

Fit Testing of P2/N95 respirators in respiratory protection programs– Guidance

1. Purpose and aims

The *Fit Testing of Particulate Filtration Respirators (PFR or P2/N95 respirators) in respiratory protection programs Guidance Document* (Fit Testing Document) has been developed to provide guidance and recommendations for decision-makers and healthcare workers (HCWs) in Queensland. The purpose of the document is to support the safe and practical integration of fit testing into respiratory protection programs. Health care workers means all workers (including non-clinical) who work in the facilities or services in scope for this guidance.

The document aims to:

- Acknowledge the primacy of health, safety and welfare of all workers at work, and all other people who might be affected by the work (i.e. our patients, visitors and community)
- Highlight the practical considerations for implementation of large-scale fit-testing programs
- Provide guidance on a prioritisation approach to support optimal allocation of effort and resources
- Explore some of the complex issues and risks associated with risk based respiratory protection programs

The guidance is based on Australian and international resources regarding respiratory protection programs, which include:

- AS/NZS 1715:2009 – Selection, use and maintenance of respiratory protective equipment
- AS/NZS 1716:2012 – Respiratory protective devices
- AS 4381:2015 – Single-use face masks for use in healthcare
- A/NZS 2243.3 – Safety in Laboratories.

Guidance on general risk and incident management is established in Queensland Health's *Health, safety and wellbeing risk management standard* QH-IMP-401-3:2018.

2. Scope

This guidance document applies to all Queensland Health healthcare settings and situations where there is a risk for infectious disease transmission. It is designed to inform local policies and to support local decision-making using a risk management framework. The guidance document incorporates

reasonable and proactive precautionary measures. When making decisions about the appropriate usage and selection of PFRs staff should perform a local risk assessment in accordance with local procedures, relevant standards and other guidance material.

3. Background

Hierarchy of control

The hierarchy of control is a system for controlling risks in the workplace. It is a step-by-step approach to eliminating or reducing risks and it ranks risk controls from the highest level of protection and reliability through to the lowest and least reliable protection. The hierarchy consists of hazard control measures broadly grouped into five categories.

Figure 1 is one representation of the hierarchy.

