



National Association of State EMS Officials

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## **NASEMSO Issue Brief: The Use of N95 Masks and Fit Testing Requirements for EMS Personnel**

### **Issue**

Several recent studies and media reports have provided conflicting information with regard to the use of N95 masks and fit-testing for exposure to airborne infectious diseases, such as H1N1 Influenza A.

### **NASEMSO Position**

The National Association of State EMS Officials (NASEMSO) believes that the health and welfare of emergency responders is critical to the Nation's emergency care infrastructure. NASEMSO supports the efforts of the Centers for Disease Control and Prevention (CDC), the National Institute of Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA) to educate medical first responders and others about the potential risks associated with illnesses that are transmitted from person to person through close contact or droplet exposure. NASEMSO urges the EMS community to implement effective administrative and engineering controls to protect medical first responders and supports compliance with OSHA's Respiratory Protection Standard [29 CFR 1910.134](http://www.cfr.gov), effective July 2, 2004.

### **Rationale and Background**

Conflicting information promulgated by national organizations, the scientific community, and the news media about the use of masks, respirators, and the utility of fit-testing diminishes the ability of the health care community, including Emergency Medical Services (EMS) to promote consistent practice among its practitioners. For example:

- 1.) One recent study conducted by an international team led by Dr. Raina MacIntyre of the University of New South Wales in Australia, reported that N-95s were superior to surgical masks but that fit-testing provided no added value. The study remains unpublished<sup>1</sup>.
  - 2.) The Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA) and the Association for Professionals in Infection Control and Epidemiology (APIC) recently urged the Obama administration to modify the guidance and issue an immediate moratorium on Occupational Safety and Health Administration's (OSHA) enforcement of the current requirements (which includes minimum of N-95 respirators and fit-testing for healthcare
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workers at risk for exposure<sup>ii</sup>.) Regarding efficacy of fit testing, NIOSH continues to support the need for initial and periodic fit testing for employees who wear respirators and believes that there is sufficient scientific evidence to support the importance of fit testing as a measure to achieve better respirator fit. NIOSH has communicated to NAEMSO that it believes the evidence supporting fit testing as an essential element of a complete respiratory protection program is “scientifically substantial.”

3.) “Surgical Mask vs N95 Respirator for Preventing Influenza Among Health Care Workers A Randomized Trial” appeared in the Journal of the American Medical Association (JAMA) in October 2009<sup>iii</sup>. This study concluded that “Among nurses in Ontario tertiary care hospitals, use of a surgical mask compared with an N95 respirator resulted in noninferior rates of laboratory-confirmed influenza.” The sample size is considered relatively small by some experts and it appears that other variables that can prevent infection among health care workers were not evaluated. The CDC refuted the findings<sup>iv</sup> and opined that “this intense discussion over respiratory protection has distracted attention from the critical importance of implementing other strategies known to prevent the transmission of influenza in health care settings. Indeed, the use of personal protective equipment such as masks and respirators should be considered the “last line of defense” in a hierarchy of infection control measures.” The CDC continues to advocate the use of fit-tested N95s for health care workers in their most recent infection control guidance<sup>v</sup>.

OSHA's revised Respiratory Protection Standard ([29 CFR 1910.134](#) and [29 CFR 1926.103](#)) went into effect April 8, 1998. (The final standard replaces the respiratory protection standards adopted by OSHA in 1971.) Establishments whose respirator protection programs for tuberculosis formerly covered under 29 CFR 1910.139 were required to adapt their programs to comply with the requirements of [29 CFR 1910.134](#), effective July 2, 2004. [Section 5\(a\)\(1\)](#) of the OSH Act, often referred to as the General Duty Clause, requires employers to “furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees”. [Section 5\(a\)\(2\)](#) requires employers to “comply with occupational safety and health standards promulgated under this Act”. Twenty-four states, Puerto Rico and the Virgin Islands have [OSHA-approved State Plans](#) and have adopted their own standards and enforcement policies. For the most part, these States adopt standards that are identical to Federal OSHA. However, some States have adopted different standards applicable to this topic or may have different enforcement policies.

