

July 22, 2010

Influenza Coordination Unit, Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Attn: Prevention Strategies for Seasonal Influenza in Healthcare Settings
1600 Clifton Road, NE., MS A-20
Atlanta, GA 30333

Re: Updated Guidance: Prevention Strategies for Seasonal Influenza in Healthcare Settings, 75 FR 35497, June 22, 2010

Dear Sir or Madam:

The International Safety Equipment Association (ISEA) is the trade association for personal protective equipment (PPE), including head, eye and face, hearing, respiratory 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 members design, manufacture, sell and service the full range of PPE, including respiratory protection, used in healthcare settings. ISEA recognizes the importance of providing comprehensive, relevant and practical guidance that will result in meaningful protection of Healthcare Personnel (HCP) exposed to seasonal influenza. We offer the following suggestions for changes which we believe will increase clarity in the guidance.

On Page 35501, first column, the third bullet point under "*V. Adhere to Droplet Precautions,*"), the proposed guidance states:

- HCP should don a facemask when entering the room of a patient with suspected or confirmed influenza. Remove the facemask when leaving the patient's room, dispose of the facemask in a waste container, and perform hand hygiene.

If an HCP is entering the room of a confirmed influenza patient, a facemask (ie, surgical mask), which is not tested or designed to protect the wearer from harmful exposures, may not be appropriate.

If CDC recommends surgical masks for protection of the wearer, there should always be a following recommendation that the wearer be given clear information as to when a NIOSH-certified respirator would be the proper choice. Surgical masks have limitations in protecting the wearer from some airborne infectious diseases, and the guidelines should include a provision for assuring that HCP have access to information in selecting the proper device.

On Page 35501, middle column, the sixth bullet point under "*6. Use Caution When Performing Aerosol-generating Procedures,*" states:

- HCP should wear respiratory protection equivalent to a fitted N95 filtering facepiece respirator (*i.e.*, N95 respirator) or higher level of protection (*e.g.*, powered air purifying respirator) during aerosol-generating procedures (See definition of respirator in Appendix).

While we believe CDC's intent is correct, ISEA believes this wording is potentially confusing. NIOSH-approved filtering facepiece respirators come in higher levels of protection than N95 (e.g. N99, P100, etc.). N95 respirators can also have elastomeric facepieces. Similarly, a powered air purifying respirator (PAPR) can be an N95.

CDC should clarify that a worker exposed to aerosol-generating procedures should wear a NIOSH-approved, fitted N95 or higher filtration respirator. Then language could be added to the definition in the appendix to note that N95 is a measure of filtration efficiency, and that N95 respirators may also be filtering facepiece, elastomeric or PAPRs.

On Page 35502, under the Appendix, CDC defines "facemask" as follows:

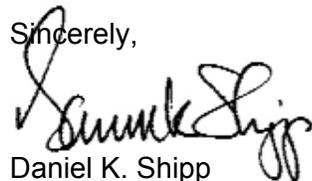
- A facemask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Facemasks may be labeled as surgical, laser, isolation, dental or medical procedure masks. They may come with or without a face shield. If worn properly, a facemask is meant to help block large-particle droplets, splashes, sprays or splatter that may contain germs (viruses and bacteria) from reaching your mouth and nose. Facemasks may also help reduce exposure of your saliva and respiratory secretions to others. While a facemask may be effective in blocking splashes and large-particle droplets, a facemask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes or certain medical procedures.

ISEA believes a rewording of this definition would clarify that facemasks are designed primarily for patient protection, and have limited value as personal protective equipment (revised text is underlined):

- A facemask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Facemasks may be labeled as surgical, laser, isolation, dental or medical procedure masks. They may come with or without a face shield. Facemasks are designed to protect the patient by reducing exposure of the wearer's saliva and respiratory secretions to others. If worn properly, a facemask may help block large-particle droplets, splashes, sprays or splatter that may contain germs (viruses and bacteria) from reaching your mouth and nose. A facemask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes or certain medical procedures.

ISEA appreciates the opportunity to comment on these proposed guidelines, and the association looks forward to continuing to work with CDC to protect the safety and health of healthcare personnel.

Sincerely,



Daniel K. Shipp
President