



August 22, 2007

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NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Re: Docket # NIOSH-036

To Whom It May Concern:

Moldex-Metric, Inc. is a major safety product manufacturer. We have been in business for more than 25 years. We are a manufacturer of NIOSH approved respirators and are committed to manufacturing products that assist in protecting the health and safety of the public.

We want to ensure that our products are fitted and used properly by the public. OSHA regulations require that each respirator be fitted to each individual user. Fit testing is one element required as part of an effective and comprehensive respiratory protection program.

We were in attendance at the public meeting on June 26, 2007 hosted by NIOSH on its proposed Total Inward Leakage Concept. As we understand it, this would be an added element for NIOSH respirator approvals. We wish to offer the following concerns on this proposed concept if NIOSH goes forward with this.

The fit test panel that was developed by Los Alamos in the 1970s has become outdated due to changing population demographics. It has become evident that in order for a fit test panel to be useful it must reflect the anthropometric measurements of the current U.S. population. NIOSH has expended a large amount of resources to develop a more up to date fit test panel. Additionally, an updated grid may be a starting point for use and development of an international grid for other parts of the world where people have inherently different facial characteristics. We applaud NIOSH in this monumental task and hope that they will continue to further this important research which is invaluable to developing better respiratory protection products for the public.

We wish to point out a few areas of concern that we believe are critical to the development of a useful and updated fit test grid. The current grids developed by NIOSH use numerous facial dimensions. Facial dimensions important in fitting respirators may not be limited to the dimensions used by NIOSH. We have found that

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by performing thousands of fit tests that there are other dimensions which are critical to the fit of respirators. One of the most important dimensions that we have discovered to effect fit is nose bridge height. The critical dimension in this regard is nasal root height which we believe should be defined as the intercanthal width bisected perpendicularly and measured to the top of the sellion. If NIOSH were to proceed with their proposed facial grid for use in their TIL program to certify respirators this may eliminate the use of respirators which are made to fit faces with low or flattened nose bridges, but which will not fit a sufficient percentage of any grid to pass the TIL protocol. This will result in the loss to workers of a respirator that is used to fit workers that cannot otherwise find a respirator that fits. This would be a very detrimental result for workers.

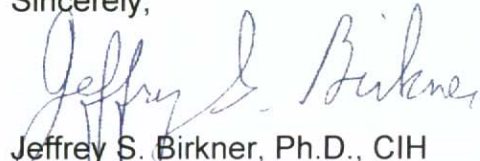
For example, it is evident that over the past several years there has been a significant shift in the ethnic population of healthcare workers in the United States. Because of the lack of healthcare workers in the United States, there has been a trend to recruit healthcare workers from other parts of the world including Asia. People from these geographic regions often have lower nose bridge height for which only a few respirators have been specifically designed for them. NIOSH's current grid does not address this population.

The other basic and possibly more fundamental concern of ours is the fact that there may not be an adequate evidentiary basis that the NIOSH grids can actually be correlated to respirator sizes. The NIOSH panel, even with the use of 35 or more people for each respirator size, will still not be able to address that grid variability which will occur temporally from one assembly of a panel to another, as well as between laboratories.

We wish to thank you for your effort in this endeavor and look forward to further discussions of the concerns that we have put forth.

We welcome the opportunity to discuss this with you further. Should you have any comments or questions please feel free to contact me at 800-421-0668, x700.

Sincerely,



Jeffrey S. Birkner, Ph.D., CIH
Vice President of Technical Services

cc: Les Boord