Miller, Diane M. (CDC/NIOSH/EID)

From: Intlperpro@aol.com
Sent: Friday, July 01, 2011 5:04 PM
To: NIOSH Docket Office (CDC)
Subject: 237 - PPT Conformity Assessment
Attachments: IntlPerPro_Response_NIOSH-237.pdf

Dear Sir or Madam:

Please find our response to subject docket.

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International Personnel
Protection, Inc.

July 1, 2011

NIOSH Docket Office
Robert A. Taft Laboratories
MS–C34
4676 Columbia Parkway
Cincinnati, OH 45226

Subject: Response of International Personnel Protection, Inc. to Docket Number NIOSH–237, Strategy to Address Recommendations Issued by the Institute of Medicine in November 2010 Report

International Personnel Protection, Inc. is a company that provides research, testing, and expertise to the personal protective equipment industry. We have been in business since 1993 and have provided services to a wide range of the PPE industry in different end user market segments. Our company was an external reviewer of the Institute of Occupational Medicine (IOM) report, "Certifying Personal Protective Technologies: Improving Worker Safety," for which we had multiple criticisms (see attached letter). We note with dismay the fact that these criticisms were not addressed as part of the report that was ultimately issued and referenced in this docket. We are further disappointed that IOM as an organization that prides itself on the precept of academic excellence chose to forego a complete peer review process for its review of invited external review comments by our company and other organizations without the benefit of any response whatsoever.

Based on the shortcomings expressed in our comments to IOM and other criticisms, it is our view that a new peer review panel be established independent of the IOM for examining the issues related to conformity assessment of PPE. The IOM report recommends that NIOSH NPPTL develop and implement a risk-based conformity assessment for personal protective technologies. We do not see that NIOSH has the legislative authority to carry out this recommendation, but more importantly, we do not believe that NPPTL has either the expertise or resources for the execution of this task. NIOSH does have legislative authority to set requirements for and control the conformity assessment (certification) of respirators. But even that process falls short in several different ways: (1) the government rule making process cannot keep up with industry demands for appropriate respiratory protection; (2) the respirator certification program cannot pay for itself (this fact was correctly stated in the IOM report); and (3) the government's own certification program fails to meet many of the basic requirements that private certification organizations are mandated to meet.

Jeffrey O. Stull, President and Grace G. Stull, Vice President

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It is foolhardy for the industry to rely on government rulemaking for standards that apply to PPE. While the rulemaking process is open and subject to public review, it is not practical and it often is not responsive. It is relatively difficult for the full range of stakeholders to participate effectively in this process. Because of these reasons, the U.S. Government through its Office of Management and Budget Circular No. A-119 looks to established and accredited standards development bodies for the development of credible, up-to-date standards. As a case in point, consider the inadequacies of NIOSH regulations in 42 CFR Part 84, Subpart H for self-contained breathing apparatus. These regulations are woefully inadequate for establishing the needed protection of firefighters during emergency and in fact, the National Fire Protection Association (NFPA) has undertaken through its open and transparent standards development process the establishment of NFPA 1981, *Standard on Open-Circuit Self-Contained Breathing Apparatus for Fire and Emergencies Services*, to provide the additional design, performance, labeling, and certification criteria that ensures appropriate levels of immediately dangerous to life and health respiratory protection for emergency responders that is not possible through the government regulations. There are other examples, where standards pertaining to respiratory protection had to be developed to fill "gaps" and inadequacies of the Federal program for respirator certification.

Costs for respirator certification are set by the Federal regulations in 42 CFR Part 84, which as expected cannot be updated in a timely fashion, and consequently fall well short of the actual costs incurred for the program. As result, a significant portion of the NPPTL budget must make up this shortfall.

There are multitude of different standards that are applied to the organizations and laboratories that engage in third-party certification. These include such standards and guides as: ISO 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies*, ISO 17025, *General requirements for the competence of testing and calibration laboratories*, and ISO Guide 65, *General requirements for bodies operating product certification systems.* To the best of our knowledge, the NIOSH NPPTL facilities do not conform with these standards or guides. Further, they are not subject to independent accreditation or auditing as is often applied to organizations that engage in testing.

It is for these reasons, that we recommend that NIOSH get out of the certification testing business altogether. We believe that the testing of respirators could be privatized at a savings to the government, particularly during these times of ramping Federal budget deficits. Instead of being engaged in testing a very small segment of the PPE industry products, it is our recommendation that the role of NIOSH be one of supervising, auditing, and enforcing the certification of PPE products that does take place, which is a role that is currently lacking throughout much of the PPE industry. The problem is not so much in the fact that products are incorrectly certified, but rather when manufacturers choose not to certify to standards that exist for specific industries or make false claims. Even when there are relatively robust certification requirements as exist for the NFPA product standards related to PPE, these standards run afoul from abuse from both manufacturers and end user organizations, which choose not to comply. The certification organizations are not empowered to do anything but to protect abuses or misuses of their "mark." This does industry little good because there is no entity that is policing the industry to responding to problems for misrepresented or misused products.

