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

From: Kline, Joann [Joann.Kline@kcc.com]
Sent: Thursday, September 30, 2010 3:54 PM
To: NIOSH Docket Office (CDC)
Subject: Kimberly-Clark Professional Comments to NIOSH Docket #137
Attachments: KCPNIOSHTILComments0910.docx

Attached please find Kimberly-Clark Professional's comments to NIOSH Docket #137 "*Total inward leakage requirements for half-mask air-purifying particulate respirators*".

Thank you for your consideration.

Sincerely,

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Kimberly-Clark

September 29, 2010

Via Email (niocindocket@cdc.gov)

NIOSH Docket Officer
NIOSH Docket #137
RIN 0920-AA33
National Institute for Occupational Safety and Health
Robert A. Taft Laboratories, MS-C34
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RE: 42 CFR Part 84 Approval of Respiratory Protective Devices

Kimberly-Clark Professional is known for innovative safety solutions for "clean" and "industrial" manufacturing settings. With the acquisition of Jackson Safety, the company offers a comprehensive line of personal protective equipment, welding and work zone safety products. The combined global safety brands of Kimberly-Clark Professional and Jackson Safety include Kleenguard, Smith & Wesson (under license) and Winchester (under license). Kimberly-Clark Professional, located in Roswell, GA, is one of the Kimberly-Clark Corporation's four business segments.

We support NIOSH's ongoing efforts to update the rules governing respiratory devices and appreciate the opportunity to provide input into the rulemaking process. We reaffirm and request continued consideration of our comments submitted to this docket on March 29 of this year, and offer the following additional comments based on policy and procedural considerations. (References are page numbers from Federal Register Vol. 74, No. 209, dated October 30, 2010 unless otherwise noted.)

Policy Concerns with TIL Test as Part of Respirator Certification

TIL Certification and User Fit Testing

NIOSH maintains that this rule is not a substitute for fit testing (Page 56143, plus other places), and we appreciate these cautions. However, two of the three objectives listed on page 56143 as the reasons that this rulemaking is necessary center around the needs of users that cannot or will not conduct fit testing for whatever reason. The proposed rule lists the following as the items that "define the need for this rulemaking" (from Page 56143):

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1. Employers may go through several rounds of trial and error before finding devices that fit all employees. This rule would reduce the number of iterations needed to complete the process.
2. Many self-employed workers, along with 40% of employers, do not select respirators based on fit testing. NIOSH TIL testing would increase the likelihood that these workers who lack fit testing will be protected.
3. Respirators issued from civil stockpiles are likely to be used without fit testing, and NIOSH approved respirators currently provide "no assurance" regarding these products to potential users.

Items two and three above are about concerns of users who do not have fit testing available or do not do it themselves. NIOSH further states that the rule will provide:

> "Increased assurance to respirator purchasers and users that NIOSH-approved respirators can be expected to effectively protect … when properly donned and used". (Page 56142)

It is unclear how proposed TIL rule will provide increased assurance to users who are already properly wearing and using these respirators, presumably including fit tests. There would actually be little benefit to users who have already been conducting proper fit tests prior to using current devices. Most overall benefit and substantially all increased assurance of effectiveness would inure to users, including those in the NIOSH situational examples above and others, who are not expected to effectively fit test devices prior to use.

So although NIOSH is careful to say very clearly that the rule is not a substitute for fit testing, the core of the rationale for the rule given in Section II.C *Need for Rulemaking* is to help increase user confidence in effectiveness in the absence of adequate or any fit testing.

A rule promulgated largely to increase device effectiveness for users who are not expected to conduct fit testing transfers some responsibility for proper fit from the user to the designer and manufacturer of the device. This, along with some of the specific requirements for manufacturer indication of intended wearers, could also transfer significant liability to manufacturers. This concern is discussed in more detail below.

Role of TIL Evaluation in a Product Certification Protocol

Most manufacturers are passionate about designing devices with broad and simple fit characteristics. This is a key focus of respirator design expertise, along with effectiveness of filter media and comfort/breathability. Fit testing and leakage analysis both have important roles in the manufacture and use of these devices in the US. However, we believe that these activities properly belong in the development and user selection areas of the issue, with dissemination of fit information in the marketing and sales consulting areas. We do not think that user fit to human subjects belongs in a product certification protocol as proposed.

Concerns Based on Proposed Procedures for TIL Testing and Certification

Proposed Allowances for Targeted Populations

The inevitable outcome of using a test panel as described in the proposed rule is for manufacturers to seek safe design ground by designing devices to maximize panel performance. This could leave users with outlier facial topographies without available fitting respirators. This concern was raised several times in 2007 as part of NIOSH Docket #36, and NIOSH appears to address it in the proposed rule by allowing a manufacturer to define a targeted population for which customized test panels would be created.

