

August 4, 2010

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

Re: Request for Information: Infectious Diseases; Docket No. OSHA-2010-0003

The International Safety Equipment Association (ISEA) is pleased to offer comments on the Request for Information on Infectious Diseases. 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 comprehensive, relevant and practical OSHA regulations that will result in meaningful protection of the nation's healthcare workforce from infectious diseases.

Below are selected questions from the RFI and the association's responses.

Question 2. While OSHA is primarily concerned about worker exposure to infectious agents in traditional healthcare settings, the Agency recognizes that there are other settings where healthcare may be provided and where occupational exposure to infectious agents may be a significant concern (e.g., drug treatment facilities, home health services, prison clinics, school clinics, and laboratories that handle potentially infectious biological materials). Please describe any other work settings with an increased risk for occupational exposure to infectious agents that OSHA should consider, including why they should be considered. Please describe the nature and extent to which occupational exposure to infectious agents is a significant concern. For example, to which infectious agents are workers in these settings exposed and how often are they exposed? Please describe any infection control measures that can be or are being used in these settings.

ISEA Comment: In addition to workplaces mentioned in the RFI, other work settings where employees could be exposed to infectious diseases include:

- Various utilities and construction worksites, which could involve exposure to rodent and bird waste. While not transmissible from person to person, the hantavirus is transmitted by aerosolized rodent excreta.
- Employer-based health facilities.
- US Customs, border crossings and immigration sites where federal workers could be exposed to infectious agents, including TB, which is active in many parts of the world, including Central America. To this point, a *USA Today* article ("Reports of sick travelers climb," July 21, 2010, page 3A) noted that "Federal health officers logged more than 3,000 cases of potentially infectious diseases among travelers in the past year, including airlines passengers with tuberculosis, whooping cough, measles, mumps and typhoid fever...";

ISEA believes the best infection control measures for the federal workforce and its contractors is to train workers on recognizing signs of infected individuals and to make certain workers in these settings have available and use proper gloves, NIOSH-certified respirators and other PPE needed.

Finally, if a person, who does not know he/she is infected and goes to work, any workplace could become a site of transmission.

Question 4. Workplaces vary in the types of infectious diseases and the number of infected individuals encountered. OSHA is interested in the types of diseases that your workplace encounters and how often they are encountered. Please describe your workplace's experience with infectious diseases over the past ten years (e.g., which diseases, how often).

ISEA Comment: OSHA must be prepared for all emerging infectious diseases.

As a general comment, the scope of any OSHA rule on infectious diseases must be as broad as possible. In addition, until scientific and peer reviewed research determines that an agent is transmitted via one form or another, the default requirement must be to protect workers from all routes of exposure, and to make certain workers use NIOSH-certified respiratory protection that is fit-tested, where applicable and other types of appropriate PPE.

Question 7. While OSHA has a Bloodborne Pathogens standard (Sec. 1910.1030) the Agency does not have a comprehensive standard that addresses occupational exposure to contact, droplet, and airborne transmissible diseases. The Agency has other standards [(e.g., Respiratory Protection (Sec. 1910.134) and General Personal Protective Equipment (Sec. 1910.132)] that may apply and, in some situations, Section 5(a)(1) of the OSH Act (the General Duty Clause) would apply. OSHA is interested in commenters' insights regarding the adequacy of existing OSHA requirements to protect workers against occupational exposure to infectious agents.

ISEA Comment: An OSHA regulation for infectious disease is needed. The regulation must be clear and be specification-based. ISEA member companies receive a vast number of questions from healthcare respiratory protection users asking "What do I need?" and "What does OSHA require?". The association understands PPE distributors receive these questions, too. Detailed regulations and clear guidance documents about the appropriate PPE and respiratory protection, written in a manner all users can understand, will be a beneficial service to all in the health-related community, other workplaces and the PPE supply chain.

ISEA believes that 1910 Subpart I, Personal Protective Equipment, offers adequate worker protection by requiring NIOSH-certified respirators that are fit-tested, unless workers are using a powered air purifying respirator; hand protection, eye and face protection and other types of PPE needed to keep workers safe.

Question 8. California OSHA recently issued a standard for occupational exposure to "Aerosol" Transmissible Diseases that covers infectious diseases transmitted through the airborne and droplet routes. IC programs that are established in most healthcare settings address exposure to contact, droplet, and airborne transmissible diseases. Please explain whether the Agency's deliberations on occupational exposure to infectious diseases should focus on only droplet and airborne transmission or if contact transmissible diseases should also be included.