The individual industries reliant on PPE have responded over the years through the development of standards and associated conformity assessment practices through the historical feedback of the individual stakeholder interests in those industries. Labor unions, such as the International Association of Fire Fighters (IAFF), and trade associations, such as the International Safety Equipment Association (ISEA), have endeavored to work with standards development bodies to put practical, up-to-date standards in place, and address certification demands in a manner commensurate to the risks involved. The IOM has failed in their analysis to consider the vast range of protective clothing and equipment used by several industries and instead focused on a limited number of market segments for basing its conclusions, which formed the recommendations provided in their report, including the subject of this particular docket. No specific instances of harm to workers have been documented to establish the need for the length and costly study that the IOM suggests that NPPTL undertake. NPPTL has neither the expertise nor resources to carry out this work. It is as if the IOM has a forgone solution to a problem, which may or may not exist, and even if it does exist to some extent, it is certainly not as universal as claimed.

It is instructive to point out that IOM study of conformity assessment practices involved a number of government-based process, including the NIOSH certification of respirators, the FDA regulation of medical devices, the Coast Guard oversight of personal flotation device testing, and the National Institute of Justice coordinated program for certifying ballistic devices. The problem with relying on the review of these conformity assessment programs is that IOM saw only a microcosm of the overall PPE industry. Moreover, the above programs represent product areas where stakeholders, regardless of how it is represented, have a limited opportunity for involvement in how the standards are structured and how conformity assessment is addressed. It is our strong opinion that the use of such programs is counter to the notion that the government should not be creating product standards or certification processes as inappropriate deemed by the IOM study. Instead, a better role would be to oversee certification processes and provide assistance to the respective government agencies for better enforcement of industry for complying with existing standards utilizing the different conformity assessment practices that have been set by industry.

We recommend that NIOSH NPPTL consider the following alternative steps to address conformity assessment of PPE.

1. The current testing program for certification of respirators should be transferred to the private sector. The supervision of this testing should remain under NIOSH NPPTL in a system where NIOSH NPPTL accredits and validates the selected testing laboratories involved in this process.

2. Through an appropriate stakeholder and peer review process, NIOSH NPPTL should investigate approaches for the review of product claims against standards. This same group should look at a potential system for ensuring product claims against standards, including the relevant conformity assessment processes are in place.

3. A detailed investigation should be undertaken to determine ways in which manufacturers could be induced to follow existing standards and end users purchase standards that meet these standards.

We do not believe the current approach outlined in the IOM report is workable. It is our hope that improvements in PPE compliance be derived through defining a more appropriate role of NPPTL within the PPE industry that is consistent with the available resources and levels of expertise.

Respectfully,

Jeffrey O. Stull

Jeffrey O. Stull

Grace G. Stull

Grace G. Stull

International Personnel
Protection, Inc.

September 2, 2010

Clyde J. Behney
Institute of Medicine
500 Fifth Street, NW
Washington, DC 20001-2721

Dear Mr. Behney:

The following are my comments as an external review on the draft report, "Committee on Certification of Personal Protective Technologies."

General Comments

My findings from the review of the report are as follows:

1. The report contains several inaccuracies, misrepresentations of information, and is incomplete.

2. NIOSH NPPTL does not have the capabilities, competence, or resources to carry out the proposed recommendations.

3. Some of the proposals are contradictory to the government's direction for use of consensus based standards.

4. The implementation of many these recommendations would yield greater costs to industry without a commensurate demonstrated return of benefits.

5. The recommendations are overly broad and too general to provide a practical direction for affecting conformity assessment.

In my judgment, the committee did not have access to appropriate information or individuals for gaining knowledge for the full range of standards and conformity processes that apply both domestically and in other countries. Consequently, this report should not be published without extensive modification and the adoption of a more practical and appropriate set of recommendations. The following sections provide the basis for my objections to the publication of this report.

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Inaccuracies, Misrepresentations, and Missing Information

Some examples from the first two chapters are provided below:

1. The report uses the acronym "PPT". Presumably this is because these same letters appear as part of the organization acronym "NPPTL". The world, and this country in particular, refer the collection of clothing and equipment as personal protective equipment or "PPE". As much as the government likes to invent new acronyms, it would be appropriate to use the same terminology and abbreviation that a substantial portion of industry and the workforce are used to.

