INTERNAL USE ONLY

Australian Government Department of Health and Aged Care	Laboratories Branch
Owner: s22	**Number: BiomE-SOP-35**
Author: s22	**Version: 1**
Active: 22/10/2021	**Review: 22/04/2023**
Title: **Particulate Filtration Efficiency – Rapid Screening**	

The Authoriser of this document, as a delegate of the Secretary for the purposes of regulation 28 of the *Therapeutic Goods Regulations 1990* (**Regulations**), has determined that the *Particulate Penetration Efficiency Assessment – Rapid Screening* assessment is a suitable test for demonstrating the compliance of the relevant kinds of device with the essential principles, and requires, pursuant to sub-regulation 28(2)(d) of the Regulations, the test to be carried out for that purpose.

Purpose

1. This Standard Operating Procedure- *Particulate Penetration Efficiency Assessment – Rapid Screening* (SOP) is intended to assist operators and analysts in efficiently quantifying the filtration efficiency of respirators included in the Australian Register of Therapeutic Goods.

2. The purpose is to outline the "rapid screening" method for assessing the particle filtration efficiency (PFE) of respirators using the Salt Aerosol Automated Filter Tester ATI 100Xs located in the Biomaterials and Engineering (BIOME) laboratory.

Salt Aerosol Automated Filter Tester - ATI 100Xs

3. The TGA laboratories' in-house developed rapid screening method for assessing respirators is based on the National Institute for Occupational Safety and Health's (NIOSH) published filter efficiency test TEB-APR-STP-0059[1], Revision 3.2, December 13, 2019.

4. Standard Testing Procedure TEB-APR-STP-0059 (STP-0059) was specifically designed to meet the requirements set forth in United States 42 CFR, Part 84, Subpart K, 84.1812 for **certifying** N95 respirators, however, the TGA in response to COVID-19 developed a "modified" protocol – *Particulate Filter Efficiency Penetration Assessment – Rapid Screening* to rapidly assess the filtration efficiency of respirators in the Australian Register of Therapeutic Goods (ARTG) listed, distributed to or used by Australian healthcare workers.

[1] TEB-APR-STP-0059-508 - https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf

[2] Code of federal Regulations – 42 - https://www.govinfo.gov/content/pkg/CFR-2004-title42-vol1/xml/CFR-2004-title42-vol1-part84.xml

Scope

5. The scope is limited to KN95/N95/FFP2/P2 and similar class disposable respirators claiming compliance with standard's requirements for particle filtering respirators that meet the definition of a medical device. The rapid screening assessment measures penetration filtration efficiency adopting industry best practice. It combines an in-house method based on a modified published test procedure using a commercially available purpose designed instrument within the context of quality system ISO/IEC: 17025.

6. The assessment is specifically developed as a means to **expeditiously** quantify the filtration efficiency of respirators claiming compliance or certification to an international standard. Only particulate filter efficiency properties are assessed, as fit testing and exhalation resistance are not a part of this assessment. Procedures performing visual inspection and if applicable, synthetic blood penetration testing are articulated within other BiomE Standard Operating Procedures (SOP).

7. The test method and principles prescribed in this SOP employs the basic particle filtration method described in STP-0059 with the following differences:

8. *Equipment / Material*

    a. Clause 3.1.1- Instead of a TSI 8130 Automated Filter Tester, BIOME uses a Salt Aerosol Automated Filter Tester ATI 100Xs that has equivalent or better specifications.

    b. Clause 3.1.5 - Instead of a 2% salt aerosol solution, the ATI100Xs uses a 4% salt aerosol solution producing similar particle size and distribution.

NIOSH CertiTest 8130 Automated Filter Tester

ATI 100Xs Automated Filter Tester

    c. Clause 5.1.1- The mg/m^3 NaCl aerosol concentration via the gravimetric method **is** routinely determined on the days that maximum penetration testing is performed. However this rapid assessment protocol **does not** load respirator filter units (specimens) with 200 mg over a typical two hour period; instead the primary purpose of

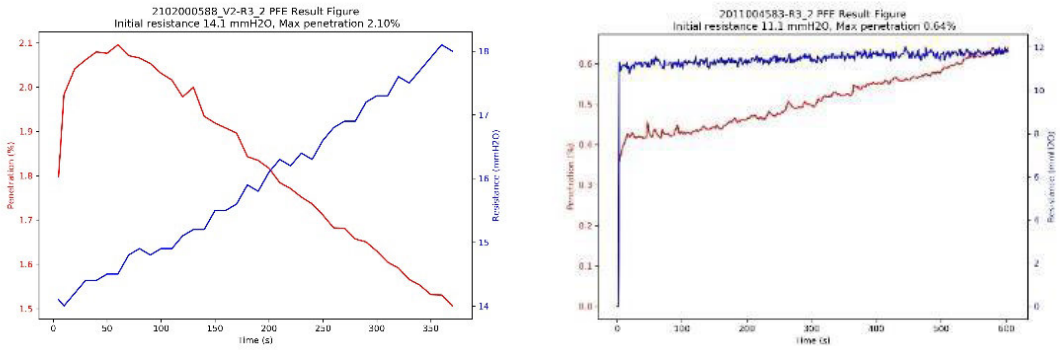
the assessment is to identify respirator peak penetration during a shorter 5-10 minute test where filter specimens are typically loaded with around 8 to 18 mg NaCl.

d. Clause 5.1.4: Verification of NaCl particle size distribution **is not** determined using **2** and **5** stacked "greenline" filter discs run at least once in each 8-hour test period as per the NIOSH STP-0059. Instead, NaCl particle size and distribution is verified using **4**, **3** & **2** stacked "greenline" filter discs. The greenline verification test is carried out straight after performing the light scattering photometer (LSC) and penetration (PENCAL) calibrations prior to each 8-hour shift.

