designated Organizations (NANDO) Information System. The NANDO Information System is an online access point for regulatory information about all Notified Bodies that Member States have designated as responsible for carrying out conformity certification and assessment procedures for products marketed in the EU, and their respective competence areas.[57] The system includes information about certification bodies, inspection bodies, and test laboratories. It also includes CA bodies (CABs) from third countries authorized through Mutual Recognition Agreements to assess products for the EU market as well as "EU CABs," which are European bodies designated to conduct assessments on products to be placed on the market in specific third countries. In addition, the NANDO Information System provides a list of all national Accreditation Bodies, including contact information.

Information and Communication System for Pan-European Market Surveillance (*ICSMS*)

The European Commission maintains an online EU-wide database called the Internet-Supported Information and Communication System for Pan-European Market Surveillance (ICSMS).[58] The ICSMS includes information on general issues relating to market surveillance activities and information on products presenting a risk, test results, provisional measures, and contacts with economic operators. All Member States are required to use the ICSMS.[59]

The ICSMS allows quick and efficient sharing of test results, product identification data, photographs, economic operator information, risk assessments including hazard data, accident information, and measures taken by surveillance authorities. It consists of an internal and a public area. The internal area is for the use of market surveillance authorities, customs authorities and EU officials.

ICSMS gathers test results on more than 47,500 products and lists more than 650 authorities in all EU and EFTA countries, and covers more than 45 EU directives (including the PPE Directive). The number of

[57] Available at http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=search.main
[58] The ICSMS web portal is at:
https://www.icsms.org/icsms/App/blankPublic.jsp?threadId=7418&callId=4&winId=1
[59] This obligation was set forth in Regulation (EC) 765/2008. Originally an independent database with only a subset of European states participating, the ICSMS was acquired by European Commission's Directorate General for Enterprise and Industry in 2011 and has expanded to include all EU Member States.

user accounts is 3,600. The database is searchable by, for example, individual products, test results, entire product groups (e.g., PPE), manufacturers, importers, dealers, and results for products from specific countries. Information can be obtained for products coming under specific directives, safeguard clause notifications, RAPEX notifications. Data confidentiality is protected by a system of access authorizations. Market surveillance authorities can add data about products not yet in the database or add comments to an already existing product information file, i.e., feedback about the activities of market surveillance authorities with regard to investigated products.

A recent European Commission study found that the exchange of information on test results and investigations help market surveillance authorities in the following ways:

- **Prompt intervention:** Information on unsafe products can be announced immediately and immediate measures may be taken.
- **Deterrence:** "Black sheep" among manufacturers can be detected earlier and punished more effectively
- **Avoiding duplication of work:** Test results by one surveillance authority are immediately made available to all other Member States.
- **Surveillance data:** Statistics can easily be generated by sector, product, etc.

In addition, the ICSMS provides a platform for implementing the European market surveillance policy by creating the basis for coordinating wide-scale market interventions against suspicious products, identifying best practices, exchanging general knowledge and experience, and creating a common approach to market surveillance (European Commission, 2013f). Discussions are currently underway regarding the exchange of information between the RAPEX and ICSMS systems (European Commission, 2012h).

Information/Training, Capacity Building

CE Marking information Campaign

To support CA and market surveillance, the European Commission conducted an information campaign during 2010-2012 about the CE marking and its requirements. The target audience included manufacturers, importers, distributors, professional associations, specialized press, and consumers. The campaign involved the creation oft included a dedicated website on CE marking, with step by-step instructions for manufacturers, by product type; a series of educational seminars and informational booths at trade shows; and leaflets, brochures, factsheets, videos, and articles in specialized

publications (European Commission, 2013j). The European Commission also developed a set of guidelines for legislators and Notified Bodies on selecting CA modules and performing CA.

Product Safety Enforcement Forum of Europe (PROSAFE)

PROSAFE is an independent organization of Europe market surveillance officials that supports a wide range of initiatives (http://www.prosafe.org/). Through PROSAFE, for example, market surveillance authorities participate the EMARS ("Enhancing market surveillance through best practice") project, which is financed by the European Commission. PROSAFE manages the project on behalf of the participating Member States. EMARS aims to ensure a basic level of expertise and practical experience in the market surveillance organizations. Through collaborative work groups of Member States organizations EMARs disseminates best practices, plans and manages joint surveillance actions and other activities, provides training in risk assessment and market surveillance, and develops guidelines.