ISEA Comment: OSHA must consider all routes of exposure.

In a June 22 Federal Register notice (75 FR 35498) proposing to update seasonal flu infection control practices for health care professionals, the CDC notes that in the past, influenza viruses have been thought to spread from person to person primarily through large-particle respiratory droplet transmission (e.g., when an infected person coughs or sneezes near a susceptible person) through the air. However, CDC now recognizes that indirect contact transmission of influenza virus via hand transfer from virus-contaminated surfaces or objects to the nose, mouth and eyes may be possible, and that airborne transmission via small particle aerosols in the vicinity of the infectious individual may also occur. CDC says the relative contribution of the different modes of transmission is unclear.

Because the route of exposure to infectious diseases could be from large droplet, contact or aerosolized droplet nuclei, OSHA must require protection against all three possible routes. This includes protection

from exposure via the respiratory system, eye and face, ears and other dermal routes, which require use of gloves and gowns. OSHA should address all types of needed PPE in any future rulemaking.

As more information becomes known, the types of PPE recommended or required by OSHA must be appropriate to the agent and the route of exposure.

Question 9. If the Agency pursues rulemaking and promulgates a standard, jurisdictions with OSHA-approved State plans will be required to cover workers who OSHA determines are at occupational risk for exposure to infectious agents, including public employees. State and local governments are defined very broadly, and would typically include such entities as a university hospital associated with a State university as well as public hospitals and health clinics. (1) What public sector healthcare or healthcare-related workers are at increased risk for occupational exposure to infectious agents? (2) Please describe conditions unique to any of these occupations that are not seen in the private sector. (3) Please describe any other issues specific to OSHA-approved State plans that the Agency should consider.

ISEA Comment: Firefighters and emergency medical technicians (EMTs) are at an increased risk for occupational exposure to infectious agents. If an individual falls ill at work or even at home, an ambulance may be called.

Public sector workers in federal-OSHA states should have the same protection as their counterparts in states with OSHA-approved plans (which are required to cover public sector workers).

It would be in the nation's interest to urge federal-OSHA states to provide their public sector workers with the same protections as workers covered under OSHA regulations. This would limit the number of people who could become vectors and spread disease to others. To this end, ISEA believes OSHA must cover as many workers as possible.

Question 22. The use of proper PPE is an essential component of an effective IC program, from airborne exposures. For example, CDC/HICPAC recommends that facemasks (e.g., surgical masks) be worn by workers when droplet precautions are implemented and respirators be worn under certain circumstances when airborne precautions are in place. Please describe how your workplace determines when a facemask (e.g., surgical mask) is used for worker protection and when a respirator is used for worker protection. How does your workplace determine which employees use a facemask and which use a respirator? If your workplace uses different types of respirators, please describe what types and when they are used.

ISEA Comment: ISEA believes facemasks (e.g., surgical, laser, isolation, procedure or dental masks labeled as FXX masks) should never be used for worker protection from airborne exposures. These devices are not designed to protect wearer from airborne exposures.

In 2009, OSHA and CDC asked the Institute of Medicine (IOM) to provide recommendations on necessary respiratory protection for healthcare workers in their workplace against nH1N1. In its final report¹ to OSHA, the IOM committee made a clear recommendation to use fit-tested N95 respirators. The report further stated that workers who are in close contact with individuals with nH1N1 influenza or influenza-like illnesses should use fit-tested N95 respirators or respirators that are demonstrably more effective as one measure in the continuum of safety and infection control efforts to reduce the risk of infection. The report also states employers should ensure the use and fit testing of N95 respirators in accordance with OSHA regulations.

The IOM report states "...the use of medical masks is unlikely to be effective against airborne transmission (Oberg and Brosseau, 2008). Medical masks are not designed to provide a tight seal to the

¹ IOM (Institute of Medicine). September 1, 2009. *Respiratory protection for healthcare workers in the workplace against novel H1N1 influenza A: A letter report*. Washington, DC: The National Academies Press.

face, and there was considerable evidence in laboratory studies of leakage of materials under and around the medical mask from the unfitted margins.”

The Food and Drug Administration, which has regulatory authority for surgical masks, states on its website “[w]hile 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. Facemasks also do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the facemask and your face.”

Moreover, speaking at a June 3 IOM meeting about Healthcare Worker PPE, respiratory protection expert Lisa Brosseau, Sc. D., concluded her presentation² on respirators and surgical masks noting that “surgical masks do not fit and will not adequately protect the wearer from aerosol exposures.”

