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Technical Bulletin

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Selection of Respiratory Protection for Surgical Procedures in Healthcare — United States

Background

Respiratory protection may be needed in healthcare workplaces when a risk exists for inhalation exposure to airborne hazards, such as particles that may contain infectious agents. As with any respirator selection process, the selection of respirators in healthcare should account for not only the inhalation hazard itself but also other aspects of the work application, such as other hazards and exposure routes and healthcare-related equipment regulations.

Respirator Regulatory Considerations

3M respirators are designed to help protect the wearer from certain airborne hazards in the surrounding environment. In the United States, these products are tested and approved by the U.S. National Institute of Occupational Safety and Health (NIOSH), a division of the U.S. Centers for Disease Control and Prevention (CDC), to provide respiratory protection to the wearer.

In the U.S., the selection and use of respiratory protection in workplaces is regulated by the U.S. Occupational Safety and Health Administration (OSHA) per the General Respiratory Protection Standard, 29 CFR 1910.134. The publication *Hospital Respiratory Protection Program Toolkit* outlines various considerations for selection and use of respiratory protection in hospitals and healthcare.[1] This document is co-authored by the U.S. Department of Labor, including OSHA, and the U.S. Department of Health and Human Services, including CDC and NIOSH.

Healthcare Equipment Regulatory Considerations

The U.S. Food and Drug Administration (FDA) clears products for marketing as medical devices, including filtering facepiece respirators (FFRs) that are indicated for use in surgical procedures. NOTE: The FDA does not have a mechanism to clear reusable respirators (RR) and powered air purifying respirators (PAPRS) for use in surgical procedures. Most 3M FFRs are not FDA cleared to be used by personnel during surgical procedures, and no 3M respiratory protection products are offered as sterile devices.

The only 3M respirators that are designed to be used by personnel during surgical procedures in the U.S. are those that are both approved by NIOSH and also cleared by the FDA. This category of respirators is referred to as surgical respirators. 3M surgical N95 respirator models include the 1860, 1860S, 1870+, 1804, and 1804S. Besides holding NIOSH approval as N95 particulate respirators, these models also undergo additional evaluations (fluid resistance, flammability and biocompatibility)[2] as required for surgical mask clearance by FDA

Selection of Respirators for Surgical Procedures

It is the responsibility of the healthcare organization to determine acceptability of any respirator to help protect their personnel and ensure compliance with the respiratory protection program requirements of the U.S. Federal OSHA or state OSHA. The

healthcare organization must also determine which tasks are considered "surgical procedures" and, if respiratory protection is required for these surgical procedures, then they would need to use FDA-cleared surgical N95 respirators for those tasks.

The *Hospital Respiratory Protection Program Toolkit* provides guidance on when to use standard respirators in healthcare and when surgical respirators are necessary. It also provides guidance on the use of reusable respirators (RR) and powered air purifying respirators (PAPRs) in hospitals.

Respirator selection and use should be based on a hazard assessment performed by the healthcare organization – which should involve occupational health and safety professionals, infection control professionals, and healthcare practitioners.[1]

Along with other facility specific considerations, the following recommendations are based on occupational health and safety principles and basic respiratory protection selection guidance and should be considered as part of the respiratory hazard evaluation process:

- Specific public health guidelines related to an infectious disease or event – CDC, WHO, etc.
- The type of respiratory protection required – bioaerosols/particulate hazards only or gas/vapor/particulate combination. Gas/vapor protection may be needed for certain disinfectants or hazardous drugs.
- Any exposure assessment data available to indicate the level of exposure reduction that is required (assigned protection factor)
- For gas/vapor exposures such as hazardous drugs, disinfectants, etc. – exposure data to inform gas/vapor cartridge changeout schedules
- Procedures which necessitate fluid resistance
- Procedures/tasks which are considered "surgical"
- Procedures/tasks which also require splash protection for the eyes
- Sterile field considerations and each healthcare organization's infection prevention policies

Surgical Field Considerations

Some FFRs feature an exhalation valve, which is intended as a comfort feature to help release the wearer's warm exhaled breath into the environment. While the CDC allows the use of FFRs with exhalation valves during certain healthcare tasks when caring for COVID-19 patients, they do not advise the use of valved FFRs in surgical procedures. During the COVID-19 pandemic, the CDC suggests that standard unvalved FFRs be used with face shields for surgical procedures when surgical N95 respirators are not available.[3]

There is no regulatory agency that evaluates respirators or surgical masks for outward leakage of particles exhaled by the wearer. Such tests are not required by the FDA nor by NIOSH. Howard et. al, 2020, investigated sterile field contamination from both PAPRs and surgical masks and found no statistical difference between their effectiveness in reducing aerosol contamination.[4] Further research is needed on the topic of outward leakage from masks and respirators.

The CDC states, *"Elastomeric respirators with exhalation valves should not be used in surgical settings due to concerns that unfiltered air coming out of the exhalation valve, potentially contaminated with microbes, may contaminate the surgical field."* CDC also states in their Strategies for Optimizing the Supply of N95 Respirators, *"Many filtering facepiece respirators have exhalation valves and should not be used in surgical settings as unfiltered exhaled breath would compromise the sterile field."*

Summary

Respirator selection is a complex undertaking, in which healthcare organizations should account for all aspects of healthcare professionals' potential exposures as well as relevant healthcare-specific considerations, such as FDA requirements for surgical procedures and maintenance of sterile fields. A thorough understanding of the risks and exposures in the environment,

coupled with a thorough understanding of both respirator performance and selection and use standards, is important in implementing an OSHA-compliant respiratory protection program in hospitals and healthcare.

References

1) Hospital Respiratory Protection Program Toolkit. https://www.osha.gov/Publications/OSHA3767.pdf
2) 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/about-fda/domestic-mous/mou-225-18-006
3) (3) U.S. Centers for Disease Control and Prevention (CDC), "Coronavirus Disease 2019 (COVID-19) Personal Protective Equipment: Questions and Answers." Updated March 14, 2020
4) Howard et al., Sterile field contamination from powered air-purifying respirators (PAPRs) versus contamination from surgical masks. Am J Infect Control. 2020 Feb;48(2):153-156.

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