

Surgical Masks & Respirators



A respiratory protection issue for the health care industry

There recent outbreak of Swine Influenza A (H1N1) virus has generated major interest in respiratory protection for biohazards that may be spread through the air.

General infection control procedures have been in use for decades, but more attention has been paid to the respiratory protection aspect in recent years. This first started with tuberculosis (TB) concerns, followed by Hantavirus, anthrax, sudden acute respiratory syndrome (SARS), avian flu (H5N1) and most recently, Swine Influenza A (H1N1) virus. These biohazards may become airborne; perhaps as the agent itself such as an anthrax spore, or as part of other airborne material such as dusts, mists droplets and aerosols. In fact, rarely does the bioaerosol exist as a naked organism. Wearing appropriate respiratory protection may reduce inhalation of these bioaerosols.

There has been a good deal of confusion in the Health Care Industry in regards to what is appropriate respiratory protection and product selection for specific applications. The two types of product involved in this confusion are the surgical mask and the respirator.

Differences between respirators and surgical masks

The biggest difference between a respirator (a respiratory protective device that meets the requirements of AS/NZS1716) and a surgical, medical, or patient care mask is the intended use. Respirators are designed to help reduce the wearer's respiratory exposure to airborne contaminants such as particles, gases or vapours. Particulate respirators are used to reduce exposure to particles that are small enough to be inhaled - particles less than 100 microns (μm) in size down to nanometre size. This includes airborne particles that may contain biological material, e.g. mould, Bacillus anthracis, Mycobacterium tuberculosis, the SARS virus, etc.

Surgical masks (even those that meet Australian Standard AS 4381 for surgical masks) do not have adequate filtering and/or fitting attributes to provide effective respiratory protection for the wearer to this range of particle sizes. They are designed to help prevent contamination of the work environment or sterile field from particles generated by the wearer (e.g.



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spit, mucous). Surgical masks may also be used to help reduce the risk of splashes or sprays of blood, body fluids, secretions and excretions from reaching the wearer's mouth and nose.

Importance of Face Fit

Face Fit performance is a critical differentiator between the surgical mask and the respirator. In the "surgical mask" standard AS 4381, there are numerous references made to the importance of facial fit in respect to the use of ties, loops and headbands and statements made that the mask should achieve a "proper facial fit" so that risk of infection (for the patient) is minimised. There are, however, no test procedures in this Standard to actually test the fitting performance of the surgical mask on any face. Neither is there a minimum requirement for filtration performance. Many surgical mask manufacturers put filtration data on the packaging, however the test conditions indicated are not standardised and these results can be misleading. Many will not comply even with the simplest filter performance requirements of AS/NZS1716 but in practice it doesn't really matter so much how good or poor the actual filter media is in a surgical mask, because significant amounts of air and contaminants will leak around the edges of the mask.

Respirators are designed to seal to the face of the wearer. Therefore most of the inhaled air is drawn through the filter media and does not leak through gaps between the respirator and the wearer's face. The filtration efficiency and face fitting capability of a respirator is tested as part of Australian Standard AS/NZS1716 to demonstrate a minimum performance requirement using standardised, testing protocols. A fit testing panel is tested wearing the respirator to ensure that the product has a reasonable performance in effectively fitting a range of face sizes. If the various members of this panel (who have a range of face shapes and sizes specified in the Standard) cannot get an effective face seal, the mask will not pass the Standard.

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Surgical masks are not necessarily designed to provide a good seal to the face. However when the concern over laser generated particles or plumes came about a number of years ago, some surgical mask manufacturers started putting filter media into their masks to appear to improve their performance, but without meeting any respirator Standard. Most surgical masks are open on the sides and do not provide for a good facial seal. Therefore, the potential for air leakage around the edges exists. It is a common misconception in health care applications that having good filter media in a surgical mask will give effective respiratory protection equivalent to an AS/NZS1716 compliant respirator. Even those surgical masks that appear similar to respirators have not been designed or tested to protect the wearer from inhalation of airborne hazards and will not provide a level of respiratory protection that meets the Standard.

Fit Testing

While a respirator may pass the standard, there is still no guarantee that a specific model will fit a specific face. To determine if they can achieve a suitable fit for regular use in a workplace, wearers must be fit tested to ensure they wear the appropriate model and size. AS/NZS 1715 “Selection, use and maintenance of respiratory protective devices” has a requirement for the selected respirator to be fit tested on the wearer prior to issue and then at least annually, or whenever there is a change in facial characteristics of the wearer. The “fit” issue and “fit testing” are often not addressed at all in many Australian workplaces and the level of protection is thereby diminished. Face fit is pivotal to providing effective protection.

Respiratory Protection Program

AS/NZS 1715 also mandates the use of a respiratory protection program to supervise and control use of respirators in workplaces, with a number of specific elements that need to be addressed. All of these elements are required to achieve a satisfactory level of respiratory protection across a workforce. However, note that no respirator will prevent the inhalation of all particles; they cannot eliminate the risk of exposure, infection and illness.

The wearer must also perform a “user seal check” each time the respirator is worn prior to entering the contaminated environment to check the respirator-to-face seal. Respirators must be donned and worn properly the

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entire time the wearer is in the contaminated area. Training and appropriate information are required to achieve the results expected with any respiratory protection product.

Historically, “surgical masks” have been used for many purposes in the health care setting, while “respirators” are now recommended for use in certain applications where respiratory protection for the wearer is required. Federal Government Infection Control and Pandemic Guidelines recommend the use of P2 rated respirators (i.e. compliant with AS/NZS1716) for aerosol generating procedures like aerosolised medication treatments (e.g. albuterol), diagnostic sputum induction, bronchoscopy, airway suctioning, endotracheal intubation, etc.

The role and targeted uses of respiratory protection in the health care sphere is still evolving. There is currently much discussion on the significance of various transfer paths for infectious diseases, especially in regards to transmission by droplet transfer versus airborne aerosol transfer. The historical Universal Precautions view still applies, but it may need to be adjusted in the light of new information coming from research into aerosol behaviour, indicating there is an airborne pathway for bioaerosols which can put health care workers at risk.

Clearly there are many unknown factors associated with the swine flu or another pandemic. Physical parameters like particle shape and size range, density, aerial transport mechanisms, thermal and electrostatic effects as well as organism specific issues like infectivity, survivability, concentration and virulence will all impact on the spread of the disease. While there is still debate and the full picture is not clear, there is, at the very least, a real case to take a precautionary approach leading to use of respirators for all applications where there is a real potential for significant airborne transfer of infectious aerosols. Although respirators are aimed at airborne precautions, it is clear that a respirator is just one of several preventative measures that can be used to help reduce exposure to airborne bioaerosols. Precautions for other transmission paths (e.g. contact, vectorborne, common vehicle) also need to be followed.

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Worker safety relies on the precautionary principle that reasonable action to reduce risk should not await scientific certainty. This was a major finding of the Canadian SARS experience – protection of the worker as well as the patient is paramount. Whenever there is concern for worker exposure to an airborne hazard - infectious or otherwise, appropriate respiratory protection should be worn.

Occupational Health and
Environmental Safety Division
3M Australia Pty Limited
Building A, 1 Rivett Road
North Ryde NSW 2113
Phone: 136 136
TechAssist Helpline: 1800 024 464
Email: techassist@mmm.com
Website: www.3m.com/au/ohs

Occupational Health and
Environmental Safety Division
3M New Zealand Ltd
PO Box 33246
Takapuna, North Shore City 0740
Tech Helpline: 0800 364 357
Email: innovation@nz.mmm.com
Website: www.3m.co.nz/safety