Because the route of exposure to infectious diseases could be from large droplet, contact or aerosolized droplet nuclei, OSHA must require protection against all three. This includes use of NIOSH-certified respiratory protection to protect the wearer.

Question 23. NIOSH regulates the testing and certification of respiratory protective equipment, has established minimum performance standards, and conducts independent testing and verification of all respirators prior to certification. The Food and Drug Administration (FDA) approval process for facemasks does not have established minimum performance standards and allows manufacturer submitted data. As noted in a 2009 IOM report, a 2008 study that examined the filter performance of nine different types of facemasks using the sodium chloride NIOSH challenge test, found wide variation in penetration (4 percent to 90 percent) of smaller aerosol particles. Therefore, the protective properties of different manufacturers' facemasks may vary. Is there a need for a more rigorous certification/approval process for facemasks and additional independent verification of the personal protective properties of these devices?

ISEA Comment: FDA distinguishes between facemasks and respirators with separate classifications for these medical devices: FXX Surgical Mask and MSH Surgical N95 NIOSH certified Respirator. The MSH classification is by definition a NIOSH-certified N95 respirator, tested to meet the 95% penetration criteria. The FXX Surgical Mask is not. Although there may be a benefit to the healthcare community to have assurance of a certain level of penetration performance for an FXX type device, this device is not a respirator.

There is a greater need for language that clarifies the fact that a facemask is only an FXX type device. The term “respirator” is used to describe a NIOSH-certified device, including an MSH-type device.

Since facemasks are not intended to create a tight seal on the face of the user to protect from respiratory hazards, a requirement for a filtration test on an FXX type device would be unnecessary and misleading.

Question 29. In order to appropriately evaluate the health status of a worker, some basic health information is needed. CDC/HICPAC recommends a personnel health service program for infection control that includes a number of components including: pre-placement evaluations, evaluation and treatment of exposure-related illnesses, and work restriction or work-exclusion policies for exposed HCWs. OSHA is interested in the prevalence, content and efficacy of such personnel health service programs.

(a) What should be included in a pre-placement medical evaluation for a worker who will be exposed to infectious agents? Please describe the possible components of the medical history and physical exam and specific tests (e.g., TB skin test, spirometry, blood tests). How are pre-placement medical evaluations of workers addressed in your workplace? What do these evaluations include? If pre-placement medical

² *Update on Respirators and Surgical Masks Review of Literature (2007-2010)*, presented at the IOM “Workshop: Current Research Issues—Personal Protective Equipment for Healthcare Workers to Prevent Transmission of Pandemic Influenza and Other Viral Respiratory Infections” June 3, 2010.

evaluations are used in your workplace, have they been effective, and what metrics are used to evaluate effectiveness? Give the rationale, including references if available.

ISEA Comment: OSHA should define “pre-placement medical evaluation.” It is unclear to ISEA if this term relates to compatibility, sensitivity, and temperament to use PPE. If so, OSHA should define this term and add “pre-placement evaluation” in an appendix to 1910.134.

Question 36. What are the potential benefits of more widespread compliance with infection control guidelines? How can OSHA best assure such compliance takes place?

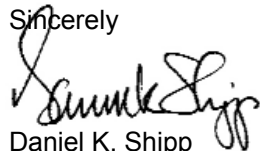
ISEA Comment: A regulation for infection control guidelines would prevent take-home exposures. OSHA recognizes the benefit of preventing take-home exposures in various regulations, such as the asbestos regulations found at 29 CFR 1910.1001(h). When asbestos concentrations exceed the PEL, OSHA specifies both use of protective garments and requirements for donning, doffing and care of these garments worn by workers.

Reducing take-home exposures would help to limit the number of potential spreaders/vectors (who could be family, friends, roommates, etc....). In addition, children are doubly at risk since there is no PPE for them and because they are usually more susceptible to infection. Moreover, if a child becomes contagious from a parent, who, for example, might be a healthcare worker, and takes the infection to school, the disease could spread geometrically.

The potential benefits of compliance with an OSHA rule on infectious diseases would be a healthier healthcare workforce, less “take home” exposures, and other beneficial workplace and public health outcomes.

ISEA appreciates the opportunity to provide answers to these questions, and the association looks forward to continuing to work with OSHA to protect the safety and health of healthcare personnel.

Sincerely



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