

Via email: niocindocket@cdc.gov

September 30, 2010

NIOSH Docket Office
Robert A. Taft Laboratories, MS-C34
4676 Columbia Parkway
Cincinnati, OH 45226

**ISEA Comments on 42 CFR Part 84 Notice of Proposed Rulemaking (NPRM)
Total Inward Leakage Requirements for Respirators, 42 CFR Part 84, RIN 0920-AA33**

The International Safety Equipment Association (ISEA) is the trade association representing suppliers of personal protective technologies, including respiratory protective devices certified by NIOSH. ISEA welcomes the opportunity to provide additional comment on the Notice of Proposed Rulemaking (NPRM) on 42 CFR Part 84 Total Inward Leakage Requirements for Respirators and offers the following comments related to the economic impact of the proposed rule.

In its discussion of the proposed regulation, NIOSH has stated that "This proposed rule is not considered economically significant, as defined in section 3(f)(i) of the executive order [12866]" (74 FR 56147). ISEA contends that the agency is incorrect in its assessment and that the total economic impact to all stakeholders could well reach over \$1 billion based on the combined estimates of factors related to annualized sales impacts, product development costs and end-user selection and training.

Size and Percentage of Market Impacted

NIOSH, in part, based its determination that the proposal would be economically insignificant on sales data from 2001 and a Frost and Sullivan report published in 2005 (74 FR 56148). The Frost and Sullivan numbers do not account for respirators used in the healthcare market, nor do they reflect devices sold due to pandemics such as the H1N1 virus where stockpiling is an issue. Furthermore, they do not capture the impact of international sales and markets. NIOSH is remiss in not assessing this aspect given that many manufacturers are global companies that sell products worldwide. Many other nations, including emerging growth areas such as certain South American countries, look to NIOSH protocols and require NIOSH certification for respiratory protection used by their workforces. ISEA believes that in using outdated market data combined with absence of data for key factors as noted above, NIOSH has considerably underestimated the true economic impact of this proposed rule.

ISEA members engaged in the manufacture of respiratory devices represent nearly 97% of NIOSH product certifications that have been issued. A survey of these manufacturers indicates that the economic impact on annualized sales is approximately \$629.7 million. This number is based on more current data and a conservative estimate of those variables that NIOSH did not consider.

A 2008 Frost and Sullivan report showed North American respirator sales in 2007 to be \$386.1 million for filtering facepiece and \$231.0 million for elastomeric half-facepiece respirators [Frost & Sullivan Report #N2E7-39 North American Respiratory Protective Equipment Market, 2008]. As ISEA pointed out in its comments to the docket filed on March 29, 2010, an ISEA-commissioned study anticipates that 90% of currently approved filtering facepiece respirators would not pass the proposed TIL protocol and 50% of currently approved half-mask elastomeric respirators would not pass. When multiplying these values with the respective North American market sales, the known impact to annual sales in North America alone can be calculated:

$$(90\%)(\$386.1 \text{ million}) + (50\%)(\$231 \text{ million}) = \$462.9 \text{ million.}$$

The Frost & Sullivan report only covers North American sales. Manufacturers report that international sales impacted by this proposed rule represent an additional 30% of sales of NIOSH-approved respirators, bringing the total impact globally to \$601.7 million.

Another shortcoming of NIOSH's determination that the proposed rule would not have a significant burden is that the data the agency relied on did not account for sales in the healthcare market. Data published by the Global Health Exchange indicate that the collective sales of respirators to healthcare facilities, as tracked by the U.S. Food and Drug Administration in 2008, was approximately \$28 million. In 2009, collective sales neared \$60 million with the increase attributed to the anticipated pandemic of the H1N1 virus. This data is not broken down by filtering facepiece or elastomeric respirators, but it is generally assumed that 95% of respirators used in healthcare are filtering facepiece models. Breaking down the 2008 healthcare sales data by this percentage and using the pass/fail assumptions from the ISEA study,

$$(90\%)(\$26.6 \text{ million}) + (50\%)(\$1.4 \text{ million}) = \$24.6 \text{ million.}$$

When combining this data with the global sales impact in other markets, the annualized sales that would be impacted is over \$626 million. This can hardly be quantified as an economically insignificant sum.

