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Sent: Wednesday, May 28, 2008 1:12 PM
To: NIOSH Docket Office (CDC)
Cc: Glucksman, Daniel (CDC safetyequipment.org)
Subject: 129 - NIOSH/NPPTL Draft Health Care Workers
Attachments: ISEA_NIOSHHCWfinal05282008_ltrhd.pdf

Attached please find ISEA comments to the NIOSH Docket Number NIOSH-129.

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May 28, 2008

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Re: ISEA Comments on the Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan, NIOSH Docket Number NIOSH-129

The International Safety Equipment Association (ISEA) is the leading trade association that represents suppliers of safety equipment. ISEA member manufacturers of respiratory protection offer the following comments on the February 2008 NPPTL Draft Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan (Draft PPE for HCW Action Plan-022208_Rev.doc).

General Comment 1 – Prioritization within the Action Plan

If NIOSH secures sufficient resources to execute the entire Plan described in the draft, much useful information will result to improve PPE for health care workers. To assure resources are available, NIOSH should prioritize the IOM recommendations for determining the most important programs and activities. ISEA sees the greatest benefit to the health care worker if NIOSH focuses on IOM recommendation #1 (Initiate and support a global influenza research network to understand and prevent seasonal and pandemic influenza and to evaluate effectiveness of currently available PPE.). Other key IOM recommendations include #6 (Emphasize appropriate PPE use in patient care and in healthcare management management accreditation and training), #7 (Identify and disseminate best practices for improving PPE compliance), and #8 (Increase research and research translation efforts relevant to PPE compliance) which relate to encouraging proper selection and use of effective PPE among health care workers and others.

Finally, for IOM recommendation #3 (Adopt a systems approach to the design and development of PPE), ISEA supports an approach that would result in closer collaboration between users, manufacturers, research and regulatory agencies. However, many of the suggested activities and projects in support of recommendation #3 have been or are being addressed by PPE manufacturers who have experience in these areas. ISEA suggests joint development of projects and activities to address IOM recommendation #3 to assure the most effective use of resources and more quickly identify PPE gaps and needs.

General Comment 2 – Scope and Ambition of the Action Plan

This program is very ambitious and can be expected to consume substantial NIOSH and NPPTL resources if implemented as written. The current process for respirator certification is often subject to delays related to current NIOSH staffing and resource levels. While we support a program that aspires to be comprehensive and thorough, we fear it may cause deterioration in current NIOSH service levels and recommend that initiatives within this project be taken on only as additional resources are made available for those initiatives.

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Additionally, the ambitious nature of this undertaking could result in process mandates (such as the proposed six-phase System Safety Plan, among others) that would require manufacturers to expend significant resources to go through the design and certification processes necessary to meet a variety of new requirements. The greater the required investment in product development and certification for segment-specific products, the fewer products will be available to the user. Therefore, we encourage NIOSH to work closely with ISEA regarding the development of programs and activities in response to IOM recommendation #3 for the system safety plan. Collaboration with PPE manufacturers will help assure that healthcare-specific devices are commercially feasible and available.

General Comment 3 – Different Certification Programs for Different Market Sectors

This Action Plan proposes new and rigorous requirements for devices for one subset of US workers –healthcare workers. Suggestions for increased pre-market testing, requirements for systematic design and realization processes, and even enhanced durability and comfort support an underlying theme of the document, that healthcare workers need enhanced protection and oversight relative to workers in other industries.

In reality, users in the manufacturing sector also wear PPE for long hours, are subject to widely varying environmental conditions, and must be able to rely on the devices to perform. The NIOSH processes in use for the manufacturing sector have been working well for decades and are continually undergoing routine adjustments to improve effectiveness for protecting workers. The same process is followed for workers in other industries, such as health care, and has resulted in differentiating features (for example, health care specific colors), to improve suitability of the PPE for the users in that segment.

Comments Related to Specific Portions of the Action Plan

From Page 3, Line 96

"Some of the major questions that need answers are:

- Is high humidity an issue with wearing respirators?"

Comment: Request clarification on this item. Does it refer to wearer comfort in high humidity environments, or the efficacy of the filtration system in these environments?

