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

From: Kline, Joann [Joann.Kline@kcc.com]
Sent: Monday, March 29, 2010 4:51 PM
To: NIOSH Docket Office (CDC)
Subject: Kimberly-Clark Professional Comments on Proposed Changes to 42 CFR part 84, RIN 0920-AA33
Attachments: KCPNIOSHTILFinal0310.docx

Please accept Kimberly-Clark Professional's comments to the NIOSH Docket, RIN 0920-AA33, as attached. You may contact me at the number below if there are any problems opening or reading the attachment.

Thank you,

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Kimberly-Clark

March 29, 2010

Via Email (niocindocket@cdc.gov)

NIOSH Docket Officer
NIOSH Docket #036
RIN 0920-AA33
National Institute for Occupational Safety and Health
Robert A. Taft Laboratories, MS-C34
4676 Columbia Parkway
Cincinnati, OH 45226

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 offer the following comments on the proposed changes to 42 CFR Part 84.

Question on Test Sample Size versus Probability of False Rejection

In *Section IV Regulatory Assessment Requirements*, NIOSH asks manufacturers to comment on the balance between the cost associated with the proposed sample sizes (15 or 35 subjects) and the cost associated with the resultant 1 in 10 chance that an acceptable device would be mistakenly rejected. We believe that the cost of the wrongful rejection would substantially outweigh the cost of testing more subjects up front to increase the probability that a compliant device will have passing test results.

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Redesigning and resubmitting a device would always carry significant costs. In this case, the problem would be amplified by the fact that the failed device was, in fact, compliant. Trying to find a "fix" for an acceptable respirator could be the design version of looking for a needle in a haystack. We would be out of the realm of making significant improvements to bring the device into compliance and into the realm of making non-obvious changes hoping for a different test result.

However, we do not believe that manufacturers should incur higher initial tests costs on all products simply to avoid a relatively high (10%) chance of an unjust test outcome. We suggest the following as alternatives to increasing sample sizes:

- A respirator that fails the first test could automatically be entitled to a retest without any product changes or added cost to the manufacturer.

- After a failed result, the manufacturer could have the option to request additional subjects to be added to the test in the manner of a double-sampling plan.

- Finally, a manufacturer could have the option of defining or redefining a subpopulation after the failure of a device on a more general test panel and resubmitting the device with no changes.

In the end, though, we would prefer an overall larger sample size as being less total cost if it minimizes the likelihood of false rejection of a compliant respirator.

Implementation

3-Year Period to "Sell and Ship" to Existing Approvals

In *Section J: Effective Date* [page 56149] the rule states that manufacturers will be able to "sell and ship" currently certified respirators for three years after the effective date of the rule. We believe that the intent is for this to apply to product that is manufactured after the effective date, not simply in inventory and available for sale and shipment. We suggest that NIOSH clarify that the ability to "sell and ship" product for three years under existing approvals also applies to product manufactured after the effective date but within the 3-year period. Otherwise it could be interpreted to mean that only "sell and ship" activities are allowed, so that only product in inventory as of the effective date could ship for three years.

Also, we suggest that NIOSH to consider a permanent exception to TIL testing for all devices holding NIOSH certification as of the effective date. Clearly these devices have been working effectively for many users for a long time. The new test protocols will tend to herd manufacturers toward the center - making devices that favor common and "average" facial characteristics. Those individuals that are outliers will find fewer and fewer effective products. Having existing devices remain available will help assure that the outlier individuals will continue to have access to effective devices.

Furthermore, some devices currently in use may not pass the new TIL limits even though they have been used effectively for years. Significant design changes to these devices or complete market withdrawal would force users to find other models. Institutional users in particular often have long and laborious processes for respirator sourcing that include finding and qualifying a new supplier and then conducting entirely new fit tests on hundreds or even thousands of employees. Employers with many employees that have already been successfully fit-tested to current respirators should not have to go through the process and cost of changing respirator models when there has not been a clearly demonstrated value in the change or even a problem identified. The fact that those same effectively-fitted devices do not fit an arbitrarily defined panel should not render them ineffective and unavailable.

