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

From: cecolton@mmm.com
Sent: Saturday, November 28, 2009 12:53 PM
To: NIOSH Docket Office (CDC)
Subject: RIN: 0920–AA33 42 CFR part 84

Attachments: Extension request Nov 28.pdf

Extension request Nov 28.pdf ...

This comment is to request an extension of the comment period.

(See attached file: Extension request Nov 28.pdf)

Thanks,

Craig E. Colton, CIH
Division Scientist
Regulatory Affairs & Technical Service
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November 28, 2009

NIOSH Docket Office
Robert A. Taft Laboratories
MS–C34
4676 Columbia Parkway
Cincinnati, OH 45226.
niocindocket@cdc.gov.

RE: RIN: 0920–AA33, 42 CFR Part 84; Total Inward Leakage Requirements for Respirators; Notice of Proposed Rulemaking

3M Company Request for Extension of Comment Period

Dear Sir/Madam:

The 3M Company (hereinafter "3M") is a major manufacturer of respiratory protection products, including N95 particulate filtering facepiece respirators. This is just one class of the respirators affected by the proposed rule listed above. We respectfully request a ninety (90) day extension (until March 29, 2010) of the comment period for this proposed rule. While we agree in principle with the proposed rule, we require this extension of time to adequately analyze the impact of this proposed rule on us as a manufacturer and the consequences to the end user.

After initial review, we believe that NIOSH may have severely erred in their judgment on the impact of this rule on current products in the market and their availability to the end user. Of significance is the fact that the benchmark study NIOSH used for analysis of this proposed rule does not conform to the process NIOSH has proposed. Yet NIOSH used this benchmark study to extrapolate the formation of its opinion regarding the impact of this rule on manufacturers and respirator supply. In addition, the statistical analysis for determining compliance to this rule deviates from normal, accepted approaches. Typically, these types of requirements allow failures in a face panel cell as long as the percentage of subjects required to pass was met. The complexities of the proposed change will require a series of well designed, statistical studies to evaluate the impact of this rule. In order to complete a rigorous, technical assessment of the proposed TIL protocol, 3M will need to complete a large number of face fit panels using a statistically relevant sample size to analyze the potential ramifications of the proposed protocol.

The rigorous assessment needed to better understand this proposed rule will require resources which will severely impact our filtering facepiece respirator operations. This in turn, diminishes the availability of these resources to help us deal with N95 filtering facepiece supply issues associated with the current H1N1 pandemic. Thus, this extension will allow us the time necessary to properly analyze the proposal while also accommodating the extra demand on resources previously allocated to address H1N1 matters.

We thank you for considering this request for an extension to the comment period.

Sincerely,

Craig E. Colton

Craig E. Colton, CIH
Division Scientist
3M Occupational Health & Environmental Safety Division