

# **ISEA** Industrial Safety Equipment Association

March 1, 1996

Dr. Bryan D. Hardin, Ph.D.  
Acting Deputy Director  
National Institute for Occupational  
Safety and Health  
4676 Robert A. Taft Laboratories  
Cincinnati, Ohio 45226-1998

Dear Dr. Hardin:

The Industrial Safety Equipment Association (ISEA) recently obtained a copy of a February 8 letter you sent to several of our member companies. The letter accompanied a draft two page "Respirator Users Notice," which apparently is intended for general distribution. ISEA is concerned about the harmful impact this document could have on the user community if it is distributed as currently drafted.

Your letter indicated that by releasing this document, NIOSH intends to recommend restrictions on the use of DM and DFM respirators and to highlight the importance of comprehensive respirator programs. While ISEA does not disagree with the intended objectives of the draft users notice, we do not believe that the draft will do what it sets out to accomplish and may actually cause unintended harm.

In fact, ISEA believes that by effectively forcing the regulated community to use more expensive high efficiency filters until 42 CFR 84 products are approved and widely available, the users notice will effectively eliminate the grandfather period for 30 CFR 11 products and inappropriately raise the cost of respiratory protection. ISEA recommends, therefore, that NIOSH not issue this notice and offers the following comments in support of our recommendation.

#### **No Notice is Needed**

ISEA does not contest the issues raised in the draft users notice regarding the use of DM and DFM filters. As you indicated, both NIOSH and ANSI have addressed concerns about the protection these filters provide against the very smallest particle sizes. It seems unnecessary, therefore, to revisit the issue in a new guidance document. Furthermore, by raising the issue of small particles in the draft users notice, NIOSH implies that it has discovered a new threat to the health of end users. In fact, these issues are well known and are understood in the general respiratory protection community. ISEA does not believe, therefore, that the users need additional notice regarding the performance of Part 11 DM and DFM respirators.

As for the importance of comprehensive respirator programs, this is clearly addressed in the Occupational Safety and Health Administration's current respiratory protection rule and need not be restated by NIOSH.

### **This Notice Will Effectively Raise the Cost of Respiratory Protection**

One of the motivating forces behind NIOSH's development of 42 CFR 84 was the need to provide end users with greater protection at a lower cost. Once Part 84 products are commercially available, this goal will be achieved. NIOSH's recommendation of new 42 CFR 84-certified respirators, however, is premature. The backlog in the certification process in Morgantown is critical and continues to grow. Granted, in part this is the result of delays caused by severe winter weather and the federal government's shutdowns and associated furloughs, but the certification process currently is taking at least six months from submission to approval.

As a result, very few Part 84 products are commercially available. Essentially, this notice would recommend the users of respirators that NIOSH has not yet approved in adequate numbers. Not only does this give an unfair advantage to manufacturers whose applications were pulled first in the July 1995 lottery period, it also overlooks the fact that Part 11 products are valid for use at least until July 1998.

Because few Part 84 products are commercially available and the vast majority of the products submitted for approval have not yet been certified, the draft notice ultimately would drive end users to purchase more expensive Part 11 HEPA filters, which is contrary to the objectives of 42 CFR 84.

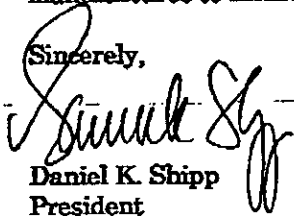
### **Elimination of Grandfather Period for Part 11 Filters**

ISEA believes that the users notice would effectively eliminate the remainder of the grandfather period established by NIOSH for manufacturing, distribution and selling DM and DFM respirators certified under 30 CFR 11. In large part, the grandfather period established by NIOSH in 42 CFR 84 was intended to give manufactures time to develop new products and have them certified by NIOSH. By pushing end users to HEPA and Part 84 products, however, NIOSH unnecessarily limits the market for DM and DFM filters and violates the spirit of the grandfather clause.

In addition, the users notice would effectively eliminate the grandfather period and raise the cost of respiratory protection without following proper rulemaking procedures. This is clearly contrary to the policy expressed in President Clinton's Executive Order 12866 and recent federal guidelines.

ISEA strongly recommends that NIOSH reconsider its decision to issue a users notice. The Institute's time and resources could be spent more productively if it focused on working with manufactures to facilitate and improve the new product approval and certification process.

Sincerely,



Daniel K. Shipp  
President