



Cal/OSHA Interim Guidance on Ebola Virus in Inpatient Hospital Settings: Answers to Frequently Asked Questions

December 16, 2014

Cal/OSHA has prepared this document to help answer questions that health care providers have been asking about our interim guidance document posted on Ebola virus in inpatient hospital settings (November 14, 2014). Please be aware that information is continually evolving and answers may change as new information becomes available.

Disclaimer: Listing particular manufacturers and equipment in the answers below does not constitute an approval or endorsement of those manufacturers or products by Cal/OSHA, the Department of Industrial Relations, or the State of California.

1. Exposure Control Plans

- **What kind of Ebola-specific information must be included in a hospital's exposure control plan under the Aerosol Transmissible Diseases standard?**

Ebola-specific procedures in the hospital's exposure control plan under the ATD standard must include procedures for screening patients for possible Ebola, placement and transportation of patients at all stages of care, training and medical services to be provided including precautionary removal, and all other measures to protect employees from Ebola.

- **Is there an existing exposure control plan template for hospitals?**

The conditions in every hospital are different. It is critical that the exposure control plans address those site conditions, such as where and how patients will be isolated and how transport to that area will occur, PPE will be donned, doffed and decontaminated, how laboratory samples will be handled, processed and/or shipped, what type of PPE ensemble will be used, etc. The full requirements for employers' exposure control plans are set forth in subsection (c) of the Bloodborne Pathogens standard – <http://www.dir.ca.gov/title8/5193.html> – and in subsection (d) of the Aerosol Transmissible Diseases standard – <http://www.dir.ca.gov/title8/5199.html>.

2. Respiratory Protection

- **Can employees who care for a suspected or confirmed Ebola patient in the inpatient hospital setting be given an N95 or other respirator besides a PAPR if the patient is not vomiting or having diarrhea?**

No. The Cal/OSHA Aerosol Transmissible Diseases standard requires that employers provide PAPRs for employees caring for a suspected or confirmed Ebola patient in the inpatient hospital setting, because with these patients, aerosol-generating procedures can be performed unexpectedly.

- **Are there PAPRs that meet the ASTM standards for protection against passage of fluids?**

The list below includes some models that have been tested for protection against passage of body fluids. This list is not exhaustive. Employers should check with vendors and manufacturers regarding other models.

- 3M Breathe Easy PAPR with 450-00-01R12 HEPA Filter and BE-10 or BE-10L hood (Tychem SL or QC); APF = 1000
- Bullard EVAEV2 PAPR with HEPA Filter and CC20 Hood (Tychem SL or QC); APF = 1000
- ILC Dover Sentinel XL HP PAPR (hood is Tychem QC); APF = 1000
- Immediate Response Technologies Pure-Air™ Bio-Response PAPR System (hood is Tychem QC)
- MSA OptimAir TL PAPR; uses Tychem QC or SL, DBL-BIB hoods; APF = 1000

Note re MAXAIR: The information we received from MAXAIR (as of 11/26/14) indicated that none of their current equipment has met ASTM F1670/F1671 or AAMI Level 4 testing criteria. (The MAXAIR CAPR is a PAPR.) If a surgical hood or other disposable fluid barrier is placed over the MAXAIR, it cannot interfere with the functioning of the respirator. We are awaiting further information from MAXAIR.

- **How can an employer use a PAPR with a small hood and add protection for the head, neck, and upper torso without voiding the NIOSH approval?**

If additional PPE is necessary to cover exposed areas of the head, neck or torso, it must (1) not be placed between the respirator and the workers body, and (2) not interfere with the operation of the respirator, including how the respirator provides positive pressure in the facepiece. If this cannot be accomplished with the existing equipment, hospitals should work with state and local health officers to solve the problem, either by arranging for immediate help to obtain the required PPE or by arranging for suspected or confirmed Ebola patients to be transported to hospitals that are sufficiently equipped.

- **Must the PAPR filter be changed every time between each use?**

The following information pertains to particulate filters only: The filter or filter covering should be wiped with disinfectant as part of the decontamination/doffing process. Once cleaned, the PAPR motor and battery units should be charged in the donning area. The PAPR must be checked before each use to ensure adequate airflow. Degradation in airflow may indicate that the filter is overloaded and must be changed. Filters must be changed when the whole unit is sent for processing and decontamination.

If a combination cartridge which provides protection against hazardous chemicals as well as particulate filtration is used, then the cartridge will either have an end of service life indicator or must be used in accordance with a cartridge change schedule.

- **How do we confirm that an N95 respirator is a “surgical” N95 meeting FDA criteria?**

The labeling as a surgical mask indicates it meets the FDA criteria. The labeling as an N95 Particulate Filter (which will also have the NIOSH approval number on the mask) indicates it has been approved by NIOSH as an N95. So this is what is commonly called a “surgical N95.” Regarding FDA-cleared respirators, NIOSH has posted a list of approved respirators, including N95 respirators cleared by the FDA: http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3healthcare.html#fda

3. PPE for the Body

- **Can employees who care for a suspected or confirmed Ebola patient in the inpatient hospital setting use a gown instead of a coverall?**

Our requirement to provide coveralls to employees entering the room of a patient with suspected or confirmed Ebola virus disease in the inpatient hospital setting is based on the nature of the infectious material that is produced by a person with Ebola virus disease and the experience of the health care efforts in West Africa. This experience has shown that contact with infectious materials must be prevented if possible.

