

July 8, 2008

Docket Officer  
Room N-2625  
U.S. Department of Labor - OSHA  
200 Constitution Avenue NW  
Washington, DC 20210

**Re: Docket No. OSHA-2008-0005  
OSHA proposed rule on workplace stockpiling of respirators for pandemic influenza**

The International Safety Equipment Association (ISEA) is the trade association for personal protective equipment (PPE), including respiratory protection, head, eye and face, hearing and fall protection; protective clothing and gloves; high visibility safety apparel; emergency eyewash and showers; first aid kits and gas detection instruments. Its member companies are world leaders in the design and manufacture of PPE for workers. ISEA is accredited by the American National Standards Institute (ANSI) as a standards developing organization, and is responsible for development and publication of numerous American National Standards for personal protective and safety equipment.

ISEA shares the common mission with OSHA to protect the health and safety of workers and supports the effort of the agency provide supplemental information for employers on respirator use in a pandemic event.

ISEA offers the following comments on the guidance provided and questions asked by OSHA in its request for comments on the proposed guidance, as published in the May 9, 2008 *Federal Register*.

*General Comments*

**Facemasks**

OSHA needs to be very clear in this section that FDA-cleared surgical, medical, procedure, dental, laser and isolation masks are not designed, tested, evaluated or certified to protect the wearer.

**Respirators**

Throughout the document, OSHA needs to be clear that terms such as “disposable,” “reusable,” “filtering facepiece,” “elastomeric,” and “N95” are not interchangeable. These terms all define specific characteristics of an air purifying respirator.

OSHA differentiates between the protection afforded by filtering facepiece respirators and reusable elastomeric respirators. However, APFs do not differentiate between half mask filtering facepieces and elastomerics. OSHA needs to clarify that according to its own regulation,<sup>1</sup> the same protection is afforded by fit tested filtering facepiece half masks and elastomeric half masks, but that higher fit factors may be achieved with full face-piece respirators and PAPRs.

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<sup>1</sup> 29CFR1910.134

## **Assumptions**

OSHA states that facemasks will only be used by employees during pandemic waves in their local community/state, not between pandemic waves, and only for tasks that pose an exposure risk.

ISEA believes that it will be difficult to define when a specific wave of active infection within a community is actually occurring. Identifying waves of infection and the time between active infection is not delineated nor is it effectively communicated during an outbreak. These periods are usually identified in a post event evaluation by surveillance data. In fact the entire period will likely to be marked by chaos and uncertainty, leading to more use of protective equipment, not less.

## **Estimating Respirator Usage**

OSHA states that facemasks are recommended to protect employees with high-frequency close contact with the general public. But OSHA should be clear that facemasks are not designed, tested, evaluated or certified to protect the wearer.

## **Stockpiling Estimates**

In table 2, note 2 OSHA provides an explanation of its recommendation for four respiratory protection devices per shift, without specifying the length of the shift. ISEA believes that it would be helpful to the user community to include examples of respirator use scenarios for shifts that are greater than 8 hours. Healthcare personnel commonly work shifts that vary in length as a normal schedule. Some are 8 hours, but more often shifts are 10 or 12 hours long. During SARS, it was common for health care personnel to work more than 8 hours once they arrived at a facility.

## **Terms/Definitions**

Terms such as “long time” and “rough estimate” should be avoided as they are subjective and can have multiple interpretations.

When OSHA discusses the need for stockpiling additional elastomeric respirator filter sets, they should state how many are needed based on pandemic duration times.

### *Specific Comments*

## **Facemasks**

Because the term “facemask” is used differently in this document than in the general population, we suggest that the definition be placed as the first sentence in this section. In addition the statement of “without respiratory protection” should be added to make it clear that facemasks do not provide this type of protection. The first sentence of the second paragraph on page 5 would read: “The term “facemask” is used in this guidance to refer to Food and Drug Administration (FDA) - cleared surgical, medical, procedure, dental, laser and isolation masks without respiratory protection.”

## Respirators

This section defines and discusses air purifying respirators. It is important to maintain the distinctions between types of respirators, whether they are single-use or reusable, and filter efficiency.