9. *Procedure*

a. Clause 5.2 - Specimens **are not** pre-conditioned at 85 ± 5% relative humidity and 38 ± 2.5 °C for 25 ± 1 hours then sealed in a gas-tight container and used within 10 hours. Instead, specimens are exposed to and tested under normal laboratory ambient conditions.

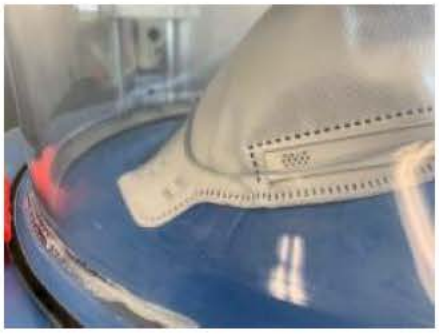
b. Clause 5.4 - The first three of 20 specimens **are not** mass loaded with 200 ± mg of NaCl to determine the method for testing the remaining 17 filters. Instead, for each specimen, testing is manually stopped 5 minutes after peak penetration has been reached or 10 minutes has expired (whichever is sooner). Penetration, flow and resistance data is automatically captured and transferred by USB cable to a computer every 1 second then recorded and plotted on a chart in near real time during testing as shown below.



Testing manually stopped 5 minutes after peak penetration and after 10 minutes of testing

c. Specimens **are not** sealed with heated bees wax. Instead, they are mounted in a purpose designed "Sterling" adapter and sealed by compressing the specimen between clear rigid plastic and EVA foam fixtures. If seal integrity cannot be established with the Sterling fixtures then masks are sealed using blu-tac putty and/or hot melt glue.

NIOSH bees wax sealing



Sterling adapter compression sealing

Loctite Mounting Putty sealing in ATI adapter

Responsibility

10. Personnel undergoing training or authorised within the quality management system are covered by this SOP. A Biomaterials and Engineering Section senior engineer is responsible for the maintenance of this procedure and general compliance with its requirements. All users of this SOP must ensure that equipment is calibrated and adhere to WHS requirements relevant to the testing environment.

Introduction

11. The BiomE section uses an ATI 100Xs Salt Aerosol Automated Filter Tester to determine the particulate filter efficiency level for KN95/N95/FFP2/P2 and similar filter specimens. The test method in this document is described in sufficient detail to allow a person knowledgeable in the appropriate technical field to operate the equipment properly, conduct the test and document results. The values reported are only to provide **an indication** of filter efficiency and are not confirmation that the product conforms to the requirements of its "claimed" certification mark. The assessment results are used to provide useful information about the filter efficiency of specimens in the context of the *Therapeutic Goods (Medical Devices) Regulation 2002- Schedule 1 Essential Principles*.

Note: This document should be used as a 'living document' that is revised and refined as the needs and demands of the testing program change and processes are further developed.

Background

12. In Australia, most disposable respirators and filters that give protection against dust and other particles are classified and marked as either P1, P2 or P3, in accordance with the Australian Standard AS/NZS 1716:2012. There are also international standards for the classification of these respirators, with the United States 'N95', European 'FFP2' and Chinese 'KN95' considered comparable to the Australian P2.

Common classification for respirators

Product Classifications	Jurisdiction	Performance Standard
P2, P3	Australia/New Zealand	AS/NZS 1716:2012
N95	USA	42 CFR 84
KN95, KP95, KN100, KP100	China	GB2626-2019
Medical Protective Masks		GB 19083
FFP2, FFP3	Europe	EN 149-2001 + A1:2009
DS/DL2, DS/DL3	Japan	JMHLW-2000
Korea 1st class	Korea	KMOEL-2017-64

13. The key differences in the performance requirements and testing between the international respirator standards are shown on page 21 of this document. This procedure focuses solely on penetration efficiency by employing a modification of the standard testing protocol described by NIOSH - *Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air Purifying Respirators Standard Testing Procedure TEB-APR-STP-0059*.

14. The BiomE ATI 100Xs Salt Aerosol Automated Filter Tester is used to test high efficiency particulate filters by using an aerosolised mixture of sodium chloride and distilled water.

15. P2/FFP2/N95/KN95 and similar respirators (filters or specimens) are typically loaded with 8 to18 mg of salt solution for between 320 seconds and 600 seconds depending on each individual penetration characteristics. The minimum efficiency for the filters tested must be equal to or greater than the filter efficiency criterion claimed for the filter class. For example, after being loaded with NaCl for up to ten minutes, a KN95/N95 particulate filter must demonstrate filter efficiencies greater than or equal to 95%.