In a memo issued by the Occupational Safety and Health Administration<sup>vi</sup>, the agency announced plans to conduct H1N1 compliance visits in upcoming months. In response to complaints, OSHA inspectors will ensure that healthcare employers implement a “hierarchy of controls” including source control, engineering, and administrative measures, encourage vaccination and other work practices recommended by the CDC. The OSHA memo states that “where respirators are not commercially

available, an employer will be considered to be in compliance if the employer can show that a good faith effort has been made to acquire respirators.” The agency says it will be looking for written receipts or documentation of backorders related to missing equipment and supplies. Since a shortage of disposable N95 respirators is possible, employers are advised to monitor their supply, prioritize their use of disposable N95 respirators according to guidance provided by CDC, and to consider the use of elastomeric respirators and facemasks if severe shortages occur. Additional OSHA references are available at <http://www.osha.gov/dsg/topics/pandemicflu/index.html>.

The Occupational Safety and Health Administration (OSHA) has published “*Enforcement Procedures for High to Very High Occupational Exposure Risk to 2009 H1N1 Influenza*”<sup>viii</sup> to coincide with anticipated OSHA Compliance visits. This directive “establishes agency enforcement policies and provides instructions to ensure uniform procedures when conducting inspections to minimize high to very high occupational exposure risk to the virus identified as 2009 H1N1 influenza of workers whose occupational activities involve contact with patients or contaminated material in a healthcare or clinical laboratory setting.” In addition to documentation of worker training and fit-testing of N-95 respirators and optimizing ventilation of vehicles transporting suspected or confirmed 2009 H1N1 influenza patients, EMS agencies will be expected to implement a system that encourages employees at high to very high occupational exposure risk to get the 2009 H1N1 influenza vaccination and provide it at no cost. A signed declination form may be used to document that the employer offered and employees did not accept vaccination.

On April 26, 2009, the Department of Health and Human Services Secretary declared a public health emergency related to the H1N1 Influenza A outbreak and the following day, declared an emergency justifying the authorization of the emergency use of certain personal respiratory protection devices accompanied by emergency use information, a first step in clearing the way for the distribution of specific N-95 respirators from the Strategic National Stockpile (SNS), should it become necessary, to the “general public.” On May 1, 2009, the Food and Drug Administration (FDA) issued an “emergency use authorization” (EUA) that permits the emergency use of certain types/models of disposable N95 respirators by the general public during this declared emergency. The agency clarified that the term “general public” was broad and included individuals performing work-related duties (such as EMS.) The specific products covered are listed in the [EUA Summary Fact Sheet](#) and the [FDA-issued EUA Authorization letter](#). **It is important to note, if respirators are used for persons performing work-related duties under the EUA issued for N95 respirators, employers must comply with the OSHA Respiratory Protection Standard.** An EUA may remain in effect for the duration (one year) of the declaration justifying the emergency use unless revoked. At that time, federal authorities must determine if the H1N1 Influenza A outbreak continues to meet the criteria for these declarations and whether or not to renew them.

## **Summary**

1. When respiratory protection is required in an occupational setting, respirators must be used in the context of a comprehensive respiratory protection program as required under OSHA's Respiratory Protection standard (29 CFR 1910.134). Additional information on the elements of a comprehensive respiratory protection program and the use of respirators can also be found at <http://www.osha.gov/SLTC/etools/respiratory/writtenprogram.html> and <http://www.osha.gov/SLTC/respiratoryprotection/index.html>. The Minnesota Department of Health also provides "easy to use" guidance (including an editable template) that addresses various components of an effective Respiratory Protection Program at <http://www.health.state.mn.us/divs/idepc/dtopics/infectioncontrol/rpp/comp/index.html>.
2. Respiratory protection is only *one component* of a comprehensive infection control plan for medical first responders. Newer evidence suggests that a *combination* of strategies is most effective to mitigate the effects of respiratory borne illnesses, including the current influenza pandemic. Vaccination of personnel, strict implementation of cough etiquette and hand hygiene practices, adequate transport ventilation systems, frequent sanitation of work surfaces, liberal sick leave policies, modified system protocols, and PPE are all considered essential elements of an effective plan.
3. States retain the legal authority to implement policies and procedures related to public health issues and concerns at the state level.
4. States are encouraged to include legal counsel and workmen's compensation personnel in policy discussions when considering a deviation from the CDC/OSHA/NIOSH recommendations and requirements on matters that impact EMS health and safety.