Between 2007 and 2012, Joint Market Surveillance (or Enforcement) Activities targeted 17 different product groups had taken place (none have focused on PPE to date). All 27 EU Member States and 2 EFTA Member States have participated in at least one of these Joint Actions. They involve administrative and surveillance cooperation between the authorities of several Member States and EFTA/EEA countries and typically focus on product testing, risk assessment, market monitoring, and the exchange of expertise and best practices related to market surveillance. The European Commission has supported a number such actions.

Through PROSAFE, market surveillance authorities also participate in the Rapid Advice Forum. The goal of the forum is to provide a rapid and informal first assessment and feedback from fellow surveillance officers (from other Member States). The Rapid Advice Forum has been operational since the spring of 2007. Through the forum, member states and the European Commission receive informal advice on a range of market surveillance related issues including procedures, risk assessment, applicable legislation and interpretation, practical experience. The advice is given on an individual basis by fellow market surveillance officers. It is not intended to represent a national position and the recipient of the advice is in no way bound to follow it. PROSAFE says the exchange of experience helps promote a harmonized approach across different member states to the same issues.

RAPEX

The European Commission has facilitated the participation of Member States in RAPEX by publication RAPEX guidelines, developing the risk assessment application and online tool, and organizing several

RAPEX seminars. Participation in RAPEX varies across Member States. Barriers to participation involve the way in which the national market surveillance networks are organized, the size (and resources) of the countries, and production and market structures.

Conclusion

The European Union's model of CA has a number of distinct features. The approach has evolved from a system of detailed technical product standards to one that allows manufacturers to select the methods used to fulfill the basic health and safety requirements established in the PPE Directive. Economic operators tend to use standards developed by independent, European standard-setting organizations for this purpose. Those organizations work closely with the EU Member States to develop standards that fulfill the requirements while also attending to international requirements (they do this through, for example, their development of standards in parallel with the ISO).

CA procedures are defined in the PPE Directive and are based on risk. They are likely to be further clarified in the forthcoming revised PPE Directive.

CA is also based on the principle of shared responsibility. Roles and responsibilities have been established for economic operators, third-party assessment bodies, Member States, the EU (including customs authorities), and non-governmental organizations. A key to the operation of pre-market compliance assessment in the EU appears to be the existence of a strong network of organizations, both public and private, to foster exchange of information, collaboration, and transparency. This builds organizational capacity, especially of those with less experience of robust compliance assessment systems, while also providing mechanisms for organizational peer pressure.

Market surveillance programs in the EU are the responsibility of the Member States and until recently, there was very little structure at the EU level to encourage consistent practices. This issue has been a major focus of the European Commission in recent years, and provides valuable insights into the elements needed for effective market surveillance. These include[60]

- adequate resources, including dedicated sampling and testing budgets and the ability to carry over funds to provide for strategic reserves in the event of emergency situations
- defined qualifications and educational resources for market surveillance inspectors
- a set clear and measurable overall performance targets and an ability to accurately monitor both individual inspectors' and the MSA's performance
- access to detailed and accurate information regarding the status of the economic operators that deal in the product sectors for which it is legal responsible. The required information includes a) location and contact details; b) category of products supplied; c) position in supply chain; d) type and effectiveness of management & quality systems; and e) previous inspection and compliant history.

[60] These elements were identified in BSI Development Solutions, 2011.

- documented inspection rules, inspection procedures, quality management systems. These should include collaboration with customs authorities at ports/airports/borders and inspections of importers, distributor, mainstream retail outlets. Close working with Customs Authorities is an integral part of market surveillance.
- documented sampling methodology to structure sample planning and documented sampling procedures for inspectors to follow
- enforcement actions that are proportionate to the risk presented by the unsafe product. A full range of enforcement powers should be made available in order to be able to select an appropriate and proportionate response to each instance of non-compliant or dangerous product.
- In addition, the overall performance of CA and market surveillance systems need to be regularly monitored to determine if they are effective and to identify improvements. This allows MSAs to better target scarce results to produce better results.

