

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

From: Lisa Tomlinson [ltomlinson@apic.org]
Sent: Monday, April 20, 2009 12:08 PM
To: NIOSH Docket Office (CDC)
Subject: 146 - (PPT) Action Planning
Attachments: Microsoft Word - APIC NIOSH PPT Letter Final 4_20_09.pdf

I have attached APIC's comments on Docket -146.

Lisa Tomlinson

Director of Government Affairs

APIC—Association for Professionals in Infection Control and Epidemiology, Inc.

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April 20, 2009

NIOSH Mailstop: C-34
Robert A. Taft Lab.
4676 Columbia Parkway
Cincinnati, Ohio 45226

RE: Docket Number NIOSH-146

Dear Sir or Madam:

Thank you for providing the opportunity for the Association for Professionals in Infection Control and Epidemiology (APIC) to provide comment on the Personal Protective Technology (PPT) Program Implementation Plan structure and content.

APIC is an international, nonprofit, multi-disciplinary organization, representing more than 12,000 infection preventionists. APIC's mission is to improve health and promote safety by reducing the risks of infection and adverse outcomes in patients, visitors, and healthcare workers.

We greatly appreciate the comprehensiveness of the PPT Implementation Plan as written and support the implementation of a state-of-the-art federal program focused on PPT. We appreciate the fact that the plan strives to achieve effective balance between program enhancement and expansion over a five year timeframe, and we acknowledge that implementation of the scope of the program is dependant upon resource availability. The emphasis on the need for a clear commitment to ensuring U.S. leadership in research, policy and standards development and certification of personal protective technologies is appreciated.

After review, we offer the following comments:

Recommendation 1:

We appreciate the acknowledgement of the need for assessment and evaluation of technology that is based in quality science. This document speaks to the philosophy of outreach to stakeholders for partnership, and we would like to recommend that APIC be included as one of those partners.

Expanding the focus of certification to other types of PPT will help standardize the product selection available to healthcare workers (HCW) for items other than respirators that are important in the prevention of infections in healthcare settings. We would like to ask that standards and PPT requirements for HCW be evaluated in relationship to operational needs within healthcare settings, which are different from industrial occupational settings (i.e. ability to communicate and care for patients while utilizing PPT). With limited resources and the addition of non-respiratory technology certification to the program, adequate assessment, evaluation,



standards development, and policies and procedures that will address the variable needs of all industries will need to be accomplished, without placing undue burden of cost and implementation requirements on them.

Recommendation 2:

We support the establishment of Research Centers of Excellence, and the collaboration needed with intramural and extramural programs to improve PPT. There should be a clearly-defined process for identifying and selecting these centers. The need for external research organization involvement so that healthcare sector needs and expertise can be differentiated from those of the general industry should be an important part of this plan. In terms of extramural community involvement, APIC would like to extend our expertise and would ask to be considered an integral part of this process as well.

Recommendation 3:

APIC supports the need for a streamlined system to expedite recall notices for product failures, post-marketing notifications, recalls and updates.

If enhancing the Respiratory Certification Process involves shifting the existing cost for respirator certification, some of which is currently absorbed by NIOSH, completely over to the manufacturer, then the downstream burden of this shift will ultimately be higher costs to the purchasers of these products.

Site audit programs should be conducted by people qualified to understand the operational use of the PPT in a given environment, as healthcare is not the same as general industry.

Recommendation 4:

Of the five recommendations provided, this one is fundamental to the success of all the others. We support the need to include HCW in the assessment of the usability of these products. We strongly support the need to identify barriers to the use of PPT and functionality of equipment.

We believe equipment should be designed in a manner that does not require repeated or ongoing fittings/measurements in order to be used, and designed based on scientific evidence related to true risk of exposure.

APIC historically and currently continues to stress the need for a disposable respirator that is ready to wear and does not require fit-testing. The fit-testing process is a financial and time consuming burden on the healthcare industry which detracts from the evidence-based tasks that are essential to the protection of our patients, visitors and staff.

Recommendation 5:

APIC believes this recommendation and plan allows for the necessary field testing that is critical to evaluating the successful use of the certified products by workers. This process will allow for developers and certifiers to glean valuable on site information that can be used to continually improve products if deficits are identified on the front lines. Specific criteria should be developed for PPT evaluation which is objective and independent of individual manufacturer



influence. We support field-testing when done by qualified individuals who understand the healthcare environment and the science behind specific protection needs.

Again, thank you for your efforts to address the critical issue of personal protective equipment for healthcare workers. APIC's member-driven committees, made up of professionals who work daily to prevent the transmission of infections, would welcome the opportunity to work directly with NIOSH on this very important action plan.

If you have any questions regarding these comments, please contact Lisa Tomlinson at LTomlinson@apic.org or by calling 202-454-2606.

Sincerely,

A handwritten signature in cursive script that reads "Kathy L. Warye".

Kathy Warye
Chief Executive Officer