## **Key Questions and Answers**

### **What are the risks for EMS personnel for exposure to infectious materials in the workplace?**

Virtually every patient encounter contains the risk of exposure to infectious materials for EMS personnel. While advances have been made to protect workers from inhaled pathogens, risks associated with patient contact are not always known. The prehospital environment is frequently chaotic and inadvertent exposure can easily occur. This unpredictable environment suggests that a range of preventative measures must be implemented to minimize the risk of transmission to communicable diseases. Because personnel may not know if and when they are being exposed to an infectious person(s), EMS agencies should use a hierarchy of controls approach to minimize exposure of medical first responders and to prevent transmission of disease within EMS settings.

### **Isn't OSHA's Respiratory Protection Standard sufficient to protect emergency response workers from exposure to infectious materials?**

No. OSHA does not have jurisdiction over state and local governments in about half of the states not to mention that compliance with standards aimed at respiratory protection depend on implementation by individual responders. Careful attention to elimination of potential exposures, as well as the use of

engineering and administrative controls will reduce the need to rely on Personal Protective Equipment (PPE), including respirators. In fact, PPE currently ranks lowest in the hierarchy of controls for protecting workers against airborne illness.

**What other measures should be considered to protect EMS personnel from respiratory pathogens?**

Newer evidence suggests that a combination of strategies is most effective to mitigate the effects of respiratory borne illnesses, including the current influenza pandemic. Vaccination of personnel, strict implementation of cough etiquette and hand hygiene practices, adequate transport ventilation systems, frequent sanitation of work surfaces, liberal sick leave policies, modified system protocols, and PPE are all considered essential elements of an effective plan.

**What is the difference between a facemask and a respirator?**

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. 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 the mouth and nose. Facemasks are not considered an effective barrier to prevent disease transmission because small droplet particles are easily transmitted around the device. (This occurs due to the lack of a seal as the masks are not designed to provide conformity to the wearer's face.)

A respirator is a protective facepiece, hood or helmet that is designed to achieve a very close facial fit and very efficient filtration of airborne particles. In addition to blocking splashes, sprays and large droplets, the respirator is also designed to prevent the wearer from breathing in very small particles that may be in the air. Respirators are considered a "last line of defense" in the Hierarchy of Controls when engineering and administrative controls are not feasible or are being put in place.

**What does "N95" mean?**

"N95 respirator" is a term used to describe the class of respirators which use N95 filters to remove particles from the air that is breathed through them. The NIOSH respirator approval regulation defines the term N95 to refer to a filter class that removes at least 95% of airborne particles during "worst case" testing using a "most-penetrating" sized particle during NIOSH testing. Filters meeting the criteria are given a 95 rating. Many filtering facepiece respirators have an N95 class filter and those meeting this filtration performance are often referred to simply as N95 respirators. Even though you see N95 on the package, it still may not be the right kind of respirator, or one that meets NIOSH approval requirements.

**How can I find out if my respirator is certified by NIOSH?**

All NIOSH-approved respirators have an approval number. With few exceptions the NIOSH approval number is not on the respirator itself, but on a separate NIOSH approval label which is found on, or within the packaging. You may readily verify that respirator approvals are valid by checking the information links on the [NIOSH Trusted-Source page](#), or in the [NIOSH Certified Equipment List \(CEL\)](#). Specific N-95 respirators covered by the Emergency Use Authorization (described above) are listed at <http://www.cdc.gov/h1n1flu/eua/summary-factsheet.htm>.

**Why should the EUA matter to state and local public health authorities?**

FDA has authorized emergency use of certain types/models of disposable N95 respirators by the general public during this declared emergency. As a countermeasure that can be deployed from the SNS, some state and local public health authorities may access these supplies when the demand exceeds the local supply. If the FDA issues an EUA to allow for the lawful distribution or dispensing of products for emergency use under certain circumstances and states do not distribute or dispense the countermeasures in accordance with the scope and conditions of the EUA, liability protections afforded by the PREP Act may be affected. (The PREP Act declaration provides immunity for any type of loss suffered by an individual who receives the countermeasure, including death; physical, mental, or emotional injury, illness, disability or condition; fear of physical, mental, or emotional injury illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption, with any causal relationship to any to stage of development, distribution, administration or use of the countermeasure.)

