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

From:

Kline, Joann [Joann.Kline@kcc.com]

Sent:

Friday, July 01, 2011 5:02 PM

To:

NIOSH Docket Office (CDC)

Subject:

Docket NIOSH-237, Strategy to Address Recommendations Issued by the Institute of

Attachments:

KCPRespNIOSH3PC070111.docx

Please accept the attached comments on the docket above from Kimberly-Clark Professional.

Thank you very much.

Joann M. Kline, JD Regulatory Technical Leader Kimberly-Clark Professional 616.785.5131 Telephone 616.785.5129 Fax

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information that is exempt from disclosure under law. If you have received this message in error, please inform us pro by reply e-mail, then delete the e-mail and destroy any printed copy. Thank you.





July 1, 2011

NIOSH Docket Office Robert A. Taft Laboratories, MS-C34 4676 Columbia Parkway Cincinnati, OH 45226 By e-mail: nioshdocket@cdc.gov

Re: Docket NIOSH-237, Strategy to Address Recommendations Issued by the Institute of Medicine in November 2010 Report: Comments of Kimberly-Clark Professional

Kimberly-Clark Professional is dedicated to providing essential solutions for a healthier, safer and more productive workplace. These include a unique portfolio of innovative, cost-effective and sustainable offerings for office buildings and lodging properties, healthcare facilities, manufacturing environments, laboratories and cleanrooms, educational facilities, food preparation and processing operations, and home professionals. Kimberly-Clark Professional offers a comprehensive array of personal protective equipment including eye and face protection, head protection, welding helmets and lenses, hearing protection, protective and high visibility apparel, and gloves as well as wiping and safety solutions that minimize risk and drive productivity. Its trusted global brands include Kleenex, Scott, Jackson Safety, Wypall and Kimtech. Located in Roswell, Ga., Kimberly-Clark Professional is one of Kimberly-Clark Corporation's four business sectors. For more information, visit www.kcprofessional.com

Thank you very much for the opportunity to comment on a potential strategy for implementing a third-party conformity assessment program for personal protective equipment ("PPE").

Need for NIOSH Conformity Assessment of PPE

First and foremost, we are concerned that NIOSH efforts to determine *how* to go about assessing PPE conformity indicate that NIOSH is satisfied that it *should* assess PPE conformity outside of respirators based on the IOM report. We are much less certain. The IOM report was interesting in its depth and approach, but was something of a theoretical exercise and only considered a small number of PPE types. We did not see how it assimilated or even considered the current actual practices of conformity assessment that are both routine and effective in the PPE industry.

U.S. workers enjoy a high level of workplace safety that comes in no small part from the quality of the PPE and other safety equipment available in this country without conformity assessment

5801 Safety Drive N.E., Belmont, MI 49306

Phone: (616) 785-6279 Facsimile: (616) 784-4740

by NIOSH or, in many cases, any entity besides the manufacturer. Manufacturers are rigorous and responsible in both the design and manufacture of these devices, with tremendous success and good track records to date. We are not aware of studies or data that indicate that defective PPE in our product lines cause any notable levels of user injuries. At a minimum, NIOSH should establish the true extent of any problem to be solved before diving too deeply into solution options.

Loss of Choice and Variety Could Dampen Use and Compliance, Increasing Injury

Workers also enjoy access to an expansive variety of these devices that increases safety by increasing acceptance and proper use of PPE. Comfort and style are extremely important to users – especially younger users – and compliance with use requirements is significantly enhanced by the extent to which an individual user can select the exact device he wants.

Inserting a government evaluation and certification step between developers and users would significantly decrease the available variety of PPE. Most conformity assessment regimens, including NIOSH's current respirator program, require detailed testing of multiple devices that are substantially similar but have differences in appearance, style, comfort features or other characteristics that only minimally or theoretically affect performance. As the cost of performing a conformity assessment for each version drives the number of variations downward, the decreasing choices will reduce worker acceptance and compliance. Items that provide safety for niche operations may become unavailable if the cost of a NIOSH conformity assessment requirement is spread over too few potential users. If these types of devices do remain on the market, the user may have to absorb enough of the increased cost to negatively affect use and compliance rates.

Many user injuries related to PPE arise from improper use of the PPE, poor fit, or failure to use any PPE at all. While a conformity assessment program may occasionally identify scattered defective PPE devices in the market, this ostensible gain could be wholly offset by the degradation in proper fit and use as workers are left to select from fewer devices as a result of the program.

Therefore, we suggest that any evaluation of risk based on lack of conformity assessment be balanced by similar evaluation of the risks and offsets that would accompany implementation of NIOSH conformity assessment.

Analyzing Risk and Projecting Improvement Incrementally

Any risk analysis with respect to incidence and effect of non-conformance should be conducted relative to the results and outputs of the current system. PPE in the U.S. is extremely effective because of the collective efforts of OSHA, safety professionals, manufacturers and employers in assuring that users are equipped with robust, effective, and quality PPE that is appropriate for the application. These efforts result in very low incidences of user injury that are related to defective

5801 Safety Drive N.E., Belmont, MI 49306

Phone: (616) 785-6279 Facsimile: (616) 784-4740

PPE. Similarly, projected improvements from a NIOSH conformity assessment system should be expressed only as the incremental improvement over the current general success level and not relative to a theoretical "zero point".

Defining Cost-Benefit Incrementally

Implementation of a NIOSH conformity assessment program for PPE will create a substantial cost burden to taxpayers, manufacturers and, ultimately, users. It would be both misleading and a disservice to inflate the benefit gained by these costs by ignoring the current high performance level of most PPE and characterizing the improvement on an "up from zero" basis. We strongly believe that any representation of cost-benefit that is not limited to incremental benefits specifically gained by implementing a NIOSH conformity assessment process would radically skew the numbers and lead to unnecessary cost burdens throughout the system. We are aware of no study or data that indicates that third party conformity assessment, alone, will significantly increase the effectiveness or quality of PPE in the U.S. or decrease injuries related to defective PPE. We do not believe that the cost burden on the system, in dollars or loss of variety and user choice, of a NIOSH conformity assessment program for PPE will result in a commensurate reduction in injuries related to defective PPE.

Consider Alternative Methods to Address a Small Number of Producers and Products

Finally, If NIOSH's investigation shows that there is defective PPE coming from a few "bad actors" on the market, NIOSH should pursue alternative avenues to target those producers and products without universally applying the same expensive controls on the much larger, fully effective portion of the industry. While imposing universal federal government evaluation of PPE might expose these substandard manufacturers and products, it would come with significantly increased costs burdens on the vast majority of good faith manufacturers who diligently and responsibly design and manufacture high-quality, robust and effective PPE, as well as the end users, employers and taxpayers.

We appreciate the opportunity to comment on NIOSH's direction and look forward to future participation in the process.

5801 Safety Drive N.E., Belmont, MI 49306

Phone: (616) 785-6279 Facsimile: (616) 784-4740

Sincerely,

/s/ Joann M. Kline

Joann M. Kline Regulatory Technical Leader