



Technical Data Bulletin

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Respirators for *Mycobacterium tuberculosis* in Healthcare Facilities

Recently, 3M has received a number of inquiries regarding the use of respirators other than the 3M Model 1860 and 1860S Health Care N95 Particulate Respirator and Surgical Mask in Health Care facilities to help reduce employees' exposure to *Mycobacterium tuberculosis*, the bacteria that causes tuberculosis.

Summary

The goal of using a respirator is to help reduce the exposure to the contaminant of concern to a level that will not adversely affect the wearer's health. According to the Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA), a National Institute for Occupational Safety and Health (NIOSH) approved N95 or higher particulate respirator is recommended to help reduce exposures to *Mycobacterium tuberculosis*. However, no safe exposure levels (i.e. the amount that can be inhaled without adverse health effects) have been set for biological aerosols, including *M. tuberculosis*. Therefore, it must be recognized that respirators can help reduce inhalation exposures but cannot eliminate the risk of contracting infection, illness, or disease. Respirators used in surgical procedures must also be cleared by the Food and Drug Administration (FDA) and be manufactured according to Good Manufacturing Practices (GMP). Each facility or individual must use the best available information in determining the appropriate respiratory protection for the level of exposure reduction that they feel is needed for potential occupational exposures to *M. tuberculosis* in their facility.

Background

OSHA regulates workplaces through the employer and specifies the types and circumstances when respiratory protection must be used. There is no OSHA requirement that the respirator be specifically indicated for exposure to *M. tuberculosis*. However, for occupational exposure to *M. tuberculosis*, OSHA accepts the use of respirators from any of the nine particulate filter categories certified by NIOSH under 42 CFR 84, as well as Powered Air Purifying Respirators (PAPR) with HEPA filters. A facility may also continue to use HEPA filters and respirators certified under 30 CFR 11 until its supply is exhausted.

Another regulatory agency, the FDA, exercises some control over the manufacturing and marketing of respirators used in health care facilities. The FDA requires respirators used in surgical procedures to meet certain FDA requirements. For example, respirators must be manufactured under Good Manufacturing Practices (GMP) in order to be used during surgical procedures. FDA regulations also apply if

the manufacturer makes a specific disease prevention claim. Although a respirator may meet the OSHA requirements for exposure to *M. tuberculosis*, it is possible it may not meet the FDA requirements for use during surgical procedures. Therefore, the manufacturer cannot promote that product for exposure to *M. tuberculosis* or other harmful aerosols *during surgical procedures*. The only 3M respirators that are currently certified by NIOSH and meet the FDA requirements for surgical masks are the 3M Models 1860 and 1860S Health Care N95 Particulate Respirator and Surgical Mask.

Respirator Use Limitations

Before selecting respiratory products for biological agents, such as *M. tuberculosis* the following must be considered:

- The airborne concentration of these agents will be unknown.
- The acceptable exposure level is not known.
- NIOSH is the government agency responsible for testing and certifying respirators. NIOSH tests and certifies respirators for use against particles, gases, and vapors. NIOSH does not, however, test and certify respirators for use against biological agents such as *M. tuberculosis*. Nevertheless, because biological aerosols are particulates NIOSH certified particulate filters and respirators will help reduce exposures to them.
- Proper fit of the respirator to the face is extremely important. If it does not fit properly, the likelihood of exposure to the *M. tuberculosis* is increased.
- Individuals wearing tight fitting face pieces must be clean-shaven.
- Respirators are designed for occupational/professional use by adults who are properly trained in their use and limitations.
- Individuals with a compromised respiratory system should consult with a physician prior to use.

Filtering *M. tuberculosis*

Biological agents such as *M. tuberculosis* are particles and can be removed by particulate filters with the same efficiency as non-biological particles having the same physical characteristics (size, shape, etc.). According to the CDC the typical size of *M. tuberculosis* is estimated to be 1 – 5 microns in size.

- Both OSHA and the CDC recommend a NIOSH certified class 95 or higher filter for capturing *M. tuberculosis* particles.
- NIOSH class 95 filters are certified to be at least 95% efficient against a much smaller particle of 0.3 microns. Therefore, the filter will be 95% efficient or greater for particles in the 1 to 5 micron size range. A NIOSH certified class 100 or HEPA filter is 99.97% efficient against this most penetrating particle size of 0.3 microns.

Importance of Fit

The fit of a respirator is as important as filter efficiency. While a respirator may be equipped with filter media to effectively capture a high percentage of airborne particles, the particles may enter the respirator through leaks around the facepiece if not properly fitted.

- Tight-fitting respirators, which have a sealing surface that contacts the face, will not provide an adequate seal when placed over facial hair.
- Bearded workers may need to use respirators that do not require a facepiece to face seal. In many instances this will consist of a powered air-purifying respirator (PAPR) with a hood or helmet.

Assigned Protection Factor

Because the safe level of exposure to *M. tuberculosis* is not established, there is no assurance that any respirator will mitigate or prevent tuberculosis infection or disease. Respirators are traditionally selected using the airborne concentration of the contaminant, the permissible exposure limit of the contaminant and the assigned protection factor of the respirator. Since the exposure limit and concentration are unknown for biological agents the traditional respirator selection method cannot be applied.

- All NIOSH certified respirators have an assigned protection factor (APF), which predicts how much the respirator may reduce a wearer's exposure.
- The assigned protection factor is only applicable when the respirator is correctly selected, properly used by a trained and fit tested wearer and the respirator is properly maintained.
- A respirator with a higher protection factor will provide greater exposure reduction when the respirator is used properly and fitted to the individual.
 - Here is an example of how to use assigned protection factors when choosing an appropriate respirator. Assume the contaminant concentration in the air is 10,000 particles. A person has passed a fit test and is wearing a half mask respirator with an assigned protection factor of 10. This means the person could expect to reduce his exposure by 10 times, resulting in a possible inhalation of 1000 particles. A full-face respirator would be expected to reduce the exposure by 50 times, resulting in a possible inhalation of 200 particles.

When a health care facility decides to make respiratory products a part of its TB exposure control plan, all aspects of the OSHA respiratory protection standard for *M. tuberculosis* (29 CFR 1910.139) must be implemented.

Respirators for Surgical Procedures

The 3M Model 1860 and 1860S are the only 3M respirators currently cleared to be used as surgical masks by the FDA.

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