  Regarding market surveillance, for example, high quality data should be collected on the MSA's resources (budget, number of inspectors), territory (geographic size, number of high/medium/low risk premises) and activities (numbers of inspection visits, samples taken, products tested, and enforcement actions). Interactions with consumers and manufacturers should also be tracked (e.g., number of enquiries & complaints, level of advice and information services provided).

As a benchmarking target, the EU offers a rich and evolving prototype of CA and market surveillance. The challenges EU officials have faced in building an effective system that removes internal barriers to trade are particularly instructive. Through the recent and ongoing changes, many of the prerequisites of an effective system are in place or are emerging. They highlight the kinds of resources, procedures, and systems that may be needed in any CA system. The evolution of the EU system also highlights the value of shared responsibilities and a collaborative public-private network of organizations and online information systems that foster communication, problem identification, opportunities to build from lessons learned, informal technical assistance, and capacity building.

Appendix E: Terminology

PCAWG List of Important Terms

TERM	*Definition/Description*	*Reference/Source*
Accreditation	Third-party attestation that a body demonstrates its competence to carry out specific tasks. These tasks include: sampling and testing, inspection, certification and registration. All bodies issuing *certificates of conformance shall be accredited.*	BS EN ISO/IEC 17000:2004 / (5.6) * See footnote
Accreditation body	Authoritative body that performs accreditation	BS EN ISO/IEC 17000:2004 / (2.6)
Approval	Permission for a product or process to be marketed or used for stated purposes or under stated conditions	BS EN ISO/IEC 17000:2004 / (7.1)
Attestation	Issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated	BS EN ISO/IEC 17000:2004 / (5.2)
Certificates or marks of conformity (certification marks)	Protected mark, applied or issued under the rules of a certification system, indicating that confidence is provided that the relevant product, process or service is in conformity with a specific standard or other normative document.	NISTIR 6014 ISO/IEC Guide 2
Certification	A procedure used to provide written assurance that a product, process, service, or person's qualifications conforms to specified requirements.	* See footnote
Certification scheme	Certification system related to specified products, to which the same specified requirements, specific rules and procedures apply	ISO/IEC CD 17067
Certification scheme owner	Person or organization that is responsible for developing and maintaining a specific certification scheme	ISO/IEC CD 17067
Conformance	PPE that meets the requirements of a standard when manufactured and set into commerce	*PCAWG Defined*
Conformity assessment	*Act of* determining directly or indirectly that requirements are fulfilled.	* See footnote
Conformity assessment body	Body that performs conformity assessment services	BS EN ISO/IEC 17000:2004 / (2.5)
Declaration	First-party attestation	BS EN ISO/IEC 17000:2004 / (5.4)

Distributor	See "responsible party"	
Environmental conditions	Wear; degradation from non-ionizing radiation (light), chemicals, temperature or humidity	*PCAWG defined*
Failure	PPE that, in use, does not provide protection to the wearer because of non-conformance.	*PCAWG defined*
First party	See "responsible party"	PCAWG defined
Hazard	A potential source of physical injury or damage to health.	ISO/WD 10218-1(2001)
Hazard Identification	Process of recognizing that a hazard exists and defining its characteristics.	OSHAS 18001 (1999), OSHAS 18002 (2000)
Incorrect use	Modifications; improper care or maintenance; use for unintended purposes or hazards of a severity beyond that for which the PPE was intended to provide protection	*PCAWG defined*
Inspection	Evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging of the conformity of a product, process or service to specified requirements	* See footnote
Manufacturer	See "responsible party"	
Non-conformance	PPE that does not meet the requirements of a standard when manufactured and set into commerce	*PCAWG defined*
Probability	Extent to which an event is likely to occur	ISO Guide 73 (2001)(DRAFT)
Regulations	Mandatory technical specifications, which may include particular standards or conformity assessment procedures	ANSI Overview of the U.S. Standardization and Conformity Assessment System
Responsible party	Party who purports the product to be compliant and has the authority to control the conformance of that product (could be a manufacturer, supplier or distributor)	*PCAWG defined*
Revocation	Cancellation of the statement of conformity	*PCAWG defined*
Risk	*Measure* of the probability and the severity of *adverse effects that result from expasure to a hazard*	ANSI/AAMI/ISO 14971:2000; ANSI B11TR3-2000; ANSI RIAR15.06-1999; ISO/FDIS 121000-1:2002(E); ISO/IEC Guide 51 (1999); Norsok Standard (Z-013) *modifications from NFPA provided in italics*
Risk analysis	Systematic use of available information to identify hazards and to estimate the risk	ANSI/AAMI/ISO 14971:2000

