Millions of workers in worksites across the United States rely on personal protective technologies (PPT) to guard them against injury, illness, or death. Construction workers on high-rise buildings need to be confident that their safety harnesses will arrest a fall, firefighters need to know that their gloves and protective turnout gear can withstand high temperatures, and healthcare workers administering highly toxic chemotherapy agents need to know that their gloves will withstand penetration. The term PPT encompasses a wide range of specialized clothing and equipment including respirators, gloves, hearing protection, fall arrest harnesses, and eye protection.

To ensure that PPT will perform as intended, government agencies, manufacturers, purchasers, testing laboratories, certifying organizations, workers, and other stakeholders participate in an array of activities that are referred to collectively as conformity assessment. Conformity assessment processes include testing to ensure that the product meets specific design or performance criteria, examining the test results to declare conformity to the specifications, inspecting manufacturing sites, and conducting post-market evaluations. Currently, the nature and rigor of the conformity assessment processes that PPT products are required to meet in the United States vary widely.

The National Institute for Occupational Safety and Health (NIOSH) asked the Institute of Medicine (IOM) to convene an expert committee to study conformity assessment of personal protective technologies other than respirators. (Respirators were excluded because processes to assess their performance are already covered under a variety of federal regulations and certification processes.) The committee was asked to examine the various approaches currently used to certify the effectiveness of PPT used by workers, to review the
implementing conformity assessment processes.

- Adequate standards for product performance, use, and testing need to be clearly specified and serve as a precursor to conformity assessment.

- The burden and cost of conformity assessment processes need to be considered.

- A total lifecycle approach is needed that includes postmarketing testing, evaluation, and surveillance, as well as an effective recall system.

- The conformity assessment process should promote and not inhibit innovation.

The report recommends that the National Personal Protective Technology Laboratory (NPPTL), which is part of NIOSH, work with other relevant government agencies, certifying and accrediting organizations, manufacturers, and end users to develop, implement, and support conformity assessment processes for PPT used in specific applications. The framework should be based, in large measure, on the degree of risk to the safety and health of the user.

In this type of tiered framework, risks would be rated as high, medium, or low, with each category requiring different levels of conformity assessment. When risks are low, manufacturers would only need to attest that their products meet certain standards recognized by the federal government. When risks are determined to be “medium,” products would need to be tested and assessed by an independent testing laboratory and certifying organization. Federal agencies would specify the required standards and require third-party testing and declaration of product conformity by accredited entities. When risks are high, third-party testing and certification would be required, coupled with government involvement to provide oversight and assist in enforcement. In such cases, the process would include the specification of design and performance standards,
periodic unannounced inspection of production facilities, evaluation of quality control techniques and standards in the manufacturing plants, product audits, and postmarketing surveillance.

The IOM report calls on the NPPTL to work with other relevant federal agencies, manufacturers, organizations, and end users to identify gaps and priorities in conformity assessment, especially for medium- and high-risk PPT use, and to engage in developing and implementing processes to improve assessments. In addition, to help foster adoption of improved PPT, government contracts should specify that PPT must meet the requisite level of conformity assessment based on the comprehensive risk-based PPT framework.

**Improve Research and Communication**

The fragmented nature of current PPT conformity assessment has resulted in multiple and diverse sources of information that employers, workers, and others need to consult in order to identify effective equipment or find independent information on PPT. The NPPTL currently maintains a Certified Equipment List that details the respirators and respirator components the agency has determined to be effective. The committee recommends that NPPTL expand its efforts to become a national clearinghouse for information on all types of PPT. NPPTL should continue its involvement in standards-setting processes and committees and should facilitate the participation of end users in voluntary, performance-based standards. NPPTL also should expand its research efforts on non-respirator PPT (based on risk assessment and opportunities) to help establish standards and develop test methods, and NPPTL should maintain a website resource that provides access to listings of all non-respirator PPT products that meet third-party conformity assessment requirements.

**Expand Surveillance**

Surveillance data on PPT use in the workplace are limited, including data on the extent and nature of PPT use. Without these types of data, there are no drivers to draw attention to PPT performance, use, failures, and interface problems that could be harming workers. As another step to help bridge the current information gap, the committee recommends that NIOSH work with other relevant government agencies to establish an electronic PPT and Occupational Safety and Health Surveillance System that includes data on PPT product effectiveness in the workplace. The new surveillance system would collect data from across the lifecycle of PPT products used in the workplace, from production to worker use and maintenance. The data would cover, among other things, failures of PPT and adverse outcomes such as injury, illness, and death that may occur while workers are wearing personal protective equipment or devices.
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Conclusion

To ensure that workers are using PPT that meets required standards, PPT products need to be consistently assessed with products used in high-risk workplaces undergoing rigorous testing and certification processes.

What will it take to make the recommended changes happen? Significant input will be needed from end users. Professional organizations specific to various occupations can reinforce the requisite conformity assessment processes. Adequate resources and staffing will be required of government agencies, labor and manufacturing organizations, standards-setting organizations, third-party testing laboratories, and others. Regulatory requirements for third-party testing and certification, where applicable, will provide the impetus for change that will result in a more consistent, comprehensive risk-based approach to PPT conformity assessment. The goal is ensuring and maintaining a safe and healthy workforce. ☞