16. For the purpose of rapid screening, respirators are not preconditioned before testing but are tested as received in normal laboratory ambient conditions.

Procedure

TRAINING METHODOLOGY

17. Operators must be trained, assessed as competent and authorised[3] in accordance with the quality management system before using the instrument or carrying out testing activities.

18. For the purposes of this SOP, **training** basically follows the three steps below:

    a. trainee observes a test being performed by an instructor,

    b. trainee completes tests on samples/specimens under close supervision of the instructor, and

    c. trainee completes a test on samples/specimens on their own

19. Competency is maintained when person has performed the operation satisfactorily within the last 18-months. Verification of competency shall be achieved by referring to the date this procedure was performed by the operator (i.e. QLIMS and tests results, etc.). If the procedure is not performed within the 18-month period retraining / re-familiarisation is required.

20. Training recorded on BiomE-Form-8 is maintained in the individual's training file within TRIM.

*Note: The **instructor/authoriser** shall be a competent person with suitable qualifications or experience related to testing.*

21. In addition to carrying out testing in accordance with documented procedures, new operators must also demonstrate underpinning knowledge and skills associated with properly and safely setting up and operating the equipment, replacing consumables, verifying correct instrument operation and performing basic maintenance activities. It is essential that all operators:

    a. read and comprehend the information contained in the entire Operating Manual before using the ATI 100Xs Automated Filter Tester,

    b. have a broad understanding of the electrical and mechanical system principles used in the operation of the ATI 100Xs Automated Filter Tester,

[3] Training and authorisation record for operator *Face Mask Testing* competency located and filed in TRIM 2015/028404

c. demonstrate competency in the proper use of the electro-mechanical equipment,

d. maintain the ATI 100Xs Automated Filter Tester as specified in *Operating Manual*, and

e. maintain and keep in proper working condition any other equipment associated with the operation of the ATI 100Xs Automated Filter Tester.

WHS REQUIREMENTS

22. Operators should consider all safety risks to themselves, others and the equipment prior to commencing testing as well as wear appropriate personal protective equipment (PPE) for the task. As a minimum, PPE should include a lab coat and enclosed footwear. Operators must read the risk assessment associated with testing filters and masks [**251291682020**] located in the TGA Risk Assessment database http://tgalqs/riskassess/index.htm.

23. In addition to the above when working with the ATI 100Xs, operators must:
    a. take care around equipment with moving parts that have the potential to cause crush injuries,
    b. be aware of slip hazards caused by water, and
    c. recognise risks of immediate surroundings.

24. Maintenance and cleaning activities including replenishing sodium chloride solution must strictly be carried out in accordance with the *100Xs Operation and Maintenance Manual*. Failure to follow specified procedures and precautions could result in **PERSONAL INJURY** or **DAMAGE** to the unit.

EQUIPMENT LIST

25. The list of test equipment and materials required to test respirators are as follows:
    a. ATI 100Xs Automatic Filter Tester – LIMS Instrument No. 33211 – [TRIM E20-325497]
    b. Analytical balance, accurate to 0.0001 grams – LIMS Instrument No. 33203 – [TRIM E20-313316]
    c. Binder temperature/humidity chamber capable of maintaining 38 ± 2.5 °C and 85 ± 5% relative humidity. LIMS Instrument No. 10292 or 33212 [TRIM 2010/020501 or E20-343149]
    d. NATA calibrated digital thermometer and humidity ambient data logger - LIMS 33215 [E20-343207]
    e. Type A/E glass microfiber filters, 127 mm diameter – Sartorious 13430-127------K. (Gravimetric testing is a daily requirement).
    f. Sodium chloride solutions in distilled water - 4% and 0.9%. [D20-881086 & D21-2775907]

g. Data acquisition system (PC or laptop) loaded with QMS approved data reader software connected by USB cable to the ATI 100Xs. (TRIM 2016/032315)

h. Glass microfibre filter media verification disks 15.24 cm (greenline), grade: HE-1071 supplied by ATI - part number #550016

i. ATI 100Xs Performance Validation Sheet – TRIM D21-2824018

j. Digital camera for photographing samples.

Note: If equipment is unavailable at time of testing, substitute with an item of equivalent accuracy and specifications. Record substitution details with the LIMS number of equipment used in the relevant spreadsheet templates.