Cost of New Product Development

In the proposed rule, NIOSH has estimated that the cost of testing "would range from \$8,500 to \$12,000 per respiratory approval" and "total testing and certification costs to manufacturers of up to \$3.1 million" (74 FR 56147). ISEA members are confident that this underestimates the cost to manufacturers for each development program and it understates the potential number of re-designs that will be required in order to comply with the proposed rule.

NIOSH has estimated that "applications for up to 500 approvals in the first two years of implementation of TIL requirements" (74 FR 56147), but claims it is not possible to estimate the number of existing products that would not meet the proposed TIL requirements. Using ISEA's previously mentioned study, it is possible to estimate a total failure rate of 70% of existing products that would have to be redesigned to attempt to pass the TIL protocol as currently drafted $[(90\%) + (50\%)] * 2$ or 350 of the 500 approvals NIOSH has cited. Redesigning each one of these 350 respiratory devices comes with costs related to employee overhead, length of time it takes to develop the project, and capital and supply costs. The average of these costs for one device can conservatively be valued at \$1.5 million. Cumulatively, the costs for redesigning could cost the manufacturing stakeholders \$525 million over two years.

As the costs for putting products on the market begin to reach this level, manufacturers may be forced to make business decisions that affect product offerings. If companies ascertain that it is not economically prudent to manufacture the variety of devices currently supplied, workers considered to be "outliers" of the panel may have little to no choice in product selection, jeopardizing their ability to work in industries and on worksites where respiratory protection is required. Manufacturers believe that the average estimated per-project cost could even exceed the \$1.5 million estimate as it may cost even more to redesign a quality product already in the marketplace. It would likely be more difficult to identify the flaws of a good product versus a poor one, requiring the manufacturer to redesign and retest multiple times in order to find the point of failure. Furthermore, the cost of new product development and redesign will carry over to other respiratory devices such as powered-air purifying respirators and SCBAs, whose products often include the same mask design as those devices covered by the proposed rule.

End-user Selection, Refit and Retraining Costs

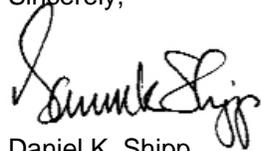
In its October 29, 2009 *Federal Register* notice, NIOSH states that the agency does do "not anticipate additional costs to consumers...as a result of the proposed TIL requirements" (74 FR 56147). It is

unrealistic to expect that businesses would not be subject to any increased expense in selecting respiratory protection for the nearly 2 million workers who wear these devices today.

Size, resources, and worker requirements vary widely, but even at a conservative estimate of \$100 per employee related to lost productivity and training, equipment costs can quickly add up and represent an economic burden to those whom the proposed rule is intended to benefit. A collective cost to the respirator wearing community can be illustrated in simple terms. By multiplying the percentage of the 2 million U.S. employees who would need to be re-tested and retrained (70 %) by the cost per employee, measured in downtime and training equipment (consensus estimate from ISEA members is \$100/hour per employee) and assuming that it takes an estimated 0.25 hour of time to find a new respirator model for an employee, the collective cost end-users would exceed approximately \$35 million.

Combining the estimated economic burdens related to sales, product development and end-user selection and training, it can be calculated that the total economic impact of moving forward with the proposed rule would exceed \$1 billion. ISEA does not see how NIOSH can justify this amount in implementing a protocol that offers no additional worker protection and is flawed in its technical rationale for reasons articulated in ISEA's previously submitted comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel K. Shipp". The signature is written in a cursive, flowing style.

Daniel K. Shipp
President