Although the comfort and effort to doff coveralls may be negatively perceived by some users, coveralls provide the best protection of all skin surfaces in the presence of the infectious materials. Body coverings used for protection against Ebola infectious materials must be tested against ASTM testing standards: F1670 (blood or bloody fluids) and F1671 (bloodborne pathogens). Gowns have not been included in the Cal/OSHA guidance document because they have gaps that can allow infectious materials to be splashed upwards onto the legs of the wearer. Coveralls prevent this contact.

In addition, please note that surgical gowns, in contrast to isolation gowns, are not designed to protect against penetration of fluids on all parts of the gown. See “ANSI/AAMI PB70:2012, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.”

- **What coveralls do you recommend to prevent the passage of infectious body fluids to the employees clothing, skin, and mucous membranes?**

The term "Tyvek" is often used as a generic term to refer to synthetic disposable garment materials. The specific brand "Tyvek" is not tested against the ASTM F1670/1671 standards and therefore cannot be considered to protect against the passage of infectious body fluids. Tychem-type suits are typically tested against ASTM F1670/1671 standards. These suits can be of different construction, including the types of seams and reinforcements, and coverings for zippers. Tychem QC and Tychem SL suits, for example, are available in different constructions; those with reinforced seams are sturdier, and the seams can better protect against passage of body fluids.

4. PPE for Legs and Feet

- **Please provide guidance on appropriate foot wear that meets guidelines for use with the suits with integrated socks.**

The exact configuration of the personal protective equipment must be consistent with the donning and doffing procedures. The CDC recommends wearing of a washable shoe. Generally, to facilitate doffing and decontamination, the inner boot or sock should be worn over the shoe, so that the entire coverall can be removed without leaving the employee barefoot. A slip-resistant shoe covering or outer boot should be worn over the coverall. If the sock is worn under the shoe, there must be a clean surface for an employee to step onto when the coverall is removed, and new foot covers or clean washable shoes must be donned to finish the doffing process.

5. PPE for Doffing Assistants

- **If the person who assists the doffer must wear a PAPR, what must the next person(s) wear?**

An employee who physically assists another employee who is doffing visibly contaminated PPE must be provided the same level of PPE as the employee who is doffing. Ideally, the doffing assistant would be the replacement worker who would then enter the patient room (e.g., at a shift change).

If the doffing assistant (second employee) does not get visibly contaminated, the third employee can assist the doffing assistant by observing but not assisting physically. If the third employee will be in the same room as the second employee but will not enter the patient's room, the third employee can be in a lower level of PPE, such as an N95 respirator, face shield, head and neck covering, isolation gown, foot and leg coverings, and gloves.

The PPE must pass ASTM testing standards: F1670 (blood or bloody fluids) and F1671 (bloodborne pathogens). This could include an ASTM F1670/F1671 rated coverall or AAMI Level 4 gown. There must be written procedures that address the handling of disposable medical waste (such as coveralls and PAPR hoods) and disinfection or decontamination of reusable equipment (such as PAPR motor units). There should be separate containers for each in the doffing area and in any other area where contaminated PPE or other equipment is to be processed for disposal or disinfection (or decontamination). The N95 respirator should be removed last and discarded into a medical waste container located at the doffing area exit door. Shower equipment should be available to all persons in the Ebola unit as the final step in decontamination.

6. PPE for Employees Cleaning Contaminated Surfaces and Equipment

- **Are there any situations where an employee cleaning surfaces contaminated with body fluids can wear a fitted, negative-pressure respirator?**

If an Ebola case or suspected case is present, a PAPR must be used.

Prior to terminal cleaning, the room should be ventilated for the minimum period specified in Table 1 (below) to achieve 99.9% removal, prior to entry. Cleaners can use a full-facepiece air-purifying respirator with appropriate cartridges for particulate filtration and adsorption of the cleaning chemicals. The employer must ensure that cleaners use cleaning methods that minimize the generation of aerosols.

Table 1, below, can be found in the CDC's 2005 tuberculosis guidelines:
<http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>

If vapor or gaseous disinfectants are used for terminal cleaning, ventilation and respiratory protection must be utilized to protect employees against those chemical hazards.

TABLE 1. Air changes per hour (ACH) and time required for removal efficiencies of 99% and 99.9% of airborne contaminants*

ACH	Minutes required for removal efficiency†	
	99%	99.9%
2	138	207
4	69	104
6	46	69
12	23	35
15	18	28
20	14	21
50	6	8
400	<1	1

* This table can be used to estimate the time necessary to clear the air of airborne *Mycobacterium tuberculosis* after the source patient leaves the area or when aerosol-producing procedures are complete.

† Time in minutes to reduce the airborne concentration by 99% or 99.9%.

7. PPE Currently Not Available

- **What should a hospital do while waiting for PAPRs and coveralls to be available?**

Hospitals should work with local health officers or the California Department of Public Health (CDPH) to solve the problem, either by arranging for immediate help to obtain the required PPE or by arranging for suspected or confirmed Ebola patients to be transferred to hospitals that are sufficiently equipped.

8. Other Settings Outside Inpatient Care

- **Will you issue guidance for PPE in other settings outside inpatient care?**

We are working with CDPH to prepare additional guidance for other settings outside inpatient care, such as emergency department and ambulatory settings, where in some cases it may reasonably be determined there is no risk that employees will be exposed to an aerosol-generating procedure performed on an Ebola patient or be exposed to another type of aerosol-generating activity.