N95 is not synonymous with filtering facepiece. N95 refers to the filter efficiency and type of aerosol and does not indicate the type of respirator. N95 filters are available on elastomeric facepieces (i.e., half or full) and filtering facepieces. ISEA recommends that the discussion of NIOSH certification in the first bullet point at the bottom of page 5 be moved to the previous paragraph:

Air purifying respirators are the type of respiratory protection recommended to reduce exposure risk to pandemic influenzas in certain occupational settings. Although the most commonly used air purifying respirators are those meeting the N95 filtration requirements, it is important to note that other National Institute for Occupational Safety and Health (NIOSH)-certified N-, R-, or P- respirators (e.g., N99, R95 and P100) provide an equivalent or greater level of exposure reduction to airborne particulates as an N95 and can be used if N95s are not available. Air purifying respirators can be divided into several types. Each of these is described below; Table 1 provides a comparison of these respirator types.

### Filtering Facepiece Respirators

The terms “disposable” and “filtering facepieces” are not synonymous. The term “disposable” indicates how the respirator is to be used rather than a type of protection. OSHA has defined “filtering facepiece” in 29 CFR 1910.134. There is no definition for “disposable.”

ISEA suggests that the first bullet point should begin “*Filtering facepiece respirators* are a type of air purifying respiratory protection in which the entire respirator facepiece is comprised of particulate filter material. They are intended to be disposed after a single use.” Delete the sentences beginning “It is important to note...” and ending “if N95s are not available” as they have been moved to the previous paragraph.

### Elastomeric respirators

The third bullet point defines “reusable elastomeric respirators,” but the last sentence notes that some elastomerics are designed to be disposed of when the cartridges need to be replaced. The word “reusable” should be deleted from the first line. Additional wording would clarify that elastomeric facepieces can be half- or full-facepiece:

- *Elastomeric respirators* are a type of respiratory protection that has a flexible, rubber-like facepiece with filter cartridges. The facepiece may be one of two styles; a half facepiece or full facepiece. The facepiece can often be cleaned, repaired and reused, and the filter cartridges can be discarded and replaced when they become unsuitable for further use. Other elastomeric respirators are designed to be disposed when the filter cartridges need to be replaced.

## Powered Air Purifying Respirators

ISEA recommends the following changes to clarify the definition of PAPRs:

- *Powered air purifying respirators (PAPRs)* are a type of respiratory protection in which a battery-powered blower pulls *or pushes* air through filters that trap particles (including those containing viruses and bacteria) that may be present, and then moves the filtered air to the wearer's facepiece, *helmet* or hood. PAPRs are significantly more expensive than other air purifying respirators but they provide higher levels of protection against airborne particulates *than half mask air purifying respirators*. It should also be noted that there are hooded PAPRs that do not require employees to be fit tested in order to use them. Additionally, a PAPR blower unit and battery can be shared by employees (who need protection at different times) who can each have their own reusable *or disposable* hood. A PAPR could be assigned to an individual person, to a staff position (e.g. a floor nurse position staffed by several employees over the course of a week), or to a location such as a treatment room or mobile treatment cart used for aerosol generating medical procedures. Consequently, several approaches can be used to limit the number of PAPRs that an employer would purchase for pandemic preparedness, as long as proper decontamination procedures *for the hood* are followed between uses or users.”

## Replacing Elastomeric Respirator and PAPR Filters

OSHA should state that filters will be contaminated after use around infectious patients so they need to handle the filters with care as they could be putting dirty filters back onto a clean respirator. Good hand hygiene is necessary. This paragraph properly warns about filters being contaminated with blood or body fluids; however, it should also state that the bloodborne pathogen standard<sup>2</sup> requires immediate removal of filters if they are penetrated by any blood or other potentially infectious materials.

### Table 1: Advantages and Disadvantages

In row 2, column 1, replace “N95 respirator (filtering facepiece)” with “Filtering facepiece respirator.” Make the same change in row 3.

In row 4, column 1, replace the term “surgical respirator” with “N95 surgical respirator” to clarify that it is a NIOSH-certified respirator.

In row 5, column 2, we also do not believe the price range includes full facepiece air purifying respirators even though they are mentioned in this box. The price range is probably somewhere in the range of \$100 – \$230 for a full facepiece.

For more information on ISEA respiratory protection programs, or questions regarding these comments, contact ISEA technical director Janice Comer Bradley, CSP.

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<sup>2</sup> 29CFR 1910.1030