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Technical Bulletin

Respirators and Surgical Masks - A Contrast

Background

Since certain disposable respirators are similar in appearance to many surgical/procedure masks, their differences are not always well understood. However, respirators and surgical masks are very different in intended use, fit against the face, wear time, testing and approval. The purpose of this document is to highlight some of these differences.

Wear Time

Respirators must be properly selected and carefully donned and doffed in a clean area, and worn the entire time in the contaminated area to have a significant effect on reducing exposure. Having the respirator off even 10% of the time in a contaminated area significantly reduces the protective effect of the respirator.

Surgical/procedure masks are typically donned for a specific procedure. For infection control purposes, masks are typically disposed of after each procedure/patient activity.

Testing

In the United States, respirators must meet test criteria stated in the Code of Federal Regulations 42 CFR Part 84. For a complete understanding of all the test criteria, the reader will need to review the standard. The filter efficiency test criteria for respirators with “N95” filter media include:

- Sodium chloride test aerosol with a mass median aerodynamic diameter (MMAD) particle of about 0.3 µm;
- Airflow rate of 85 liters per minute (lpm);
- Charge-neutralized test aerosol; and
- Preconditioning at 85% relative humidity (RH) and 38°C for 24 hours before testing.

Common tests for surgical masks include: particle filtration efficiency (PFE), bacterial filtration efficiency (BFE), fluid resistance, differential pressure and flammability. Each test is briefly described below.

PFE

The PFE test is a quality indicator for healthcare surgical masks. The PFE test is not an indicator of respirator protection performance. The filter media of a surgical mask with a very high (>95%) PFE may be less than 70% efficient when tested with the NIOSH N95 test method. The results of the surgical mask PFE testing and NIOSH filtration efficiency testing should not be compared. Conditions of the PFE test include:

- Polystyrene latex sphere test aerosol;
- Approximately 0.1 µm in size;
- Airflow rate of 28 liters per minute (lpm);
- Un-neutralized test aerosol; and
- No preconditioning.

BFE

This test assesses the ability of a mask to provide a barrier to large particles expelled by the wearer. It is not a filtration efficiency test, and it does not evaluate the mask’s ability to provide any protection to the wearer. Two methodologies are available: the “Modified Greene and Vesley Test” or American Society of Testing and Materials (ASTM) method F2101-01.

Fluid Resistance

The fluid resistance test is typically conducted based on the ASTM Test Method F 1862, "Resistance to Penetration by Synthetic Blood," which determines the mask's resistance to synthetic blood squirted at it under varying pressures.

Differential Pressure (Delta-P)

The Delta-P test is typically conducted based on the "Method 1 Military Specifications: Surgical Mask, disposable (June 12, 1975)", MIL-M-36945C 4.4.1.1.1. Delta-P is the measured pressure drop across the surgical facemask material and is related to the mask's breathability.

Flame Resistance

Surgical masks intended to be used in the operating room undergo testing to determine the flammability by class. FDA recommends that Class 1 and Class 2 flammability materials be used. FDA recommends the use of one of the standards below to test flammability.

- CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles
- NFPA Standard 702-1980: Standard for Classification of Flammability of Wearing Apparel
- UL 2154

Conclusion

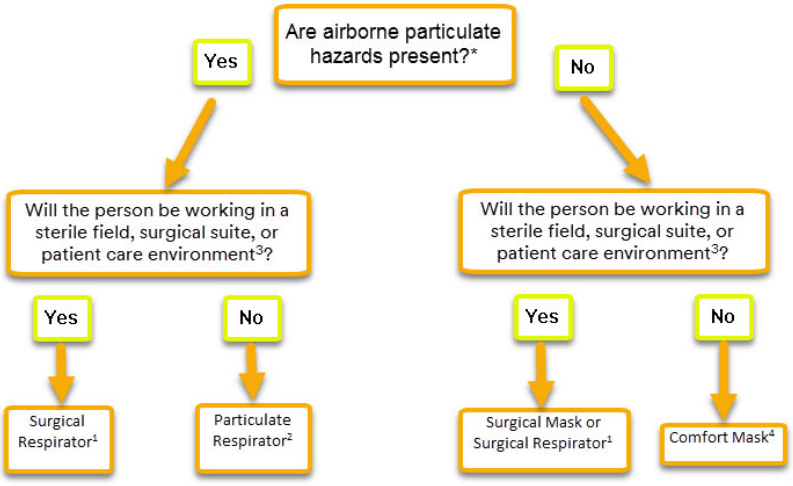
In conclusion, surgical masks are intended to help put a barrier between the wearer and the work environment or sterile field. They may help keep spit and mucous generated by the wearer from reaching a patient or medical equipment. They can also be used as a fluid barrier to help keep blood splatter from reaching the wearer's mouth and nose.

However, surgical masks cannot provide respiratory protection unless they are also designed, tested, and NIOSH-approved as a respirator. If a wearer wants to reduce inhalation of smaller, inhalable particles (those smaller than 100 microns), they need to obtain and properly use a NIOSH-certified respirator. If the wearer needs a combination surgical mask and a particulate respirator, they should use a product that is both cleared by FDA as a surgical mask and tested by NIOSH as a particulate respirator or otherwise be described as a health care respirator or surgical N95.

Respiratory versus Surgical Mask Decision Tree[1,2,3,4]

The following decision tree highlights potential considerations for the selection of respirators verses surgical masks.

Figure 1: Respirator versus Surgical Mask Decision Tree



1. In the U.S., surgical masks and surgical N95 respirators are cleared by the FDA for use in surgery. Surgical N95 Respirators are also approved by NIOSH.
2. In the U.S., particulate respirators are approved by NIOSH.
3. Patient care with potential exposure to high velocity streams of blood such as intravenous lines, surgery, emergency room, etc. Consult with your infection control manager.
4. Comfort masks are not designed to protect lungs from airborne hazards, are not NIOSH approved or FDA cleared.

Here are some additional considerations to keep in mind when selecting a respirator for use in a health-care work environment.

- Selection of respiratory protection for occupational hazards is typically based upon the airborne concentration of the substance that the wearer is exposed to and the occupational exposure limit (OEL) of that substance.
- Biological agents, such viruses and bacteria, do not have OELs; therefore employers should consider available guidance when selecting respirators. The U.S. Centers for Disease Control and Prevention (CDC) has recommended that respirators offering more protection, such as powered air purifying respirators (PAPRs), may be considered in situations when high exposures to bacteria and viruses are possible.
- The occupational use of respirators in the U.S. is regulated by OSHA, and in the U.S., the use of respirators in all workplaces must be per OSHA standard 29 CFR 1910.134.
- Tight-fitting respirators such as the particulate respirators shown cannot be worn with facial hair or anything else that may interfere with the seal.

Resources

For more information regarding the differences between surgical masks and respirators, here are more resources:

1) Healthcare – Mask vs. Respirator Video - https://multimedia.3m.com/mws/media/1054432O/healthcare-mask-vs-respirator-video.mp4
2) NIOSH science blog “N95 Respirators and Surgical Masks” Lisa Brosseau, ScD, and Roland Berry. October 14th, 2009 https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/
3) OSHA Fact Sheet: “Respiratory Infection Control: Respirators Verses Surgical Masks”, https://www.osha.gov/Publications/respirators-vs-surgicalmasks-factsheet.html
4) U.S. Food & Drug Administration: “Memorandum of Understanding Between the Food & Drug Administration/Center for Devices & Radiological Health and the Centers For Disease Control & Prevention/National Institute for Occupational Safety & Health/National Personal Protective Technology Laboratory”, https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm587122.htm

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