Risk assessment	Overall process comprising a risk analysis and risk evaluation.	ANSI/AAMI/ISO 14971:2000; ISO/FDIS 121000-1:2002 (E); ISO Guide 73 (2001)(DRAFT); ISO/IEC Guide 51 (1999); Norsok Standard (Z-013)
Risk evaluation	The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria	CB018-1999 based on AS/NSZ 4360-1999
Risk management	Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, and controlling risk.	ANSI/AAMI/ISO 14971:2000
Risk reduction	Actions taken to lessen the probability, negative consequences, or both, associated with a particular risk	ISO Guide 73 (2001) (DRAFT)
Second party	Purchaser or user	ISO/IEC 17000
Severity	The extent of potential credible harm	SEMI S10-1103
Standards	Market-driven product and service specifications (e.g., technical requirements, management systems)	ANSI Overview of the U.S. Standardization and Conformity Assessment System
Supplier	See "responsible party"	
Supplier's declaration	Procedure by which a first party or supplier conveys assurance that the object of conformity fulfills specified requirements	National Conformity Assessment Principles for the United States (2007)
Surveillance	Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity	BS EN ISO/IEC 17000:2004 / (6.1)
Third party	An independent entity that has no interest in transactions between the 1st and 2nd parties	ISO/IEC 17000
Type test	A test carried out on samples that represent production for the purpose of determining conformity	ISO/IEC 17000
Unilateral arrangement	arrangement whereby one party recognizes or accepts the conformity assessment results of another party	BS EN ISO/IEC 17000:2004 / (7.7)

PCAWG List of Terms Which May be Referenced

TERM	*Definition/Description*	*Reference/Source*
Acceptable risk	The outcome of a decision process of determining an acceptable option. The choice of an option (and its associated risks, costs and benefits) depends on the set of options, impacts, values and facts examined in the decision-making process	(Fischhoff et al., 1982), Policy Sciences 17 (1984) 123-139 / Elsevier Science Publishers B.V., Amsterdam
Acceptance / acceptance of conformity assessment results	Use of a conformity assessment result provided by another person or body.	BS EN ISO/IEC 17000:2004 / (7.6)
Appeal	Request by the provider of the object of conformity assessment to the conformity assessment body or accreditation body for reconsideration by that body of a decision it has made relating to that object	BS EN ISO/IEC 17000:2004 / (6.4)
Audit	Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled	BS EN ISO/IEC 17000:2004 / (4.4)
Conformity Assessment	Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (This may include any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.)	National Conformity Assessment Principles for the United States (2007)
Conformity Assessment	Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled	BS EN ISO/IEC 17000:2004 / (2.1)
Likelihood	A qualitative description of probability or frequency	CB018-1999 based on AS/NSZ 4360-1999; HB 203-2000, based on AS/NSZ 4360-1999
Multilateral arrangement	Arrangement whereby more than two parties recognize or accept one another's conformity assessment results	BS EN ISO/IEC 17000:2004 / (7.9)