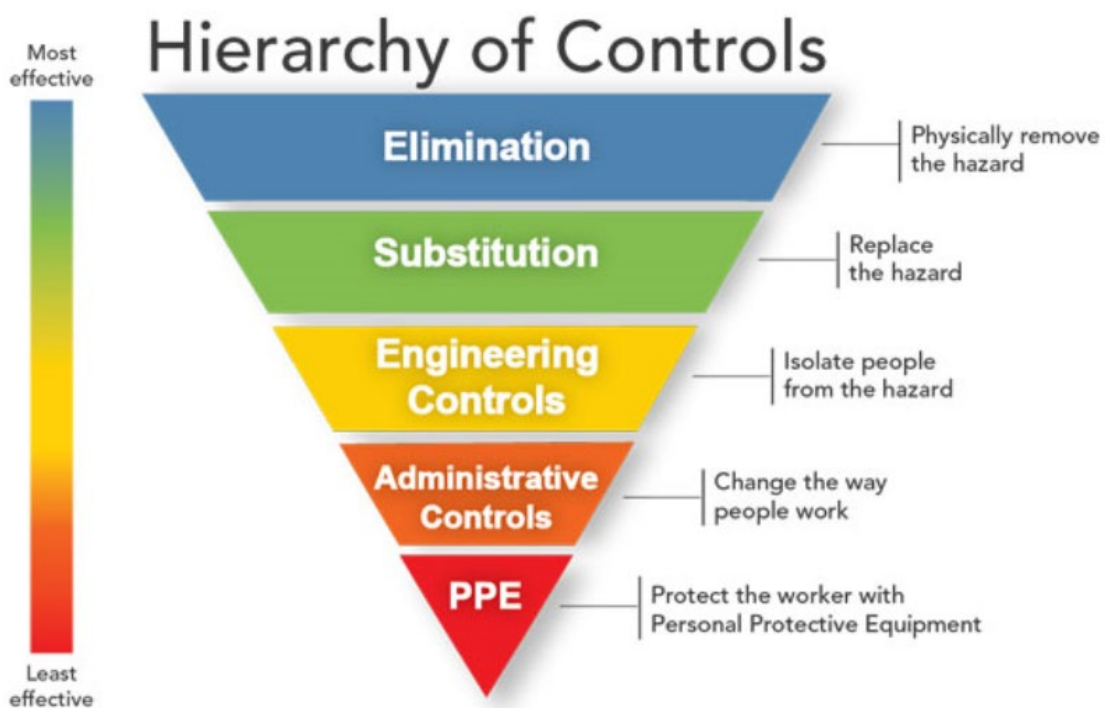


Figure 1. Hierarchy of control. Source: <https://www.cdc.gov/niosh/topics/hierarchy/default.html>

Eliminating the hazard and risk is the highest level of control in the hierarchy, followed by reducing the risk through substitution, isolation and engineering controls, then reducing the risk through administrative controls. Reducing the risk through the use of protective personal equipment (PPE) is the lowest level of control and is also considered the least reliable.

All other measures should be taken to remove or control the risk to workers and patients where it is practicable to do so without the need for PPE. During the provision of healthcare, the use of respiratory protection will be an essential element of defence in the hierarchy of infection prevention measures. It is important that healthcare workers perform a local risk assessment prior to fitting PPE to inform their use and selection of PPE.

The Department of Health has published [Minimising the risk of infectious respiratory disease transmission in the context of COVID-19: the hierarchy of controls](#) which provides additional information regarding the hierarchy.

Respiratory protection programs

Where respiratory protective equipment is required to be worn, Australian/New Zealand Standard 1715:2009 requires that a respiratory protection program be established. Respiratory protection programs include several elements that are designed to protect workers from workplace respiratory hazards including airborne infectious agents, dust and other particles.

Hospital and Health Services are responsible for implementing the elements of a respiratory protection program in accordance with Australian/New Zealand Standard 1715:2009.

A respiratory protection program includes the following components:

- Identification and appointment of a program coordinator or administrator
- Selection of appropriate TGA registered P2/N95 respirators for fit testing which will be those available for staff to use in practice
- Training:
 - for staff to perform fit testing and assessment. These staff should complete annual competency assessments.
 - for staff in the proper use of respirators including the requirement to fit check
 - to raise awareness of the transmission risk of airborne pathogens
- Documented risk assessment process to identify those staff to be included in a fit testing program including those working in high risk clinical areas
- Appropriate storage of respirators in accordance with manufacturer's specifications
- A documented process for the management of non-disposable respirators. The following should be included: storing, inspecting, disposing of respirators, appropriate reprocessing, testing, repairing and maintenance of respirators in accordance with manufacturer's instructions
- Regular program evaluation
- Record keeping of fit test results

It is essential that healthcare workers who are required to wear a respirator are trained and assessed for competency in the use of all PPE as part of an ongoing training program. An adequate face seal is required for the effective and reliable performance of respirators.

Australian/New Zealand Standard 1715:2009 describes two types of facial fit test that may be used in healthcare facilities.

The principles outlined in this guidance aim to support thoughtful and responsible implementation of fit testing into respiratory protection programs, prioritised by risk.

4. Definitions

For a respirator to provide its designed protection, it is essential that an adequate face seal is achieved between the facepiece of the respirator and the face of the wearer. End users should also check facial fit to ensure the right respirator products have been issued and that they are wearing the respirators properly. This is achieved through Fit Testing and Fit Checking

Fit Checking

Fit checking is the minimum standard required each time a P2/N95 respirator is put on to ensure it is applied properly. Fit checking must be performed each time a respirator is used, regardless of whether previous fit testing has been performed. Healthcare workers are to be instructed about how to perform a fit check. No clinical activity should be undertaken until a satisfactory fit has been achieved. Fit checks ensure the respirator is sealed over the bridge of the nose and mouth and that there are no gaps between the respirator and face. Training in the correct process for fit-checking should occur at the time of the fit testing procedure

Fit Testing

Fit testing is a validated method to determine whether a specific make, model and size of respirator achieves an adequate seal on an individual's face. Fit testing can be qualitative or quantitative (described below). The fit testing procedure also provides an opportunity to ensure HCWs are properly trained in the correct use of the respirator including fit checking each time the respirator is used.