Section 2.2 (Page 18, line 682):

2.2 Usability – Maintain biomechanical efficiency and sense of touch and feel, odor-free, hypoallergenic, accommodate wide range of users (face and body profiles), compatibility across various elements of the PPE ensemble and with other equipment (e.g., stethoscope), non-startling to patients and families, facilitates communication with others (verbal, facial).

Comment: These issues are addressed by currently available respirators. The respirator program manager or person doing the selection must take these issues into account when selecting appropriate PPE. All respirators are designed to be odor-free and hypoallergenic and accommodate a wide range of users.

Section 2.2.2.1.1 (Page 18, Line 705), and other places throughout the document:

"... NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel and cooperative efforts with third party certification authorities and laboratories"

Comment: This clause, along with several others throughout the document, suggest an expansion of the scope of NIOSH activities. Expanded authority over PPE covered by current consensus standards (for example, eyewear, hearing protection, and hardhats) is unnecessary. Providing regulatory oversight to PPE manufacturers who currently adhere to consensus standards is an inefficient use of scarce NIOSH resources and increases product development costs. Resources are better utilized in addressing the Plan priorities as outlined above. Increased product development costs will limit available PPE per general comment #3 above.

Section 2.3.1.1.3.1 (Page 19, Line 238):

"The comfort of a respirator may impact the user's ability to tolerate long periods of use as would occur in the healthcare environment during a pandemic influenza...This data is of potential importance in situations, such as a pandemic influenza, where lengthy work shifts (e.g., >12 hours) can be anticipated...."

Comment: Respirators are designed to last for long work days (12-16 hours) typical in some heavy manufacturing industries. As "long duration" respirators currently exist, there is no need to expend resources to identify approaches to develop "long duration" respirators for health care.

Section 2.3.1.1.3.2 (Page 19, Line 751):

"The PPT Program is undertaking a 2008 study ... to determine carbon dioxide and oxygen levels in healthcare workers who wear respirators ... for prolonged periods as would occur in a pandemic influenza. If elevated CO2 levels or depressed O2 levels are measured that would lead to symptoms, mitigation strategies can be developed."

Comment: The impact of this initiative would be minimal. There are data available that show this is not problematic with respirators used in other combinations. We cite this as an example of an item that should have a lesser priority than the three core items noted in General Comment 1, above.

Section 2.4 (Page 20, Line 774):

"Durability – Adequate wear life, Strength—(tear, tensile, burst), Abrasion resistance, Corrosion resistance."

Comment: Heavy manufacturing usage requires more durability than health care usage. Identifying approaches to address durability should not be a Plan priority.

Section 2.7 (Page 21, Line 840)

"...Product cost, total life cycle cost....."

Comment: PPE manufacturers fully understand product costs and are continually searching to reduce costs in response to pressure from PPE program managers. NIOSH should not expend resources to identify capabilities to increase cost effectiveness of PPE, which is already being addressed by PPE manufacturers.

Section 3.2 (Page 24, Line 881):

"What immediate systemic or strategic measures can be taken to facilitate closer collaboration between healthcare workers (end users), PPE manufacturers, and certification or regulatory agencies on the design and development of PPE for healthcare?"

Comment: ISEA fully supports all forms of partnering and education programs, as they benefit all interested parties, and is in favor of this entire initiative.

Section 3.2.1.2 (Page 24, Line 892):

"Currently ... (m)any medically-related Occupational Medicine tasks (e.g., respirator fit testing, audiology testing and review, baseline pulmonary function interpretations, etc.) are overseen by Internal Medicine and Family Medicine practitioners who may have limited training in these areas. The PPT Program has developed a one-day Occupational Medicine rotation at NPPTL ...that offers instruction in such areas as ... respirator fit testing"

Comment: This is a valuable program for resident physicians, and we recommend it be expanded to include comprehensive training in the nature, selection, use and maintenance of respiratory devices in addition to proper fit testing. This knowledge will give physicians an understanding of the importance of adequate resources to assure an effective respiratory protection program for health care workers at their respective institutions.

Section 4.1.1 (Page 28, Line 925)

"What technologies can improve fit to circumvent the need for fit testing?"

Comment: This activity regarding identifying technologies to improve fit should be a lower priority in the Plan. The primary focus of the Plan should be to assure adequate respiratory protection is in place and that the respiratory protection program is complete (for example, includes fit testing) and is effective.

Section 4.2.2 (Page 28, Line 953):

"Could a non-disposable respirator be designed that could easily be decontaminated and cost-effective?"