SODIUM CHLORIDE

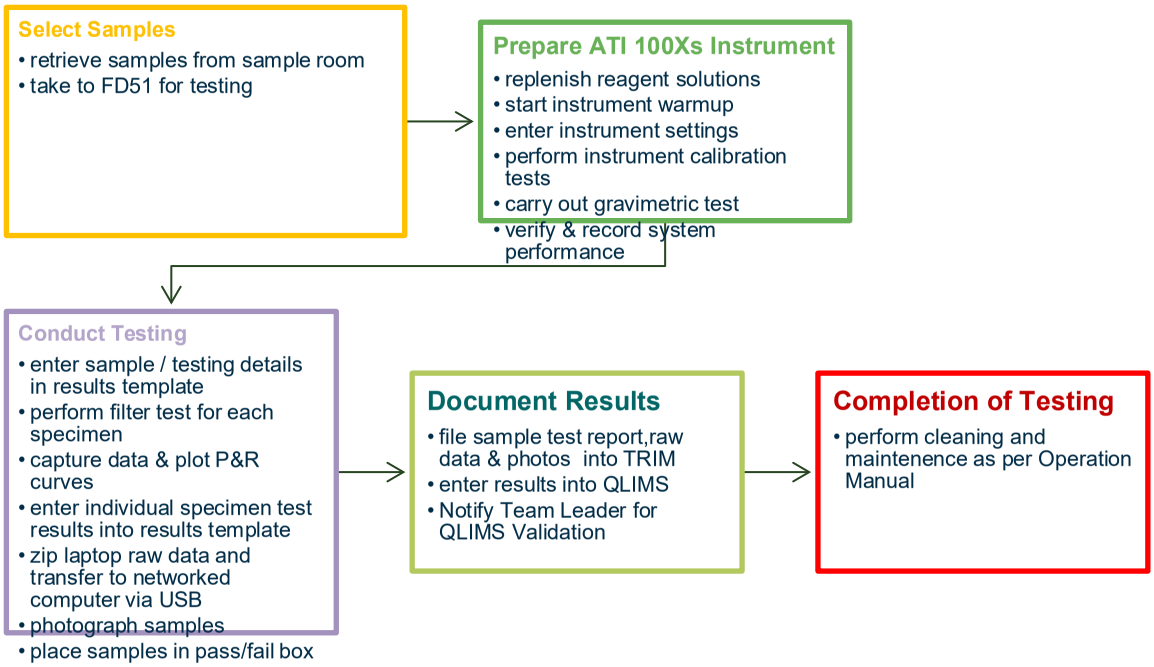
26. Reagent grade sodium chloride (NaCl 4% and NaCl 0.9%) solutions are sourced from Microbiology Section's Media Prep unit via the Sterilisation and Media Ordering database (SAMO) located here [D20-189742]. Instructions on how to use the SAMO are located in TRIM E17-29098.

27. Ensure 4% and 0.9% salt solution stocks do not drop below 10 working days (consumption is typically about 1 litre of 4% and 500 ml of 0.9% per day of testing). Order reagent grade salt solutions in batches of 5 litres. For example; 15 x 1 litre of 4% NaCl & 10 x 1 litre of 0.9% NaCl sodium chloride in 2 litre Schott bottles from Media Prep 2 weeks in advance of when it is actually needed.

28. Media Prep will deliver the NaCl to the laboratory when it had been made and quality inspected.

TESTING PROGRAM MAP

29. The program map below provides a basic visual representation of how the testing program is intended to work.



SAMPLE MANAGEMENT

30. Samples are given a unique LIMS number when they are indoctrinated into the testing program.
31. They are normally stored in restricted access room FE15 before undergoing testing.
32. The identification of samples and specimens must be known at all times. The process for relocating samples from one to another is as follows:
    a. ensure samples are easily identified by their LIMS no
    b. take the entire sample ensuring it is properly sealed in bag
    c. do not split samples
    d. fill out sample bag labels as required
    e. on completion of testing return the sample/s to FE15.

RANDOMISED SAMPLING:

33. This rapid assessment uses convenience sampling; a non-probability sampling technique whereby samples are drawn from the population based on their availability.

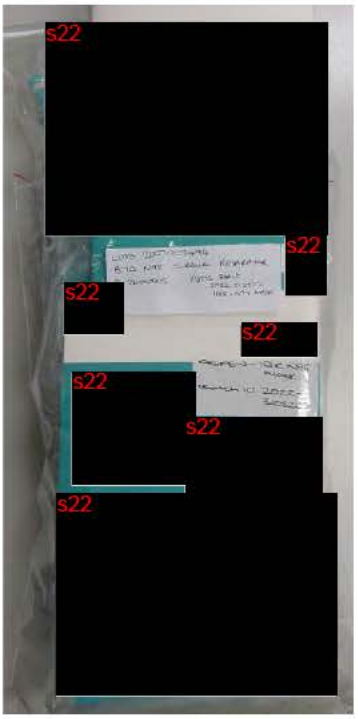
34. Respirator filter specimens are then selected at random from the sample provided.

    a. respirator boxes/packages are segregated from a single batch (i.e. same LIMS #).

    b. twenty two (22) specimens are selected from the various boxes and placed in a labelled clean sealable plastic bag with one of the flattened boxes inside a sealable plastic container bin ready for testing.

    c. unused specimens are returned to their original box/packaging.

Note: There could be up to three batches of 22 specimens from the same sample (or 66 respirators in total) ready for testing. The batches should be easily distinguishable from each other.



Example of 22 respirators with box

PREPARING INSTRUMENT FOR TESTING

Testing Requirements and Conditions

35. Prior to beginning any testing:

    a. confirm that all measuring equipment employed has been calibrated in accordance with the QMS system and QLIMS equipment schedule

    b. confirm reagents are of suitable quality and quantity (i.e. exactly 1 litre) and have not expired

    c. confirm suitability of test reference media (Green line paper)

    d. confirm high pressure air supply to instrument is set to 95 +/-5psi @ 311 l/min, and

    e. ensure laboratory ambient conditions are within the following:

        - ambient temperature: 20 to 35° C
        - ambient humidity: 45% to 70%
        - ambient pressure[4]: 97.3 to 105 KPa.