Qualitative

A qualitative fit test is a facial fit testing giving pass or fail results and relies on the wearer's subjective response to an aerosolised test agent.

A flavoured test agent such as saccharin or Bitrex™ (a bitter tasting substance) is used at a sensitivity level that demonstrates the user will be able to appropriately sense the presence of the test agent within the respirator by taste, smell or the urge to cough if the fit of the respirator is not adequate.

Quantitative

A quantitative fit test gives objective numerical results through the use of specialised particle counting equipment (such as a PortaCount™ Plus machine). It measures how much air leaks into the wearer's breathing zone. It does not rely on the subject's response to a test agent.

5. General Considerations

1. PPE is the lowest order of control within the hierarchy of controls and is only a part of the total hazard control measure(s) which must include training, fit-checking and may also include concierge/buddy/spotter practices. These controls are to be applied in addition to other hazard controls, including elimination of the risk of exposure (which may include usage of eye protection, gowns and gloves), substitution, engineering and administrative controls continue to form the essential foundation of healthcare worker protection.
2. When the demand for both physical and human resources are extreme, full implementation of fit-testing for every healthcare worker assessed as requiring a P2/N95 respirator when utilising airborne transmission-based precautions may not be reasonably practicable. Fit testing must occur in line with the Australian and New Zealand Standard while there is capacity so that fit-testing remains compliant with the relevant standard.
3. A risk stratified approach, with prioritised fit-testing directed towards the locally identified highest risk situations, is an appropriate way to manage limited resources and the required implementation of PPE controls
4. Staff must be clearly informed of their rights and responsibilities regarding respiratory protection programs.

Decisions regarding implementation of fit-testing should:

- Be focussed on practical risk reduction
- Prioritise those staff who are assessed as at being of greatest risk of exposure
- Address both physical and psychological safety
- Provide for transitional measures for staff who are working in high-risk environments, but who have not yet been able to be fit-tested, subject to operational requirements.

6. Recommended approach to Respiratory Protection Programs

A risk-management framework is to be applied to ensure that staff working in areas with a significant risk of exposure to diseases transmitted via the airborne route are fit tested and are aware of how to perform a fit check.

All healthcare facilities should:

- Maintain their fit testing resources and have them accessible
- Have a respiratory protection program that regularly evaluates the risk of exposure to potentially infectious airborne agents in specific settings and subsequently determines which employees are required to undertake fit testing.
- Give consideration to developing a risk-based approach where the risk to exposure to infectious agents (and PFRs would act as a protective measure in these circumstances) is constant.
- Ensure that an educational program for fitting, removal and disposal of N95 respirators is provided focusing on the location and process for safe removal and disposal of respirators to prevent the risk of transmission of healthcare associated infection.
- Consult with unions on the application of fit-testing and the application of risk assessments in the workplace that determine fit-testing being undertaken.
- Inform staff of limitations of qualitative fit-testing and explore options for quantitative fit-testing where ever possible.

A local evaluation of risk is required due to variations in the local environment. When applying an infection prevention risk management approach, the following factors increasing the risk of transmission of infection should be considered:

- Routine care of patients with infections demonstrating regular airborne transmission across distance such as tuberculosis or measles
- Aerosol generating procedures (AGPs) in patients with respiratory infections (including COVID-19) including:

- instrumentation or surgical procedures on the respiratory tract e.g. intubation, bronchoscopy, tracheostomy, disconnection of closed ventilator circuit, ENT, maxillofacial/transsphenoidal or thoracic surgery involving the lung
- non-invasive ventilation, induced sputum collection, high-flow nasal oxygen
- upper GI instrumentation involving suctioning of respiratory tract
- some dental procedures including high speed drilling
- cumulative exposure to the patient and infectious agent i.e. prolonged contact, enclosed space, suboptimal ventilation, Aerosol Generating Procedures (AGPs) or Aerosol Generating Behaviours (AGBs), exposure during period of high infectivity

In accordance with the facility's respiratory protection program, fit testing must be undertaken:

- at the commencement of employment for employees who will be working in clinical areas where significant risk of exposure to infectious agents transmitted via the airborne route has been assessed¹ This may include assessment of risk based on the risk matrix included in the Pandemic Response PPE guidance documents, which considers health facilities, residential aged care and disability accommodation services, community health and in-home settings and corrections and which are available on the Queensland Health website [here](#) or other sources for other respiratory pathogens including the National Tuberculosis Advisory Committee ([NTAC](#)).
- when there is a significant change in the wearer's facial characteristics that could alter the facial seal of the respirator (e.g. significant change in body weight, facial surgery or growth in facial hair).
- at regular intervals in accordance with relevant standards—AS1715:2009 recommends annual fit testing. Healthcare facilities must ensure that they have a respiratory protection program that regularly evaluates the risk to which healthcare workers are exposed and determines which employees are required to undertake fit testing.

7. Fit Testing within workplace Respiratory Protection Programs

Only respirators (disposable and non-disposable) included in the Australian Register of Therapeutic Goods (ARTG) should be used in healthcare settings and considered in respiratory protection programs.

Fit testing includes the following components:

- Identification of fit test method
- Identification of a fit testing program coordinator or administrator

¹ An assessment of risk is to also take into consideration matters related to air ventilation and air quality. Whereas, addressing the matters of air ventilation and air quality are outside of the scope of this document, noting of air ventilation and air quality are considerations when determining risk related to PPE usage and the need for fit-testing as per this guidance document.

- Ensuring adequate numbers of personnel competent in fit testing training and assessment (either by training of an adequate number of internal staff or utilisation of external expert services).
- A process to identify which employees are to be included in a fit testing program including those working in high-risk clinical areas, and the priority for testing
- Selection of P2/N95 respirators for fit testing which are same make, model and size of respirators that employees are expected to use in the workplace
- Appropriate storage of disposable respirators according to manufacturer's specifications (e.g. temperature and humidity control) and stock control.
- A procedure and schedule for non-disposable respirators use must include: fit testing, storage, inspection, reprocessing, repair and maintenance as per manufacturer's instructions. Note further guidance on use of Powered Air Purifying Respirators (PAPRs) is under development.
- Training in understanding transmission risk of airborne pathogens
- Training in the proper use of respirators including fit checking
- An evaluation framework to ensure the program responds to the needs of employees based on local risk assessment
- A documentation system should be established to record HCW fit testing results (baseline and ongoing). Records of HCW fit testing results will be made available to both HCW and managers (see section 12 for more detail of documenting results of staff fit testing).

8. Fit Testing Personnel – program administrator

There is no current industry standard qualifications required by staff engaged to perform fit test assessments. Commercial fit test providers and occupational hygienists provide services under a competent person model. Queensland Health staff with requisite skills and knowledge may be suitable for appointment as program administrator. Refer to ISO 16975-3 and *AS/NZS1715:2009 Selection, use and maintenance of respiratory protective equipment* for further guidance.

Fit Test Program Administrator

Australian/New Zealand Standard 1715:2009 requires that an individual is assigned the responsibility to implement and coordinate the respiratory protection program. The program administrator should be suitable trained with an understanding of the key principles of respiratory protection and an understanding of workplace hazards. Australian/New Zealand Standard 1715:2009 recommends that the administrator is an occupational health and safety professional.

Function of the role

- The Fit Test administrator role includes establishment of local fit test training programs, conducting train the trainer and annual competency assessment for fit test trainers.
- Assessment of competency to perform fit testing assessment of the fit trainer administrator shall be supported by the HHS to perform fit testing at a facility level.

Fit Test Trainer

Training required for role

- Appropriate training as determined by the fit-test program administrator.

Function of the role

- Train the fit-test operators in fit-testing, including ensuring Fit-test operators are aware of relevant guidance, standards and legislation.
- Liaise with the fit-test program administrator to check that current training is up to date.

Fit-Test operator

Training required for role

Successful completion of training as determined by the fit-test program administrator.

Function of the role

- Conduct respirator fit-testing for staff in accordance with relevant guidance.