2. On page 1-6, the report indicates that free trade agreements are removing historical trade barriers. While it is true that the marketplace has become substantially more global in nature, it is a fallacy to believe that existing standards are not barriers for trade around the world. The most obvious example is the European Economic Community. Personal protective equipment (PPE) products sold in the EEC must bear a CE mark that for at least "complex" products means that the products are evaluated through a European notified body for conformity to the PPE Directive (89/686/EEC). Any notion that standards are being harmonized through the International Standards Organization is another misrepresentation. Having been the lead person responsible for United States involvement for International Standards Organization (ISO) standards related to PPE from the early 1990s through 2008, I can attest to the fact that there is standards "competition" and that Europe clearly dominating the world with its standards (this is a business not a safety issue). It is also no coincidence that the American Society for Testing and Materials changed their name to "ASTM International" and the National Fire Protection Association (NFPA) considers their organization to be international in competition with ISO and other regional standards bodies.

3. In the section on Respirator Certification beginning on page 2-2, insufficient emphasis is placed on the deficiencies of the current NIOSH respirator certification program.

    - The report fails to point out that other organizations have been forced to create their own respirator standards because the Federal regulations are able to adapt quickly enough to meet changing product technology and test methodology. The inception of NFPA 1981 for firefighter self-contained breathing apparatus is a case in point. More recently, the NFPA undertook the development of a wildland respirator standard, which was actually hampered by inflexible government regulations. Similarly, the International Safety Equipment Association (ISEA) established ANSI/ISEA 110, *American National Standard for Air Purifying Respiratory Protective Escape Devices*, to overcome a gap in respiratory protection standards.

    - As much as NIOSH might tout that it uses a public-driven rule making process, this is not a process that facilitates or more importantly provides for the direct participation of interested parties outside the government. The government chooses the input it wishes to consider in writing its regulations. It is not a consensus-based process as is provided for other forms of PPE in various standards development organizations.

- Even though the NIOSH certification program has been in existence for decades, only recently has the agency made any attempt to gain laboratory accreditation to ISO 17025 or its predecessor standards. This is clearly not acceptable for other conformity assessment organizations. The fact that this accreditation has been "in process" for some time demonstrates an inability for the government to move quickly for adopting industry practice towards conformity assessment.

- Whatever statistics that are applied to the speed of the NIOSH certification process, all respirator manufacturers that I deal with find the process extremely slow. Any requirement for specialized testing evokes even further delays.

- Even though there is some manufacturing site audit activity that takes place, NIOSH admits that it does not have the budget to perform these audits consistently. Further, there is no follow-on testing program to ensure that products remain unchanged in the marketplace.

- The report states that the codification of the fee schedule as part of the regulations does not cover the costs of the program. Changing the regulations to update these fees is a losing proposition because they will only have to be changed again and again (through the rule making process). This is one reason why NIOSH should get out of the testing business altogether.

4. The process of medical device (PPE) is totally mischaracterized. The report attempts to define the reliance of the FDA on consensus standards and that healthcare products follow a risk-based model. Reliance on consensus standards is only partly true. The FDA does recognize industry standards; however, the 510K process by which most medical device PPE is cleared for the market is based on comparing product claims and using tests as represented by the predicate device manufacturer, which may or may not be standardized. Only in a few limited cases, does the FDA require the manufacturer to apply a specific standard. Moreover, inconsistencies in the review process lead to disparate levels of performance among products. It is actually the PPE industry itself that works to reference and use industry standards. The FDA process is perceived as more of a perfunctory obligation rather than a true benefit to the end user for PPE. The idea that the PPE is classified based on risk is false. The classification of medical devices is established for the full range of healthcare products and not specific to PPE; moreover, a prevailing aspect of medical device use is infection control, not protection of the healthcare provider.

5. The healthcare industry is another example where the government writes ambiguous standards. OSHA 1910.1030 prescribes protective clothing as acceptable when it prevents contact of blood and other potential infectious fluids from reaching the wearer's skin or underclothing, but does not provide any means for demonstrating this performance. Consequently, it has been up to industry to define test methods and specifications for defining this level performance, most notably by the American Association for Medical Instrumentation (AAMI) as part of their PB-70 standard.

6. Under hearing protection, the fact that the EPA is only now updating regulations that were promulgated in 1979 should have been a clue to the committee that the government in unable to promote standards that keep pace with new product technology and testing methods.

7. The report fails to mention one area of the personal protective equipment industry, which works well with little government intervention. The electrical utility PPE industry has a comprehensive set of standards beginning with a generalized OSHA standard and ending with a number of specifications and test methods developed by voluntary consensus organizations.