[4] D20-1015177 NOTE TO FILE Air Pressure FD56 & FD51

Before you begin

36. Ensure ATI 100Xs power cord is connected to a switched on electrical outlet via an uninterruptable power supply.

37. Ensure compressed air source shut-off valve is turned on and the wall regulator reads between 90 & 100 psi.

38. Check aerosol generator solution level. If necessary remove the top of the aerosol generator and fill with exactly 1 litre of pre-mixed 4% sodium chloride solution to the blue line on long black tube. Replace the generator top and attach the lines to their respective fittings. (Page 119 of Operations & Maintenance Manual).

39. Remove the cap from the replenishment reservoir and ¾ fill to the marked line with pre-mixed 0.9% sodium chloride solution. Replace the cap, fully insert the feed line into the cap mounted quick-connect fitting and place the replenishment reservoir in its recess with the cap/fitting towards the top. (page 120 Operations & Maintenance Manual)

40. Switch on the instrument by pressing the “green” power switch and allow at least 20 minutes warm-up before performing gravimetric/LSC/Pencal.

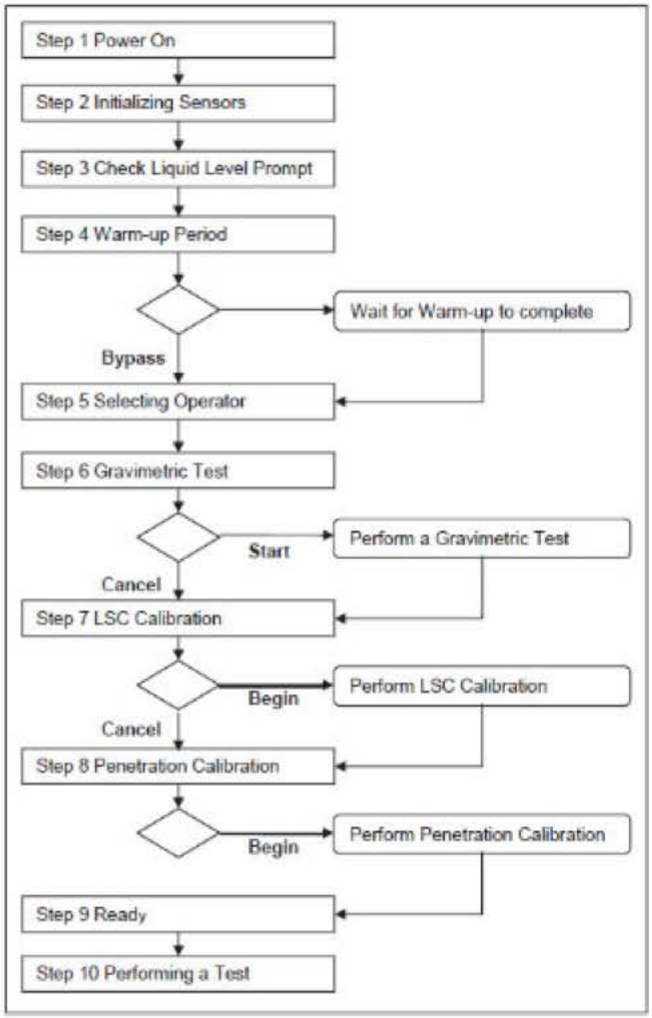
Calibrating Instrument and Verifying Performance before Testing

Note: The following steps involve following prompts on the digital screen in the required order. Operator requires a PIN "0"

Calibrate instrument

41. If the machine has been shut down (i.e. not left on standby), the gravimetric test, light scattering photometer (LSC) and penetration calibrations PenCal) including greenline verification must be completed prior to any testing to ensure accurate measurement results.

42. To do this, the Operator must complete the routines (steps 1-10) in the order presented on pages 57-62 of the 100Xs Operation and Maintenance Manual. Alternatively, "Start-Up" sequence tutorial can be viewed on ATI 100Xs website: https://ati.zendesk.com/hc/en-us/articles/360003021651-100X-Startup-Sequence-

