MOLDEX
Ideas that wear well.

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Rec'd 2/6/08

February 1, 2008

NIOSH Mailstop: C-34
Robert A. Taft Lab.
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 major manufacturer of NIOSH approved respirators
and are committed to manufacturing products that assist in protecting the health and
safety of the public. We have an in-depth understanding of the use of respiratory
protection in the United States and the world, and have substantial knowledge of the fit
testing performed by our customers, fit testing performed by us in-house on existing
products and fit testing performed by us to develop new products.

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.

The fit test panel that was developed by Los Alamos in the 1970s has become outdated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 wide range of anthropometric profiles 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 for other parts of the world where people have inherently different
facial characteristics. We applaud NIOSH in this monumental task and hope that NIOSH
will continue to further this important research which is essential to developing better
respiratory protection products for the public.

We agree that fit testing and characterizing the facial characteristics of populations that
will wear respiratory protection is an integral part of the use of respiratory protection
devices. We also believe that much more work needs to be done. It is important that
these efforts be focused on the most important aspects of respirator research so that
limited resources can be utilized most effectively. With this effort in mind, we wish to

offer our comments to the recommendations made in the Institute of Medicine's report, "Assessment of the NIOSH Head-and-Face Anthropometric Survey," as well as the NPPTL facial anthropometrics research roadmap.

With regard to IOM's comments and NIOSH's responses to the IOM's conclusions, only the most important points will be addressed and are provided as follows:

IOM Conclusion 2-1: The NIOSH-sponsored Anthrotech report did not adequately address the potential impact of measurement error on the validity and quality of the anthropometric face dimension data.

Moldex Comment: NIOSH's response is that a new study has been initiated to investigate how face size and respirator fit change over time and that they will incorporate IOM's comments in future studies. Unfortunately this does not address the extensive work that they have already performed. It is important for NIOSH to do the appropriate reassessment of their previous work as this work is critical to the future utility of the NIOSH fit test panel.

IOM Conclusion 3-1: The proposal and NIOSH-sponsored Anthrotech Report did not adequately define or represent an appropriate target population

Moldex Comment: Although NIOSH states there is little demographic information on respirator users and the new NPPTL panels incorporates the best available information, we believe that this is a critical element in any anthropometric panel. It is important for NIOSH to allocate resources to identify this demographic information prior to performing further research and also apply that information to previous studies.

IOM Conclusion 4-2: The proposed NIOSH-sponsored Anthrotech face panel selects larger-dimension faces at the expense of the smaller faces currently included in the LANL face panel, even though some of these small faces still make up a considerable proportion of the workforce.

Moldex Comment: Although NIOSH states that the NPPTL panel already covers more than 95% of the current U.S. workforce and goes on to state that this information was validated, this does not agree with their earlier statement in 3-1 that there is little demographic information on respirator users and the new NPPTL panels incorporate the best available information. It is difficult to understand how on the one-hand NIOSH states that they have little information on the user population yet they have characterized 95% of the current U.S. workforce. If the workforce that they have characterized is not 95% of the user population then this calls into question the validity of the NPPTL panels. We suggest that NIOSH go back and allocate resources to readdress this issue. This is a particularly critical issue where the respirator use demographics may rapidly shift from an industrial based user population to a healthcare based user population in the event of pandemic or a terrorist act using some type of biological agent.

IOM Conclusion 4-3: The proposed NIOSH-sponsored Anthrotech face panel is likely to be more representative of current U.S. workforce than the LANL panel, but information is not available to determine the extent to which the new panel provides a better fit for the workforce.

Moldex Comment: IOM recommends to NIOSH that they do a study comparing the new NIOSH panels with the LANL panels. NIOSH states that such a comparison is difficult because of intra and inter-subject variability seen in fit test data. This comment by NIOSH calls into question the validity of the use of panels to predict the fit of a respirator, which is what we understand is one of the things that NIOSH would like to implement. Certainly the panels are useful tools in developing new products, ensuring that existing products are efficacious to the user community, but it seems that NIOSH, by their own admission, calls into question some of the practices that they would like to use the panel for. We recommend that NIOSH carefully analyze what these panels will be used for. The question of comparing the LANL and NIOSH panels is less important than the conclusion made by IOM in 4-2 above.

IOM Conclusion 4-4: The present state of knowledge does not permit the committee to conclude with any degree of confidence that respirators that fit the proposed NIOSH-sponsored Anthrotech study face panel are likely to fit 95% of the population of workers who should be using respirators. Further, the committee was unable to determine a level of confidence or margin of error for the proposed face panel. However, the proposed panel, based on newer data, appears to be more representative of the population than the 30-year-old data used in the e L face panel.

Moldex Comments: NIOSH states that after the NPPTL total inward leakage (TIL) program for half masks is implemented, a project will be initiated to determine how well future certified respirators using the new total inward leakage requirement and the NIOSH panel fit the user population. This seems a little bit backwards. If these are issues that need to be resolved they must be resolved prior to implementing the NPPTL total inward leakage program. Failing to address these issues could severely disadvantage efficacious products already on the market and must be adequately dealt with prior to the implementation of the TIL program.