9. Facial Seal of Respirators

An adequate seal may be difficult to achieve for people with facial hair. The effectiveness of a tight-fitting facepiece, such as half-face or full-face respirators that use straps, relies on an effective seal with the wearer's face. If the respirator does not fit properly, the wearer will not get the expected level of protection. Facial hair that lies along the sealing surface of a tight-fitting respirator prevent an effective seal. Therefore, it is a requirement that there is no hair growth between the skin and the facepiece sealing surface in order to achieve a fit. AS/NZS 1715:2009 (Appendix B) provides guidance in relation to beards, moustaches, sideburns, stubble growth and long hair (see also the CDC guide on Facial Hairstyles and Filtering Facepiece Respirators <https://www.cdc.gov/niosh/npptl/pdfs/facialhairwmask11282017-508.pdf>) Other factors that may interfere with facial seal includes jewellery, facial makeup and creams.

10. Failing Fit Test

- Employees who fail a fit test with a certain respirator must be tested with a second and if required subsequent respirator(s) to ensure the correct brand and size is determined in relation to facial features and ability to maintain a facial seal.
- Where repeated fit test has failed, the employee must be referred to the Fit Testing Program Administrator in consultation with their Line manager for re-evaluation and development of a plan.
- Fit testing can be repeated if new stock of different specifications becomes available.

11. Staff unable to comply with Respiratory Protection Requirements

The requirement for use of PPE and to remove facial hair as necessary is a lawful direction. Employees can refuse a lawful direction for certain prescribed reasons (such cultural and religious reasons). Where a circumstance of non-compliance arises, the following broad steps are recommended in reaching a resolution:

- Consult with the employee
- Exploring different options (such as another work location remote or flexible work)
- Potential to take leave.

12. Recording of Fit Testing

All fit testing results will be recorded in a database accessible to relevant staff:

- Name of employee and payroll number
- Work location/s
- Date fit test performed
- Medical screening/evaluation of the prospective users to determine their physical and psychological suitability to wear respiratory protective equipment
- Size and brand of respirators that were successfully fitted and outcome of fit test
- Size and brand of respirators that were unsuccessfully fitted or not tested (e.g. failed fit check)

In addition, workplaces should maintain a record (e.g. in Riskman) of any instances where staff have continued to work in situations where P2/N95 respirator were required but where the respirators were not available or a fit test was not successful. The reporting of these instances will be monitored by the system to ascertain compliance with relevant standards and legislation and to better monitor staff safety in working in environments where risk of exposure to significant known [or notable and unusual] infectious agents exists.

Staff who may be at risk of tuberculosis or other airborne disease transmission can continue to work pending formal fit-testing provided they wear a PFR which meets fit checking requirements. Fit testing should be prioritised for this group and the following should be recorded:

- duties performed and the assessed risk level;
- what alternative duties were offered;
- what services would be affected if the employee accepted alternative duties;
- what concerns were raised by the employee, and how were they addressed.

Any information recorded about the reasons for an employee continuing to work without adequate PFR must be provided to the employee. The employee must be given an opportunity to provide alternative information to be attached to the workplace statement. A dispute mechanism is to be in place, with assistance being offered early to prevent avoidable escalation.

13. Communication of results of Fit Testing

- Staff should be advised of the size and brand of respirators that were successfully fitted and be provided with the relevant documentation for future reference by the HCW.
- Staff should be advised of criteria for further fit testing (recommended annually or sooner if there is a significant change in facial features)
- Workplaces should implement methods for collection of aggregate fit test results in order to inform procurement. Staff should be advised that their fit-testing results will be used for this purpose.

14. Relevant Legislation and Standards

The Queensland *Work Health and Safety Act 2011* provides a consistent framework to secure the health and safety of workers and workplaces. Workers and other persons at the workplace (including patients, visitors etc) must also take reasonable care for their own health and safety; and care that their conducts, acts or omissions does not adversely affect the health and safety of others.

<p><i>The Queensland Work Health and Safety Act 2011</i></p>	<p>Provides a consistent framework to secure the health and safety of workers and workplaces. Workers and other persons at the workplace (including patients, visitors etc) must also take reasonable care for their own health and safety; and care that their conducts, acts or omissions does not adversely affect the health and safety of others.</p>
<p><i>The Queensland Work Health and Safety Regulation 2011</i>, describes how to prevent or minimise risk at the workplace.</p>	<p>Division 5, Section 44 (3) of the Regulation describes how to prevent or minimise risk at the workplace and includes provisions specifically regarding PPE suitability, size, fit, maintenance, hygiene and use.</p>
<p>1. Australian/New Zealand Standards</p>	<p>AS/NZS 1715:2009 - Selection, use and maintenance of respiratory protective equipment</p>