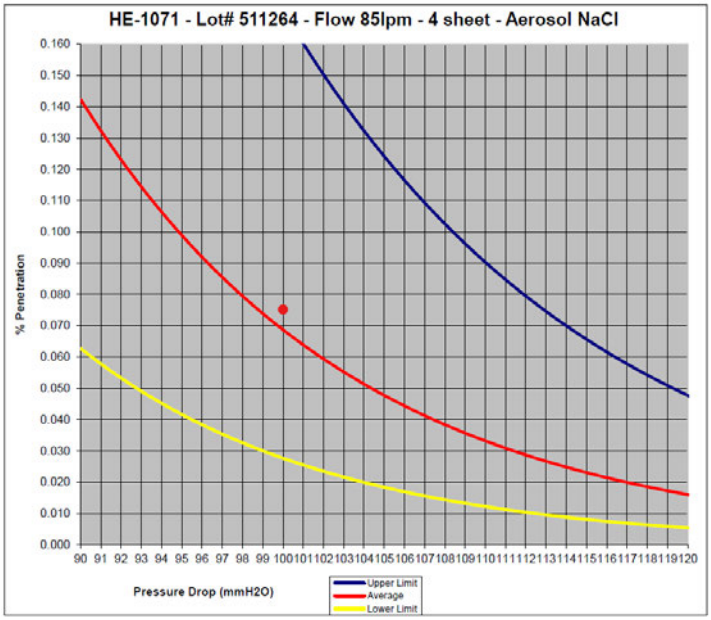


Verify System Performance

43. After gravimetric test, LSC and penetration calibration (PenCal) is complete, a validation test using reference filter "greenline" media is performed to verify system performance before testing any respirators. (NIOSH TEB-STP-requires instrument verification at least once in each 8-hour test period to ensure that the aerosol distribution is within the acceptance zone). The verification test is carried out at the start of the days' testing and again after eight hours of testing; results recorded on form D21-2824018 and filed in TRIM E20-354732.

44. The technique for validating ATI 100Xs system performance and test data (sometimes referred to as the "greenline media test") uses standard, or "calibrated," filter media. To verify system integrity, the aerosol penetration through standard media sheets is measured and compared against expected values for the filter material. This test verifies that the flowrate and particle size and distribution meet normal operating criteria and that the tester is, overall, operating as expected.

45. Graphs of penetration versus resistance (pressure drop) for different numbers of media sheets are located in TRIM D21-2422561. When performing verification tests using the standard media sheets, the test data should fall within the acceptance zone (i.e. between yellow & blue curves) on the applicable graph. To obtain differing levels of aerosol penetration, the media sheets are stacked together. Each reference graph will list the number of standard media sheets used to obtain the penetration range of interest. *Note: The graphs are relevant to 85 l/min only.*



46. Set the instrument as follows:
    a. **Filter Test Mode**
    b. Flowrate 85 l/min
    c. Load time 8 seconds
    d. Sample time 2 seconds

47. To evaluate the lower range of penetration values (or about 0.07%), stack four (4) sheets of unused filter media (green line down) onto the bare metal chuck; perform a "filter test" and record the penetration, flow rate and pressure drop (resistance) on the *ATI 100Xs PFE Performance Validation Spreadsheet* [TRIM D21-2824018]

Media sheets on chuck

48. For middle range penetration values (or about 0.3%, remove the top sheet (you should now have 3 sheets), perform a "filter test" and record the penetration, flow rate and pressure drop (resistance).

49. For higher range penetration values (or about 1.8%), remove the top sheet (you should now have 2 sheets), perform a "filter test" and record the penetration, flow rate and pressure drop (resistance).

50. Confirm all readings for penetration and resistance fall within the acceptance zone on the respective media graphs. Save the spreadsheet PFE Validation Sheet – [*today's date]*" in TRIM container E20-354732.

Note: Test data falling outside the "acceptance zone" could indicate a problem with the instrument setup and should be investigated before testing any specimens. Recalibrate instrument and repeat verification test with 4 new sheets until a successful outcome is reached or alternatively contact Team Leader.

RECORDING RESULTS

51. Test data is captured by a laptop connected to the ATI 100Xs instrument and as soon as each specimen is tested its initial resistance and maximum penetration is manually transcribed from the laptop display to a test results spreadsheet on the desk top. On completion of testing, the desktop test results spreadsheet is filed in TRIM and its relevant test information is used to populate QLIMS.

52. The *Rapid PFE Results Template* spreadsheet [D20-3377358] is semi-populating and calculates particle filtration efficiency based penetration values input, the number of masks tested and failed. The spreadsheet is also used to record the ambient conditions and reagents used to perform the test.

53. On desktop before testing perform the following steps:

    1. Create a folder on the desktop and rename it the sample's LIMS No.
    2. Drag the *Rapid PFE Results Template* spreadsheet from TRIM to the desktop folder and rename it as "*Rapid PFE Results_LIMS number-R3"*
    3. Drag the *ATI 100Xs Performance Validation Sheet* from TRIM D21-2824018 to the desktop folder and rename it as "*Performance Verification Sheet_DDMMYY"* only if you are starting the instrument from cold. (i.e. not standby)
    4. *Inside the desktop folder create a file and name it "LIMS number-R3_Photos". (this is where you will transfer photos from the camera to)*

54. The Rapid PFE Results spreadsheet populates certain fields automatically however the analyst still needs to enter the specific information shown in blue below. Where applicable, ensure that the information recorded is consistent with the sample's QLIMS record. If you find inconsistencies between information presented in QLIMS and on the device packaging, consult with the Test Manager.

Sample Details	Equipment Details	Assessment Results

TGA sample number	room temp/RH reading	filtration efficiency %
certification claimed	reference filter media sheets #	initial airflow resistance mmH_2O
	NaCl 0.9% & 4% batch #	

55. Respirators claiming PFE compliance to two or more standards are required to comply with the most stringent PFE rating claimed. For example, a mask claiming compliance to P2 (94%) / N95 (95%), is required to comply with the N95 (95%) claim.