IOM Conclusion 4-5: The ultimate utility of the data collected in the NIOSH-sponsored Anthrotech study is limited because the study did not include the collection of fit-testing data along with facial measurement.

Moldex Comments: We agree wholeheartedly with the IOM that contemporaneous data would have been much more useful than NIOSH's attempt to correlate fit and facial dimensions after the Anthrotech study was completed. This was a serious flaw in the Anthrotech study that should have been considered and accounted for prior to undertaking this study.

IOM Conclusion 4-6: Proper analysis of facial dimensions have not been performed for half face respirators; lip length and menton-sellion length may not be the most appropriate dimension to use when developing anthropometric face panels:

And

IOM Conclusion 4-7: The use of multiple features in the development of face panels is likely to be inherently better than the use of just facial height and width, but it is not yet well understood which features are directly relevant to fit and how they can best be combined.

Moldex Comments: We agree with IOM and have previously provided comments to NIOSH that we believe that dimensions such as nasal height are critical dimensions in formulating a fit test panel.

IOM Conclusion 5-1: The proposed NIOSH-sponsored Anthrotech face panel represents an improvement over the LANL face panel, and its application is likely to improve the availability of respirators that fit a broader segment of the workforce. However, the committee also found that this study could have been greatly improved. In addition, the NIOSH face panels require periodic update.

Moldex Comments: We agree with the IOM on these points.

IOM Conclusion 5-2: Qualitative fit testing is a subjective process and does not provide NIOSH certification personnel with a specific value to analyze leakage around the face piece.

Moldex Comment: Although we agree that quantitative fit testing should replace qualitative fit testing for the certification process, we believe that qualitative fit testing has provided adequate information to properly certify respirators and will continue to do so until the qualitative procedures are replaced.

IOM Conclusion 5-3: The failure to use anthropometric face panels for certification of filtering face-piece respirators may result in families of respirators that do not adequately fit some of the population of workers who should be using respirators.

Moldex Comments: We agree that fit testing of filtering face piece respirators should be included in the NIOSH certification protocols as long as these protocols are reasonable and have been properly vetted by the public and stakeholders.

IOM Conclusion 5-4: Manufactures (sic) of multiple-sized face pieces often have difficulty obtaining certification for each individually sized face piece.

Moldex Comments: IOM recommends that the certification requirements should be modified such that NIOSH encourage manufacturers to develop specific sizes designed to fit underrepresented anthropometric categories. Certification requirements should be modified to allow families of respirators (e.g. small, medium, and large) to be certified against a fit-test panel and not specify what portion of the panel each individual size respirator must fit, provided that the family adequately covers the entire panel. Moldex agrees with this recommendation with one caveat. We do not necessarily believe that every family of respirators must fit the entire population. If a product is designed for a particular population segment then that family of respirators may only address the identified population segment. We believe that this was the intent of the IOM committee, but was not clearly stated.

Comments to the NPPTL Facial Anthropometrics Research Roadmap

Some of the comments to NIOSH's Roadmap have already been addressed in the comments above. Therefore, this section will only address those new items that have not already been addressed.

NIOSH's mission to do research is an important one. We believe that the health and safety of the worker is of paramount importance. With this in mind we believe that it is imperative that NIOSH choose research projects that will provide the greatest benefit to the workforce. Careful consideration must be given to the types of research that NIOSH should conduct given limited critical resources.

NIOSH Proposal: NIOSH proposes to conduct a study to determine the rate at which respirator fit changes as a function of time for a representative sample of subjects wearing filtering face piece respirators. They will look at individuals for up to 36 months and attempt to determine how fit changes over time.

Moldex Comments: We do not see great value in such a study. Given the fact that respirator wearers are required to be fit tested at least annually, we are not sure how such a study tracking change of fit on individuals over a three year period will be useful. Additionally, given the fact that only 220 individuals will be tracked and the inherent variability in fit testing data it seems unlikely that the outcome will provide useful data. If the intent of this study is to determine if fit testing is required on an annual basis, it is our position that the annual testing requirement promotes an essential educational component of the respirator program and also assures a well fitted respirator.

If NIOSH intends to move forward with the TIL program they need to do a great amount of work in determining the appropriateness of the bivariate measurements and likely should reanalyze their data and determine other additional appropriate facial dimension parameters. Also, they should devote their resources to making sure that their statistical analyses of their anthropometric panels are adequate. We believe that the public would be better served in channeling NIOSH resources in these directions rather than to
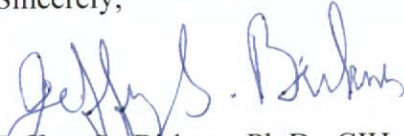
determine how respirator fit changes over a three year period, when in fact the time limiting factor for facial fit and associated changes is governed by the annual fit testing requirements.

We thank you for allowing us to provide comments on NIOSH's research objectives and would welcome further discussions.

Please feel free to call me should you wish to discuss any of these issues in further detail.

Sincerely,

Jeffrey S. Birkner, Ph.D., CIH
V.P. Technical Services