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

From: robert.weber@mmm.com
Sent: Friday, July 01, 2011 12:13 PM
To: NIOSH Docket Office (CDC)
Subject: 3M Comments to NIOSH Docket 237 on Recommendations Issued by the Institute of Medicine in November 2010
Attachments: 3M Comments to NIOSH Conformity Assessment NIOSH Docket 237 July 1 2011 .pdf

Attached you will find 3M's comments on the recommendations issued by the IOM regarding Conformity Assessment. Comments are being submitted to NIOSH Docket 237.

Regards
Bob Weber

3M

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NIOSH Docket Officer
NIOSH Docket #237
NIOSH Docket Office
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RE: Strategy to Address Recommendations Issued by the Institute of Medicine in November 2010 Report; Comment Request

3M Company Comments

Dear Docket Officer:

3M Company (**3M**), through its Occupational Health and Environmental Safety (OH&ES) Division, is a major manufacturer and supplier of respiratory protective devices throughout the world. 3M has invented, developed, manufactured and sold National Institute for Occupational Safety and Health (NIOSH) approved respirators since 1972. 3M is also a leading manufacturer of personal protective equipment (PPE), including eye, face and head protection, hearing protection, body protection and high visibility garments. 3M employs experienced engineers and technical professionals for the development of respirators and other PPE. Many of these people have been and are involved with the development of conformity assessment standards for PPE. Our technical staff has performed research on the performance of respirators and other PPE and their uses, presented and published these data in numerous forums and assisted customers with the development and administration of effective PPE programs. In sum, we have substantial experience in all phases and applications of PPE.

We are pleased to provide NIOSH with our comments on the strategy to address recommendations issued by the Institute of Medicine in its November 2010 report to the request for comment published May 11, 2011, in the *Federal Register*.

3M has always been an advocate and innovative leader in advancing the importance of PPE. These comments and suggestions are included with this letter.

3M appreciates the opportunity to supplement our comments and knowledge to NIOSH Docket #237.

Sincerely,

Robert A. Weber
Manager, Regulatory Affairs, Quality Assurance and Technical Service
3M Occupational Health & Environmental Safety Division

3M Comments on Strategy to Address Recommendations Issued by the Institute of Medicine in November 2010 Report; Comment Request

[76 *FR* 28791]

The following comments are in response to the comment request published in the *Federal Register* of May 11, 2011, on Strategy to Address Recommendations Issued by the Institute of Medicine in November 2010 Report placed in NIOSH Docket #237.

General Comment

The recommendation being made by the Institute of Occupational Medicine (IOM) is that NIOSH and, specifically, the National Personal Protective Technology Laboratory (NPPTL) expand its role and perform conformity assessment evaluations for personal protective equipment (PPE) in addition to respirators.[(1)] The undertaking of conformity assessment and all of its elements: standards development, testing or inspection, accreditation, attesting to conformity assessment, communicating the fact that the product conforms, and testing and evaluating the products that claim conformity with a PPE standard, for all PPE (not technologies) is a major task. It will require substantial amounts of manpower, time and money. Based on our experience as a manufacturer of NIOSH-approved respirators, this potential additional set of responsibilities causes grave concern because NIOSH is already short on resources and struggles to meet their intended timeline for respirator approvals today.

The logical step in any standard development effort is to establish a need; therefore, we believe the first level of analysis should involve identification and quantification of any legitimate issues with performance of PPE in the US. We are aware of anecdotal references to problems, but none that have had true investigations and documentation provided and the root cause or problem identified. If there are specific documented cases, these should be evaluated and then a determination made as to whether a conformity assessment program or an improved conformity assessment program would have identified the problem.

It is not sufficient for the IOM, National Academy, or anyone else simply to declare that just because it might be a good idea to test PPE, that the NPPTL now has the responsibility to certify all PPE. Without identifying a need, this recommendation does nothing but arbitrarily expand NIOSH's role and expends vital resources without any promise of improving worker safety. If a worker safety need is explicitly identified by this process, NIOSH needs to publish those findings. We also believe that without this first step, this action does not conform to Executive Order 13563 that "benefits justify the costs."[(2)] Without an identified problem, the benefits and subsequent cost cannot be determined. In addition, it does not appear that other alternatives have been explored to NIOSH directly regulating conformity assessment as required by the Executive Order.[(2)]

If there is no consistent problem that this program can address, then the need and use of resources to add this task to NPPTL should be questioned.

We believe the first priority needs to be to make sure that any new tasks taken on by NPPTL that are not legislatively mandated do not detract from existing programs such as the respirator certification program. In fact, one could argue NPPTL needs to reallocate resources to help with the current delays in the certification program before making the decision to develop and implement this conformity assessment program. Delays by NIOSH in processing submissions are costly to manufactures as it results in delayed product launches and delayed sales. This, in turn, slows the progression of new and modified products getting to the US workforce.

We believe that NIOSH has a legislative mandate to certify respirators and in order to perform conformity assessments on other PPE a similar mandate would need to exist in order to ensure ongoing support. A recommendation such as this which does not address responsibilities to existing programs or provide a plan to secure additional resources to staff new responsibilities lacks the thoroughness that is needed to ever implement such a major change. While the concept may be worthy of pondering, it seems most appropriate to reevaluate and ask NIOSH to first identify the perceived problem before assimilating relevant information to formulate a plan for addressing the problem. The information and final plan should incorporate such information as estimates of the resources needed to properly staff the proposed solution and the method for securing necessary funding.

Specific comments

The following comments address the specific recommendations from the IOM report:

(1) Develop and Implement Risk-Based Conformity Assessment Processes for Non-Respirator PPT;
(2) Enhance Research, Standards Development, and Communication; and
(3) Establish a PPT and Occupational Safety and Health Surveillance System.