Inherent Limitations of NIOSH Capabilities in Product Standardization and Conformity Assessment

The report reads as having the objective for justifying the existence of the NPPTL organization and reinventing its roles with respect to PPE standards and certification. If the organization is unable to adequately accomplish the limited role for the responsibilities that it currently has, then it is sheer folly to expand that role into new areas for the following reasons:

- It is impossible for the Federal Government to develop and maintain standards through the Federal regulation process. This process is slow, generally does not always gain the input of the affected populations, and is impossible to keep updated. Any continued reliance on government regulations which in turn references to PPE standards provides diminishing returns as PPE standards through most consensus organizations are subject to periodic and frequent change.

- NIOSH has an over reliance on public meetings and input to the rules making process via the Federal Register as source of information on proposed respiratory and other PPE standards. End users and most other interested parties other than manufacturers simply don't have the resources to attend these meetings or provide their input.

- The NIOSH laboratories are not accredited and do not have the incentives that commercial conformity assessment organizations have to provide responsive, accurate testing and certification services. NPPTL should not be in the testing business. The whole aspect of respirator certification by the NIOSH demonstrates inherent problems and limitations of government-run certification. In 1995, I was asked by the NIOSH Division of Safety Research via Rich Duffy to conduct an analysis of the ability for NIOSH to expand its capabilities to the certification of emergency service PPE other than respirators. My findings were that it would be prohibitively expensive and impractical, requiring an enormous increase in the organization's infrastructure to conduct this testing.

- NIOSH NPPTL has not provided a consistent track record for supporting standards development efforts. While funding is provided for some projects, internally operated projects have typically not provided successful outcomes. For example, work towards surrogate chemicals for CBRN testing has yielded no useful output for industry and work on permeation testing of toxic industrial chemicals provided no results whatsoever.

Inappropriate Role of Government for Standards Development

The Office of Management and Budget Directive in the area of standards use by government clearly directs the government to use consensus standards in lieu of creating their own standards. Therefore, recommendations for government-led standards development are clearly inappropriate both in the public and private sectors, particularly when resources outside the government, which must be managed on the basis of good business practice, are available.

The government should not dominate or lead consensus and voluntary standards development processes. This role is inappropriate because the government is put in the position where it must take sides on specific arguments. This requires that individuals at NIOSH NPPTL act on their own cognizance without confirmation of decisions at higher levels and removes any appearance of impartiality on the part of the government. Consequently, like OSHA participation in these groups (and NIOSH involvement a decade ago), NIOSH NPPTL participation should only occur in a non-voting status. NIOSH NPPTL personnel should further not serve as chairpersons for committees because the chairperson sets the agenda for the committee (which controls its technical direction) and is required to break tie votes by casting their vote.

Unnecessary Cost to Industry

Many industries are already struggling with difficult economic circumstances. The addition of further governmental burden through increased taxes to promote expansion of government activity into areas of conformity assessment with questionable benefits is not warranted. No cost-benefit analyses have been performed to show that the increased role of the government by NIOSH NPPTL would provide measurable increases in worker safety.

Industry is already bearing the burden of regulations and programs that provide little value. In many cases, industry has responded on their own to meet emerging issues for creating standards in new technology areas or industry sectors where significant risks exist. For example, the electrical utility industry has been able to establish a series of standards which serve as a basis for improved worker safety and education. As another example, ISEA is already working on an industry conformity assessment standard that will provide a basis for industries establishing the level of conformity assessment that is commensurate the need and risk.

Infeasible Recommendations

The recommendations provided by the committee are largely over generalized and impractical:

- The call for working with other government agencies to create conformity assessment processes for PPE other than respirators sounds like a mission statement that fails to establish how such a process would occur.

- It is already been pointed out that public meetings of stakeholders are generally ineffective in capturing information about the actual risks and problems with PPE in the workplace. In most cases, effective standards have been created through voluntary, consensus standards organizations through the balanced input of their memberships.

- No specific means of providing surveillance for the industry use of PPE have been described. No assessment has been made for the ability to expand the referenced systems to completely different industries and work forces.

- The creation of a "national database" is impractical and requires judgment on the part of the database managers to decide on the legitimacy of product claims. Management of such a database at the government level would be replete with errors and outdated information. Prior attempts by government agencies to even cover a limited proportion of PPE have not succeeded. Current certification organizations already provide lists of certified products.

- NIOSH NPPTL is unable to keep up with respirator certification demand and unable to accommodate in a timely fashion the need for changes in respirator standards.

- Research direction within NIOSH NPPTL is fragmented and akin to an academic enclave where the choices for research often reflect the specific interests of the current staff rather than external needs that have been legitimately identified.

- No consideration has been given the range of competencies and capabilities that are needed to contemplate the implementation of any of the recommendations.

Conclusion

Given the reasons provided above, the report should not be published. The committee should rethink its recommendations within the confines of a realistic role account for its past record of providing conformity assessment.

Please contact me if you have any questions about these comments.

Sincerely,

Jeffrey O. Stull

Jeffrey O. Stull