Office of Management and Budget (OMB) Circular A-119, revised February 19, 1998	Directs the Secretary of Commerce to issue guidance to the agencies to ensure effective coordination of federal conformity assessment activities	NIST 15 CFR Part 287
Product	Result of a process	BS EN ISO/IEC 17000:2004 / (3.3)
Reciprocity	Relationship between two parties where both have the same rights and obligations towards each other	BS EN ISO/IEC 17000:2004 / (7.11)
Residual risk	The risk that remains after safeguarding measures have been taken.	ANSI RIAR15.06-1999
Risk	Combination of the probability of an occurrence of harm and the severity of that harm	ANSI/AAMI/ISO 14971:2000; ANSI B11TR3-2000; ANSI RIAR15.06-1999; ISO/FDIS 121000-1:2002(E); ISO/IEC Guide 51 (1999); Norsok Standard (Z-013)
Risk	Combination of the likelihood and consequence(s) of specified hazardous event occurring.	OSHAS 18001 (1999), OSHAS 18002 (2000)
Risk estimation	Procedure used to assign values to the probability and consequences of a risk	ISO Guide 73 (2001) (DRAFT)
Sampling	The selection of one or more specimens of a product, process or service for the purpose of evaluating the conformity of the product, process or service to specified requirements	* See footnote
Standardspanels	ANSI Standards Panels are cross-sector coordinating bodies established to promote the development and compatibility of voluntary consensus standards and conformity assessment programs necessary to support national and global priorities.	ANSI Overview of the U.S. Standardization and Conformity Assessment System
Testing	Determination of one or more characteristics of an object of conformity assessment, according to a procedure	BS EN ISO/IEC 17000:2004 / (4.2)
The National Technology Transfer and Advancement Act (NTAA)	In February 1996, the NTAA of 1995 was enacted by Congress. Section 12 of the Act directed NIST to coordinate conformity assessment activities of federal, state and local entities with private sector technical standards activities and conformity assessment activities with the goal of eliminating any	NIST 1S CFR Part 287

unnecessary duplication of conformity assessment activities.

Appendix F: PCAWG List of Participants

#	POC Name	Organization	PCAWG Role
		NIOSH NPPTL Members	
1	Berry Ann, Roland	NIOSH/NPPTL/OD	Compliance and Enforcement Lead, PCAWG Oversight, NPPTL Deputy Director
2	Book, David	NIOSH/NPPTL/SCSST	Products and Standards Sub-group Chair
3	Coffey, Chris	NIOSH/NPPTL/OD	Surveillance Data Sub-group Chair
4	Coyne, Judi	NIOSH/NPPTL/SCSST	Prioritization team / Surveillance and Outreach
5	D'Alessandro, Maryann	NIOSH/NPPTL/OD	PCAWG Chair and oversight / Terminology Sub-group Co Chair / Enforcement and Compliance Group Chair
6	Krah, Jackie	NIOSH/NPPTL/SCSST	Prioritization team / Surveillance and Outreach
7	Newcomb, Bill	NPPTL PSD	Terminology Sub-group Co Chair
8	Sporrer, John	NIOSH/NPPTL/OD	Public Health Analyst and Logistical Coordinator / Terminology Sub-group Co Chair
9	Szalajda, Jon	NIOSH/NPPTL/PSD	Risk Sub-group Chair
		PCAWG External Members	
10	Carnahan, Lisa J.	National Institute of Standards and Technology (NIST) 100 Bureau Drive, Stop 2100 Gaithersburg, MD 20899-2100	
11	Corrado, Steven D.	Principal Engineer – Personal Protective Equipment Underwriters Laboratories 12 Laboratory Drive Research Triangle Park, NC 27709-3995	SME on PPE testing and certification
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13	Duffy, Richard M.	Assistant to the General President International Association of Fire Fighters (IAFF) 1750 New York Ave NW Ste 300 Washington, DC 20006-5395	Surveillance Data Sub-group
14	Fiers, Rudy	Senior Safety Specialist Occupational Safety and Health Administration (OSHA)	OSHA SME on PPE compliance and enforcement
15	Gillerman, Gordon	Director, Standards Services National Institute of Standards and Technology (NIST) 100 Bureau Drive, Stop 2100 Gaithersburg, MD 20899-2100	Terminology Sub-group
16	Gleason, Patricia A.	President of the Safety Equipment Institute (SEI), 1307 Dolley Madison Blvd. Suite 3A McLean, VA 22101	Terminology Sub-group / Enforcement and Compliance Group
17	Gulledge, Beverly	Regulation & Certification Manager Scott Safety 4320 Goldmine Road PO Box 569 Monroe, NC 28110	
18	Hamilton, Bill	OSHA - Standards and Guidance 200 Constitution Ave, N.W. Room N3609 Washington, DC 20210	Products and Standards Sub-group / Enforcement and Compliance Group
19	Johnson, James S. Ph.D., CIH, QEP	JSJ and Associates 7867 Cypress Creek Court Pleasanton, CA 94588	Products and Standards Sub-group
20	Kline, Joann M. JD	Regulatory Technical Leader Kimberly-Clark Professional 5801 Safety Drive N.E. Belmont, MI 49306-8832	Terminology Sub-group / Risk Sub-group / Enforcement and Compliance Group
21	Kojola, William	Department of Occupational Safety & Health AFL-CIO 815 16th Street, NW Washington, DC 20006-4101	Risk Sub-group