**What is the OSHA fit-testing requirement?**

Fit testing is required for all negative or positive pressure tight-fitting facepiece respirators. The OSHA respiratory protection standard requires that fit testing be performed before an employee first starts wearing a respirator in the work environment, whenever a different respirator facepiece is used, and at least annually thereafter. This requirement pertains to any workplace where respirators are necessary to protect the health of the employee.

**What types of fit-testing protocols meet the OSHA standard?**

Fit testing may either be *qualitative (QLFT)* or *quantitative (QNFT)*, and must be administered using an OSHA-accepted QLFT or QNFT protocol. These protocols are described in mandatory [Appendix A to 1910.134](#).

**When should I wear the respirator?**

For updated public health recommendations about when and where to use respirators during the H1N1 Influenza A emergency, please refer to [H1N1 Flu](#).

**The California Department of Public Health (CDPH) recently issued a state recall of a specific N95 respirator, indicating that the product failed 60% of the fit tests of health care workers. Why hasn't a national recall been implemented?**

The 3M 8000 masks in question were recalled by the state of California because there have been significant problems reported with regard to (inadequate) fit-testing. Cal/OSHA is not prohibiting use of the 3M 8000 per se, it strongly recommends against using this model for prevention of aerosol transmitted disease and urges employers, if they decide to issue a respirator of this model to any employee, to assure a successful fit test with that employee. The only respirators that have been recalled by California are the 3M 8000 N95 respirators (there are several sub-series of the 8000 with different face molds, such as 8210, 8211, 8511, 8612, 8670 and more that are not affected by the alert.) 3M maintains that the 8000 mask meets NIOSH 42 CFR 84 N95 requirements. The 3M 8000 mask is still currently listed on the [NIOSH list](#) for approved respirators. NIOSH has advised NASEMSO that it is conducting an investigation of the Model 8000 respirators intended to help answer whether the CDHP experience was the result of any defect in the product itself, difficulty in achieving adequate fit among a particular population of users, or the result of procedural difficulties in implementing fit tests. NIOSH

will take appropriate remedial actions if the investigation determines there are non-conformance or performance issues that would result in reduced worker protection with the use of the Model 8000 respirators.

This brief is provided for informational purposes only. Establishment of a comprehensive respiratory protection program with all of the elements specified in OSHA's Respiratory Protection standard (29 CFR 1910.134) is needed to achieve the highest levels of protection. Additional information on the Respiratory Protection standard is included in Appendix C in *OSHA 3328-05R 2009 Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers* at [www.osha.gov/Publications/OSHA\\_pandemic\\_health.pdf](http://www.osha.gov/Publications/OSHA_pandemic_health.pdf).

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## Resources

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National Highway Traffic Safety Administration-- Office of Emergency Medical Services

- [EMS Pandemic Flu Guidelines for Statewide Adoption](#)
- [Preparing for Pandemic Influenza: Recommendations for Protocol Development for 9-1-1 Personnel and Public Safety Answering Points \(PSAPs\)](#)

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<sup>v</sup> CDC Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel. Retrieved January 9, 2010 from [http://www.cdc.gov/h1n1flu/guidelines\\_infection\\_control.htm](http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm).

<sup>vi</sup> OSHA Statement re: H1N1-related Inspections, October 14, 2009. Retrieved January 9, 2010 from [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=NEWS\\_RELEASES&p\\_id=16602](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=16602).

<sup>vii</sup> OSHA Compliance Directive: CPL-02-02-075. Enforcement Procedures for High to Very High Occupational Exposure Risk to 2009 H1N1 Influenza. Retrieved January 9, 2010 from [http://www.osha.gov/OshDoc/Directive\\_pdf/CPL\\_02\\_02-075.pdf](http://www.osha.gov/OshDoc/Directive_pdf/CPL_02_02-075.pdf) .