Additional comments are provided related specifically to the request for comments on the NIOSH, NPPTL intention to implement "a multi-year strategy to address Recommendation 1 of the IOM report to develop and implement risk-based conformity assessment processes for non-respirator PPT."

The scope of the proposed conformity assessment program is extremely broad addressing <u>all</u> PPE. Assuming NPPTL obtains the resources to explore the IOM's recommendations, the first breadth of this program needs to be evaluated, especially when conformity assessment for many PPE has existed in some form for years. We believe the first step strategically for NIOSH is to narrow this scope.

We suggest NIOSH identify the entire breadth of PPE and then determine what is meant by "all". Then a determination needs to be made if all PPE on that list needs to be subjected to a conformity assessment program overseen by NPPTL. From that list, any remaining PPE that is subject to some form of conformity assessment by another government agency, (e.g., procedural masks used to protect against splash of blood borne pathogen containing materials evaluated by the FDA or flotation devices by the Coast Guard) should be excluded. The resulting PPE list should then be prioritized for consideration of conformity assessment.

The next logical step seems to be what NIOSH identified as step 3 in the *Federal Register,* "finalizing the conformity assessment terminology to be used in the effort." To this end, we strongly encourage NIOSH to adopt already accepted language. NIOSH should use the language developed in existing ISO standards.[3]

Related to this subject is the use of the term Personal Protective Technology (PPT) versus more commonly known and accepted PPE. All of the current standards for conformity assessment address PPE and not PPT, and the proposed assessment will be on articles which function as PPE only. Conversely, something such as gas adsorption is a technology and, while this may be studied by NPPTL (as instructed when the change from Morgantown, WV, to Pittsburgh, PA, occurred) is appropriate, gas adsorption would not be subject to conformity assessment until the technology is incorporated into an article of PPE such as a respirator. Because of the potential for confusion and the need for manufacturers, distributors and employers to clearly understand expectations for assessment, we suggest that clear, concise language be employed in any future recommendations.

Once the list of PPE that "needs" a conformity assessment has been identified and narrowed down, NIOSH could then begin with the first published point of its strategy, "defining the standards to be included in the process."

If NIOSH proceeds with this action, consideration needs to be given as to how NIOSH would then identify the PPE on the market which complies with current standards. We believe NIOSH should use existing performance standards and not rewrite them. PPE must already meet these standards as an OSHA requirement. Various products experts have spent tremendous hours, energy and effort developing these standards. We believe that NIOSH should only develop standards where none exist and should not perform the testing to determine initial conformity. NIOSH should restrict its activity to determining conformity perhaps as an audit or oversight-type process. We do not currently have a recommendation as to whether this should be done by looking at the product claims and markings or by NIOSH testing these products to the identified standards. The latter process will take many resources including time and money. In addition, NIOSH will need to develop the expertise for performing these tests before it could use its results to make this determination. Incorrect results reported by NIOSH could cause great confusion in the marketplace and damage to the reputation of good products and manufacturers in a very competitive marketplace.

Strategy steps 4, 5 and 6 published in the *Federal Register* get at the crux of IOM Recommendation One; however, these steps also cause great consternation as it appears to us that "risk" is not understood or is being used in an atypical manner. Risk typically involves two elements of probability: probable frequency and probable magnitude (i.e., likelihood and severity). We think it is difficult to apply this thinking to PPE types. The risk to the user of the PPE will depend on the hazard and environment rather than the type of PPE. For example, the risk to the hard hat user depends on the item that could strike the head rather than the hard hat they wear. PPE selection is more important for reducing the hazard where there are different levels of a PPE, such as with respiratory protection (e.g., half facepiece vs. full facepiece) than the actual PPE type. Selection is not evaluated in conformity assessment. It appears that risk is being used in a way that might indicate a lab coat as low risk and a bullet proof vest as high risk. This does not appear to be risk but rather a way to prioritize based on intended use.

Additional concerns raised in the IOM report deal with the occurrence of fraud/counterfeit PPE in the marketplace and how this impacts PPE users today. If an employer uses counterfeit PPE, the conformity assessment program will not prevent this occurrence without provisions that allow NPPTL to take action to prevent it. NPPTL would need an aggressive process for addressing fraudulent activities. If not, imposing further requirements and restrictions on manufacturers already making a good faith effort to comply voluntarily with standards while delivering PPE to the marketplace will have the effect of widening the gulf between those who choose to achieve conformity and those suppliers who already circumvent the conformity assessment system by fraudulently affixing conformity marks but make little or no effort to deliver compliant product. Thus, the incentive to circumvent product testing may increase as a result of this activity - not decrease.

In summary we believe the following order to be the correct sequence of steps.

NPPTL would:

- Determine if a clear, identifiable problem can be articulated or whether the need is just a perceived problem,

- Determine if a conformity assessment program as NPPTL envisions will have benefits commensurate with the costs incurred, which includes determining if alternatives to direct regulation of conformity assessment by NPPTL exist (if an identifiable problem is articulated),

- Secure resources to undertake the strategy development without detracting from existing programs,

- Determine the scope of PPE to be covered and which PPE have consensus standards already in place,

- Develop a position on the appropriateness and validity of PPE performance levels set by consensus standards.

- Develop conformity assessment terminology which uses existing standards and language,

- Develop a conformity assessment plan using existing consensus standards with a plan for handling fraudulent or counterfeit products, and

- Prioritize equipment to be subjected to conformity assessment and develop methods.

References

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

2. The President. Improving Regulation and Regulatory Review, Executive Order 13563 of January 18, 2011. *Federal Register* 76(14): 3821-3823 January 21, 2011.

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