However, a rule allowing targeted populations does not mean that manufacturers will find it economically viable to design devices to targeted populations. Most devices are currently designed to provide a flexible and widespread fit that may accommodate some portions of the mainstream users (general panel) along with some outlier users (targeted panel). This broader population of potential users helps spread design and production costs over higher sales volume. It may not be justified to dedicate research and design resources to devices targeted to outlier facial characteristics with eventual sales supported only by the targeted population.

Also, differences between panels assembled by manufacturers for development and those assembled by NIOSH for certification could cause NIOSH to reject the certification application after the manufacturer has already made a significant investment in a niche device. The best way for the manufacturer to avoid this is to define the targeted population narrowly and precisely, in turn shrinking the potential user population and sales base even more.

Requirement that Device Instructions Describe Intended Users

The proposed rule requires a manufacturer to describe the intended user base in the device instructions – either narrowly for targeted populations or more broadly for general populations. This requirement could increase liability for manufacturers. A description of the users for which the device is intended could easily be seen as a claim or representation that the device will be effective for users that fit the description. The more detailed and narrower the description (as for devices targeted at certain populations), the easier this step in logic becomes. A manufacturer could become liable for user injury if the user reasonably self-identified with a manufacturer's intended-user description, regardless of any other considerations.

Costs of Redesigns and Lost Sales

We are extremely concerned with the costs associated with the proposed rule, especially to the extent that many of the costs could be avoided with a different testing approach. NIOSH's benchmark study suggests that fewer than 10% of all devices (and substantially no filtering facepieces) would pass the rule as proposed. (*Presentation titled "Proposed Total Inward Leakage Testing in NIOSH Certification Benchmark Testing" by Newcomb (NIOSH)* at NIOSH Docket #36.) The most generous NIOSH estimate is that 70% would pass based on the same benchmark study. (Page 56142)

The cost of responding to failures in these numbers is staggering, particularly considering that the study consisted of devices that have been used successfully for years. The cost of redesigning a device, including engineering resources and retrofitting production equipment, would typically be comfortably over $1,000,000 per device or device family. (More details regarding this cost estimate as developed by industry survey will be included in comments to the docket submitted by ISEA in September 2010.) Applied across the dozens and even hundreds of devices that NIOSH predicts will fail the test, the cost will quickly become unmanageable by the industry.

There are also indirect costs that have not been estimated. Many manufacturers use common seal components across several devices. A failure of a single device that leads to a design change for a common component could drive NIOSH recertification costs for all items that use that component. Also, many manufacturers market these devices globally and are subject to certification programs in other countries. A product revision to meet the new NIOSH requirement would necessitate recertification efforts in other countries.

It must also be noted that these costs are based on an assumption that manufacturers would, indeed, choose to redesign products that had failed the NIOSH test. The manufacturer may withdraw the product from the market entirely rather than incur redesign costs. Not only would this amplify the general issue of unavailability, it would also create significant loss of sales and the commensurate loss of US jobs throughout the stream of commerce.

Effect of Testing Variability

The issue of redesign, market withdrawal and overall costs are further complicated by the fact that the test method proposed does not precisely distinguish good from bad devices. (Study conducted by International Safety Equipment Association, *Submission to Docket by D. Shipp (ISEA); 3/29/2010* at NIOSH Docket #137.) At minimum, it would create a broad borderline or gray area of product compliance.

The estimate of $1,000,000+ given above to redesign and retool after a failure is based on a typical design process driven by known product needs and fairly straightforward solutions. It is

much more difficult and expensive to try to implement a design "fix" for an item that is either very close to compliant or even actually compliant. The potential unreliability of this test would make manufacturers spend endless resources on phantom problems based only on artifacts of the testing, not the product itself.

Conclusion

We do understand and support NIOSH's desire to perform some kind of evaluation of product configuration – specifically seal and user interface – for these devices. However, we believe that the approach should not try to encompass user fit specifically. We suggest that NIOSH continue the effort but look for a more objective, possibly equipment-based, method without the instabilities and design consequences of using a human-subject panel. Alternatively, we ask that NIOSH investigate and consider aligning the process with other known successful approaches, specifically EN149. This would help designers concentrate efforts on fewer varied test schemes and more on developing truly protective products.

Again, we appreciate the opportunity to comment on the proposed rule.

Sincerely,

/s/ Joann Kline

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