56. The Standard Filter **Load Test** challenges the respirator with salt aerosol until a defined test interval has expired, an alarm parameter value has been exceeded or a user interrupt command is received. Percent (%) penetration, resistance (mm H_2O) and test flow (l/min) are displayed in real time throughout the test interval on the instrument digital display and also captured on the USB cable connected laptop. In addition, penetration and resistance data is displayed and plotted by a data reader program on the laptop used to record the values during and on completion of each test.

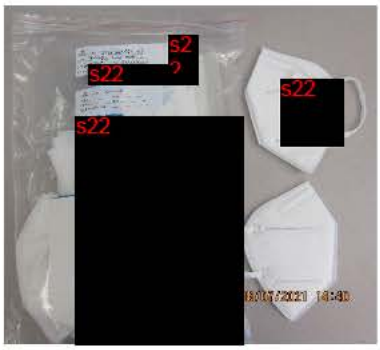
57. The initial airflow resistance (mmH_2O) and maximum penetration (%) values displayed by the laptop are manually transcribed by the operator into the *Rapid PFE Results* spreadsheet for each of the 10 to 20 individual specimens as soon as each one is tested.

58. Ideally, ten specimens from the sample batch are tested and their results recorded; however, if one specimen fails out of the ten, by a small amount then an additional ten (total 20) are to be tested and results reported. If two specimens fail by a small amount or one specimen fails by a large amount in the first batch of ten - then only the ten samples are tested.

59. Each specimen is challenged with aerosolised salt particles until the test is terminated. The operator manually stops testing five minutes (300 s) after maximum penetration is reached or when 10 minutes (600 s) has expired. The laptop data reader program will visually indicate and sound an alarm to cease testing five minutes after maximum penetration has been sensed or when ten minutes have expired. Most respirators reach maximum penetration within the first few minutes however testing should not be stopped before the alarm sounds. The operator stops the test by placing fingers in the ATI 100Xs actuators to raise the chuck and then selects “Abort Accept” on the ATI 100Xs display.

Note: Place ATI 100Xs instrument in STANDBY when not actually performing a test within the next 30 minutes otherwise HEPA filters will clog and need replacing prematurely.

60. Before commencing testing, take a clear close-up photo of the sample batch/bag. If possible rearrange the package so that its batch # is visible through the plastic bag. Include two masks showing a different side.



61. Randomly select 10 specimens from all those available in the batch/bag.

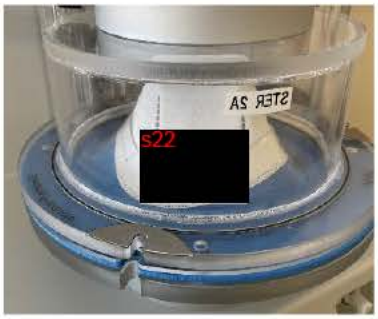
62. Select the most suitable adapter/holder with internal mounting fixture and seal the specimen to prevent leakage. Make certain there is no potential for leakage. Three (3) clamps can be used to close the adapter if the specimen is overly bulky.

63. On the ATI 100Xs display select Test – **Load Test**

64. Confirm flow rate is set to **85.0** litres / minute

65. Place adapter with mounted specimen between instrument chucks.

66. Take a close up photo of a specimen between the chuck whilst it is being tested. Ensure the identifying logo etc. is visible in the photo. Only one photo per batch is required.



67. On instrument laptop connected to the ATI instrument:

    1. Create a sample folder on desktop and rename it with the sample LIMS number ending in "-R3".
    2. Copy and paste the "*ATI_Data Reader.bat*" program  from desktop into the sample's folder.
    3. Double click on that folder's *ATI Data Reader.bat* icon to start the laptop data acquisition program.
    4. Confirm sample's LIMS number is correct.
    5. At the "Sample ID" prompt on the next line below - type number "1". This is the number of the first respirator's data about to be recorded. Note: *Repeat this step for every respirator tested incrementing the next sample ID number.*

    6. Laptop hit "enter"- *Note: data will be captured within a few seconds after chuck closes.*

68. On ATI 100Xs display
    - select **LOAD TEST**
    - press **CANCEL** gravimetric test
    - select **BEGIN**

69. Commence testing by simultaneously placing a finger into each of the electro-optical actuators.

70. Within the first few seconds of chuck closure observe the ATI 100 Xs display penetration reading and get ready to abort the test by placing both fingers simultaneously in the electro-optical actuators if the reading is uncharacteristically high and caused by a potential sealing problem.

71. Confirm within the first 5 seconds or so of chuck closure that the data is being captured by the laptop program and that resistance and penetration plots do not indicate an obvious leak.

    a. If a leak is suspected, immediately abort the test, reseat/re-seal the specimen, re-start the test with the same specimen (re-titled "#n.1) and observe the charted data. If the specimen data appears as before then continue testing and place a note in the results sheet comments section. If resealing fixes the leak then abort the test and retest another specimen in its place and note in the results sheet comments section.

72. When the laptop data reader alarm sounds stop the test by placing fingers in electro-optical actuators and raise the chuck.

