Dragon, Karen E. (CDC/NIOSH/EID)

From: Bobby Arash [barash@sflf.com]
Sent: Friday, August 31, 2007 10:16 AM
To: NIOSH Docket Office (CDC)
Subject: MS-C34, TIL - Docket # 036: Comments from Triosyn Corp.
Importance: High
Attachments: Docket NIOSH 036 - TIL testing.doc

To whom it may concern,

As a stakeholder we would like to submit our comments regarding NIOSH Reference Docket # NIOSH 036. Please attached document.

Best regards,

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Triosyn Corp.

31 August 2007

Attention:
Robert A. Taft Laboratories
NIOSH Docket Office
4676 Columbia Parkway
Cincinnati, OH 45226

RE: Reference Docket # NIOSH 036 - Comments on the Total Inward Leakage program for half-mask air-purifying particulate filtering respirator certification

In June 26, 2007, NIOSH/NTTPL held a public meeting regarding the new proposal for the total inward leakage testing and criteria for the performance testing for the new test methods. The goals of this meeting was to present the new strategies with the aim to increase the level of protection for the users of particulate respirators by reducing the inhalation, dermal and injury hazards posed by the products approved to be placed on the market. Due to the comments and responses received regarding this meeting, NIOSH has elected to extend the deadline until Friday, August 31, 2007, to submit comments to the NIOSH Docket Office on this subject matter.

Triosyn Corp. finds the draft initiative a very timely and would like to thank all the stakeholders for their contributions in this work. We believe that the new proposed testing model is a great step forward for the harmonization of the testing methodology and also to update the existing protocols to reflect the most current scientific developments. The proposal is an excellent scientific work albeit its needs of refinements, in particular with regard to its applicability as a regulatory tool to be used for the certification of particulate respirators and the impact assessment supporting the test method. Consequently, we would like to forward the following comments on the proposal:

- After assessing various documents related to the docket we believe hat there is a lack of proper impact assessment to support the new proposed method. Triosyn Corp. approves of a more realistic TIL testing and acceptance criteria as a regulatory tool, however, the proposal does not provide evidence of an increased level of protection for the wearer compared to the current testing method.

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- NIOSH/NTTPL have as a basis for a new TIL testing method provided evidence that the average facial symmetry of the US population has changed these past decades and as a corollary a new approach to assess fitness is concluded to be needed. Triosyn Corp. finds that the evidence presented undeniably reflects the most current population dynamics but the assessment does not provide evidence of causality between this dynamic change and respiratory related injuries in the country i.e. an increased level of injury.

- Title 29 CFR 1910.134 requires that each employer develop and implement a written respiratory protection program with required worksite-specific procedures and elements for required respirator use. This respiratory program includes among others provisions regarding selection, maintenance of respiratory products as well as fit testing. Title 42 CFR 84.118 defines the manufacturer design liability as "Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either by providing more than one facepiece size or by providing one facepiece size which will fit varying facial shapes and sizes."

  Consequently, the requirements are such that each individual employer is liable to ensure that the needs of the individual wearer is met by supplying a respiratory product adequate to the individual needs while the manufacturer is liable to ensure that the respiratory products remain within the scope of a benchmarked range of facial symmetry. This legal constellation ensures that the manufacturer's product liability with regard to fitness is limited.

- By introducing the facial symmetry into the certification procedure of respiratory products as an end-point, NIOSH/NTTPL will shift the burden from the employer to the manufacturer. This is a cumbersome responsibility since the manufacturer is not always involved in the fit testing procedure of the final end-user. This disruption of liability also creates practical legal problems and is without doubt a disproportionate measure where not only the protection of the users is not increased but also the manufacturer liability is increased without justification.

- Fit testing should be a requirement in order to ensure "proper use" and it should not be a burden upon the manufacturer, considering a manufacturer cannot guarantee that the produce is misused by an end-user. By adding the facial symmetry as an end point as part of the overall assessment for an approval will increase the manufacturer's liability without being proportional to the level of increased protection i.e. misuse will become the liability for the manufacturer rather then the end-user.

- The new testing procedure is inevitably proved to entail a massive increase to the costs of acquiring a certification of a respiratory product. This increase to the costs is unmotivated. In addition, this is deemed as an anticompetitive measure

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that could potentially be against the antitrust legislation. NIOSH/NTTPL has not provided any evidence that justifies the additional costs that burden the industry, and certainly does not represent the current Federal agencies'' philosophy concerning "least burdensome approach".

- Manufactures are asked to pretest their respirators prior to submitting them to NIOSH/NTTPL. This testing will be conducted following the NIOSH STP for fit testing. It would be an excellent opportunity for the manufactures, if NIOSH would accept the pretest results as acceptance criteria for the fit test requirements without asking them to pay for a 2nd round of testing to be conducted at NIOSH/NTTPL.

- Finally, Triosyn Corp. believes that the new testing procedure sidesteps from a global harmonization of the requirements for respiratory products. We believe that this new method will give rise to unreasonable international trade barriers. The understanding of industry is that the federal government strives to harmonize and align the 42 CFR 84 requirements for respiratory products with other standards such as EN149 or AS/NZS1716 in order to decrease potential trade barriers.

Best regards,

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