22	Lovasic, Susan L.	Principal Investigator DuPont Protection Technologies	Products and Standards Sub-group
23	Love, Michael D.	President Gateway Safety Inc. 11111 Memphis Avenue Cleveland, OH 44011	Enforcement and Compliance Group
24	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 11 S. Paca St. 2nd Fl Baltimore, MD 21201	Enforcement and Compliance Group
25	Pfriem, Dale B.	ICS Laboratories, Inc. 1072 Industrial Parkway North, Brunswick, Ohio 44212 - U.S.A.	
26	Platner, James (Jim) W.	Assoc. Director/ToxicologistCPWR: The Center for Construction Research and Training 8484 Georgia Ave, Ste 1000Silver Springs, MD 20910-5618	Products and Standards Sub-group / Risk Sub-group
27	Rodríguez, Jr, J.A. CSP, SGE	Senior Manager, Environmental, Health & Safety Raytheon Technical Services Company LLC 22265 Pacific Boulevard Dulles, Virginia 20166	Surveillance Data Sub-group
28	Seitz, Teresa A.	NIOSH DSHEFS	Surveillance Data Sub-group
29	Shaw, Dr. Anugrah	Professor, Human Ecology / Operations Richard A. Henson Center 2113 University of Maryland – Eastern Shore Princess Anne, MD 21853	Products and Standards Sub-group
30	Shipp, Daniel K.	President International Safety Equipment Association 1901 N. Moore St. Arlington, VA 22209	Products and Standards Sub-group / Enforcement and Compliance Group
31	Stull, Jeffrey O.	International Personnel Protection, Inc. Correspondence: P. O. Box 92493, Austin, TX 78709-2493 Shipping: 7809 Adelaide Drive, Austin, TX 78739	Products and Standards Sub-group / Risk Sub-group
32	Weber, Bob	Manager of Quality, Regulatory Affairs and Technical Services 3M Occup Health & Env Safety 3M Company 3M Center, Building 235-2E-91 St. Paul, MN 55144-1000	Surveillance Data Sub-group / Risk Sub-group
33	Zeigler, James P.	J.P. Zeigler Co., LLC 5130 Keitts Corner Road Mechanicsville, VA 23111-6471	Risk Sub-group
NIOSH NPPTL Consultants (will participate on an as needed basis)			
34	Beamer, Bryan Robert PhD, PE, CSP	University of Wisconsin	Risk Sub-group
35	Haskell, Bill	NIOSH/NPPTL/PSD	Products and Standards Sub-group
36	Landsittel, Doug	Statistical Consultant, University of Pittsburgh	Surveillance Data Sub-group / Risk Sub-group
37	Metzler, Rich	NIOSH/NPPTL/OD	PPE SME consultant on all working groups
38	Oke, Charles	NIOSH/NPPTL/SCSST	Surveillance Data Sub-group
39	Parker, Jay	NIOSH/NPPTL/TEB	Enforcement and Compliance Group
40	Perrotte, John	NIOSH/NPPTL/SCSST	SCSST member leading effort to develop the strategy for the Products and Standards Database
41	Peterson, Kristina	RTI	Enforcement and Compliance Group
42	Rethi, Lynn	Consultant	
43	Shaffer, Ron	NIOSH/NPPTL/TRB	Surveillance Data Sub-group