2-Year Period to Seek Modification of Existing Approvals to Include TIL Testing

We are very concerned with the prospect of NIOSH trying to process 500 additional applications in two years, despite the fact that it would only be a partial test for TIL performance. This could not only jeopardize the continued availability of current protectors that may remain in the queue beyond the two-year limit, but could also hinder the approval rate of new and unrelated products.

We are also concerned that not all respirators will make it through the review in two years. In this case, the manufacturer could only ship one additional year (until reaching the 3-year overall limit) and then would have to either discontinue the product or resubmit it for full certification. In either case, the manufacturer incurs cost without having any ability to affect the underlying capacity constraints that create the problem.

We would like NIOSH to clarify, either in the final rule or by other means ahead of the rule:

- Whether a device must only be *submitted* within the two years or actually *approved* within the two years.

- Whether an existing device that fails the TIL test could be resubmitted after design tweaks under a request to modify the certification (TIL testing only) or if it would have to be resubmitted for full testing.

- What resources NIOSH will add or outsourcing it will contract to help absorb the workload and how any added resources would be quickly trained to assure consistent application of tests and interpretation of results.

We further suggest that NIOSH modify the 3-year limit for shipping existing product to allow any device that has been submitted for modification of certification within the 2-year window to continue to ship indefinitely, as long as it is in the testing queue, even if it goes beyond the three years.

Failure Rate of Current Devices to the New Test Proposal

In *Section II Background*, NIOSH describes the benchmark test in which 30% of the 101 currently approved devices tested did not meet the TIL limit of 1% [page 56142]. However, in *Section IV Regulatory Assessment Requirements*, NIOSH states:

> "For the leading U.S. respirator manufacturers … likely to represent a majority share of the current market supply of NIOSH-approved products covered by this rulemaking, NIOSH benchmark testing indicates that the new TIL requirements can be met by current products without additional development or manufacturing costs." [Page 56147]

These statements facially appear to be contradictory, and the resolution of which is correct would make a significant difference in the effect of the rule both financially for manufacturers and for availability to users.

We request that NIOSH describe the difference between these two statements in terms of which product set led to the 30% rejection rate in the benchmark testing and which product set led to the conclusion that most would pass. If the two statements were not made with reference to different product sets, then we ask NIOSH to clarify the reasons for two apparently different conclusions or, in the alternative, withdraw the incorrect conclusion.

Panel Make-Up, Statistics, Test Method, Policy, Populations, etc.

Kimberly-Clark Professional concurs with the concern and content of remarks posted by other manufacturers and ISEA to the NIOSH NPPTL Docket #036 after the public meeting held on June 26, 2007. We also concur with the comments surrounding the test methodology, the relation of the benchmark testing to the test procedures proposed in the rule, and all other technical concerns submitted by ISEA to the docket in March, 2010, as well as the findings and conclusions of the expert panel convened by NIOSH and whose report is attached to the ISEA comments.

Effect of Concurrent Consideration of the Proposed TIL and QA Rules

We are very concerned with the timing of this rule in relation to the proposed changes to 42 CFR 84 *Quality Assurance Requirements for Respirators* [NIOSH Docket #109, RIN 0920-AA04]. It is reasonable to predict that if any rule is promulgated for TIL, the auditors surveying manufacturers' quality systems will expect to see at least some activity related to assuring the TIL performance. These two rules have an interactive effect on manufacturing costs.

Unfortunately, we cannot exactly understand the effects of the QA rule on our costs and systems without knowing what the TIL rule will look like. Conversely, we also can't reasonably assess cost of ongoing implementation of the TIL rule without knowing the final outcome of the QA rulemaking process.

We therefore feel that we are unable to effectively participate in the Notice and Comment rulemaking because the interrelatedness of these two rules make it difficult or impossible to fully comment on each individually.

Consideration of Other Current Approaches

Finally, we ask NIOSH to consider other established respirator standards for TIL, including the European approach described in EN 149. These methods may have long histories that can inform NIOSH's deliberations on the final rule, and harmonized requirements lead to reduced costs throughout the stream of commerce.

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

Sincerely,

/s/ Joann Kline

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