Comment: We request clarification of the intent and scope of this question, as there are currently non-disposable respirators (i.e., elastomeric respirators) available that can be decontaminated. What are the gaps between what is available and the intent of this question?

Section 4.2.3 (Page 29, Line 958):

"Study of efficacy of user seal checks on filtering face-piece … the value of the user seal check has not been adequately demonstrated in the literature."

Comment: The user seal check is important, as it requires the user to evaluate fit in a subjective way every time he dons the respirator. It requires that he regularly interact with the device in a way that creates awareness of the importance of device fit and user interface. However, we acknowledge that the published record is incomplete as to the effectiveness and/or best method with regard to this important activity. We recommend that any study of this activity include elastomeric devices in addition to filtering face-pieces because the value of a fit check may not be definable in absolute terms, but only in relative terms[1]. The study and resultant publication should emphasize, though, that a user seal check cannot be substituted for formal fit testing.

Section 4.4 (Page 29, Line 971)

"Designing respirator facepieces to integrate medical devices such as a stethoscope and to improve communication between the user and others."

Comment: We are concerned that this statement implies that medical devices would be considered accessories to the respirator in the respirator certification process. The integration of medical devices should be addressed through the Respiratory Protection Program selection process in the same manner as other equipment, such as protective eyewear.

Section 4.5.1.2 (Page 29, Line 989):

"Respirators utilized in healthcare settings were not designed for that particular venue."

Comment: We disagree with this broad statement. There are devices currently on the market that have been designed with the healthcare sector specifically in mind. However, we acknowledge the value of increasing collective knowledge regarding performance and utility requirements in any market segment.

Sections 4.6.2.1 and 4.6.2.2 (Page 30, Lines 1022 and 1023):

"Add colorimetric write-up" and "Add innovative indicator write-up for chemical protective clothing (CPC)."

Comment: Request clarification as we do not know the meaning of these two items.

Section 5.3.10.4 (Page 35, Line 1141):

"Metabolic evaluation of N95 respirator use with surgical masks…"

Comment: NIOSH should evaluate breathing resistance of N100 respirator against that of the N95 respirator covered with a surgical mask. We have experience with N100 respirators and

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[1] Myers, W.R., M. Jaraiede and L. Hendricks. Effectiveness of Fit Check Methods on Half Mask Respirators. *Appl. Occup. Environ. Hyg. 10(11)*:934-942; 1995.

based on prevalence in the marketplace, N100 respirators are not creating physiological effects for users. If the breathing resistance of an N95 respirator with a surgical mask overlay is less than that for an N100 respirator, than there should not be any metabolic issues for an N95 respirator with a surgical mask overlay.

Section 10.1 (Page 53, Line 1448):

"Incorporating pre-market field testing requirements into NIOSH certification for respirators."

Comment: We disagree with this proposal. The somewhat cumbersome nature of the current process can result in delays in achieving certification. Adding a field test would add additional time and complexity for what may be questionable benefit. Field test results would likely be less stable, repeatable and reliable than the current controlled lab testing program.

Section 10.3 (Page 53, Line 1461):

"Requiring certification of other types of PPE (e.g., gowns, gloves)."

Comment: We object to this proposal for PPE currently addressed by consensus standards. Standard PPE such as safety spectacles, faceshields, gloves, etc., have been manufactured and used successfully for decades without NIOSH (or other government) oversight of specific devices, manufacturers or processes.

Requiring standard PPE to achieve NIOSH certification for use in healthcare would almost certainly result in fewer devices being available to healthcare workers as the cost of the process would force manufacturers to limit the number of devices certified. Many devices that would be completely effective in a healthcare setting would be unavailable simply because of the prohibitive cost of certification across a product line. This segment of US workers would have far fewer options available for comfort, fit and style – key drivers in the proper use of standard PPE.

Section 11.1 (Page 56, Line 1490)

"Workplace effectiveness studies"

Comment: ISEA supports these types of studies which determine the effectiveness of respiratory protection for protection against micro-organisms. In order to conduct these studies, reliable methods need to be developed for measuring concentrations and viability of micro-organisms inside and outside the respirator.

Please contact Janice C. Bradley, ISEA Technical Director if you need additional information.

Thank you for your consideration.

Sincerely,

Daniel K. Shipp
President