	<p>AS/NZS 1716:2012 - Respiratory protective devices</p> <p>AS 4381:2015 - Single-use face masks for use in healthcare</p> <p>A/NZS 2243.3 – Safety in Laboratories.</p>
2. International Standard	ISO 16975-3 Respiratory protective devices, selection use and maintenance- Part 3 Fit-testing procedures First Edition 2017-09
3. Australian Guidelines for the Prevention & Control of Infection in Healthcare (2019)	☑ Recommends that where there is a high probability of airborne transmission due to the nature of the infectious agent or procedure then a correctly fitted P2/N95 respirator should be worn
4. National Safety and Quality Health Service Standards: Standard 3 - Preventing and Controlling Healthcare Associated Infections Criterion 3.7.1	- requires infection prevention and control consultation regarding policies and procedures that address personal protective equipment.
5. Health, safety and wellbeing risk management Standard, QH-IMP-401-3:2018	This Queensland Health Standard establishes the requirements for managing work health and safety (WHS) hazards and risks.

15. Recommendations

Workplaces should develop systems to:

1. Clearly identify high- and medium- priority healthcare workers to be enrolled in a fit-test program
2. Continue to ensure training on the use of respirators reinforces the requirement for the wearer to perform a fit check every time a respirator is fitted.
3. Where qualitative fit testing against available PFR stock is unable to confirm a fit, provide second tier access to quantitative testing in order to provide an objective result.
4. Where a fit-fail is confirmed, take measures to ensure alternative management – either through reallocation of duties, or development of an alternative, personalised PPE plan.
5. Establish processes to be followed when a staff member requires respiratory protection and no respirator for which they have been fit-tested for is available, noting that AS/NZS 1715:2009 provides guidance on this matter.
6. Maintain a database of fit testing outcome data, including name, date, payroll number, and result of testing and of instances where staff have continued to perform duties in situations where the wearing of a respirator and compliance of fit testing was required by relevant legislation, standards and guidance.

7. Ensure that an educational program for fitting and removal of respirators is provided that focuses on the location and method for safe removal respirators to prevent the risk of transmission of healthcare associated infection (self-contamination).
8. Consultation with Health and Safety Representatives within the organisation should occur when implementing arrangements to comply with legislation, standard and guidance for fit testing and use of P2/N95 respirators.

16. References and Resources

- Interim infection prevention and control guidelines for the management of COVID-19 in healthcare settings. Queensland Health, Version 1.14 4 October 2020
- Respiratory Protection Against Airborne Infectious Diseases Clinical Guideline v1.4 June 2020 South Australia Health Clinical Guideline No.: CG099
- Respiratory Protection in Healthcare Version 1 August 2020 NSW Health Clinical Excellence Commission
- Victorian Respiratory Protection Program guidelines September 2020 (Version 1.1) State of Victoria, Australia, Department of Health and Human Services, 25 September 2020
- CDC guide on Facial Hairstyles and Filtering Facepiece Respirators <https://www.cdc.gov/niosh/npptl/pdfs/facialhairwmask11282017-508.pdf>
- The use of face masks and respirators in the context of COVID-19. Infection Control Expert Group. 28 October 2020.

18. Consultation

This guidance has been developed in consultation with:

- Safety and Wellbeing, Corporate Services Division, Queensland Health
- The Queensland Health Statewide Infection Clinical Network
- Clinician and HSCE representatives from the COVID Response Group (CRG)
- Communicable disease branch, Queensland Health
- Union representatives

19. Review

This guidance will be reviewed as new information becomes available.

20. Approval and implementation

Document custodian:

Dr Jillann Farmer

Approving officer:

Dr Jillann Farmer, Deputy Director General Clinical Excellence Queensland

Approval date: xx March 2021

Version control	Date	Prepared by	Comments
V0.1 – V0.09	Sep 2020-Feb 2021	Fit-testing working group and then PPE Working Group of the CRG.	New document
V0.10	11/3/21	Dr Alex Markwell on behalf of PPE Working group	Incorporating further feedback and updated national guidelines
V1.0	25/3/21		Endorsed by CSLF