73. Wait for the data reader to display the test outcome. Transcribe the penetration and resistance readings displayed on the **laptop** plot into the sample's test results spreadsheet and add pertinent observations or comments where needed; e.g. Pencal test carried out after #5 mask / auto replenishment sounded for 2 seconds, specimen #6 retested, clamps used, etc. If maximum penetration was not reached within 10 minutes include the comment "testing ceased for specimen #3 after 10 minutes and before maximum penetration was reached".

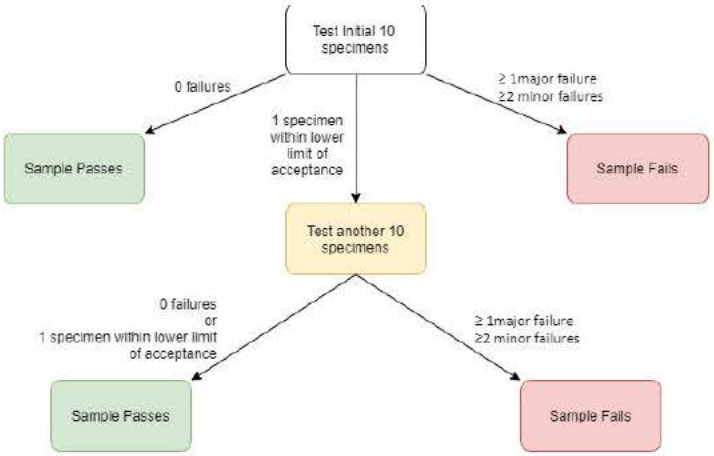
74. Number each tested specimen's edge with biro on completion of test. Tested batch that passes may be disposed however all specimens in a failed batch are to be zip bagged, labelled and placed in original sample bag.

75. Rapid screening assessment requires at least ten specimens to be tested (or more depending on outcome). The decision rules for PFE including what constitutes a minor and major fail are

documented here: D21-3053847, D21-356973.

	Failures or lower limit of acceptance	Action	Failures or lower limit of acceptance	Result
Test Initial 10	0			Sample Passes
	≥ 1 = Major Failure ≥ 2 = Minor Failure			Sample Fails
	1 within lower limit of acceptance	Test another 10	0 or 1 lower limit of acceptance	Sample Passes (Total of 2 within lower limit of acceptance)
			≥ 1 = Major Failure ≥ 2 = Minor Failures (in this group of 10)	Sample Fails

76. Analyst's decision tree



77. **Initial 10 specimens (specimens 1-10)**

- If all specimens tested pass – cease testing, sample passes.
- If only 1 specimen is within the lower limit of acceptance, another 10 specimens of the same sample must be tested to determine the overall result – continue testing.
- If 1 or more specimens less than the lower limit of acceptance – cease testing, sample fails.
- If 2 or more specimens within the lower limit of acceptance – cease testing, sample fails.

78. **Follow-up 10 specimens (specimens 11-20)**

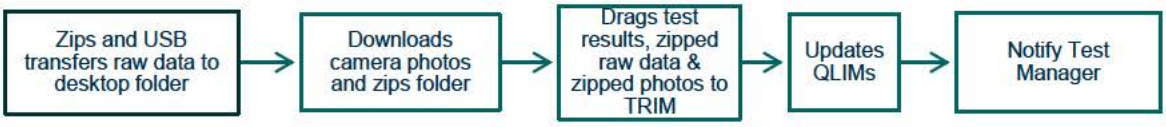
- Test another 10 specimens from the same sample, only if 1 specimen was within the lower limit of acceptance.

- If all specimens tested pass – cease testing, sample passes.
- If only 1 specimen within the lower limit of acceptance (2 in total) – cease testing, sample passes.
- If 1 or more specimens less than the lower limit of acceptance – cease testing, sample fails.
- If 2 or more specimens within the lower limit of acceptance (≥3 in total) – cease testing, sample fails.

79. Scrutinise the specimens that fail testing and document any obvious physical differences in the results spreadsheet comment section. Take a clear in-focus photo of any physical differences.

Note: **PERFORM a "PEN CAL"** *after every 5 respirators tested or if replenishment pump sounds longer than 2 seconds.*

80. When 10-20 specimens have been tested the **Operator** is to:



a. Close down the data reader program on instrument laptop then zip the folder containing the sample raw data records and transfer these using a USB to the sample's LIMS container in TRIM.

b. Download the respirator-in-chuck, batch packaging and if applicable, failure photos from the camera into the sample photo folder named [*LIMS Number_PFE_Photos*]. Zip this file and transfer it to the sample's TRIM container.

c. Save test results spreadsheet "[*LIMS Number]_PFE_Assessment Results_"DD-MM-YYYY*" located in the desktop folder and drag it into the sample's TRIM container.

d. Fill out the label on the sample batch zip-lock bag.

e. If the sample batch passes, dispose the specimens that were tested.

f. If the sample batch fails testing, place all 10 or 20 individually numbered specimens into a separate labelled zip-lock bag and put this inside the original sample batch bag.

g. Place the sample batch into the relevant Pass / Fail sealed storage container.

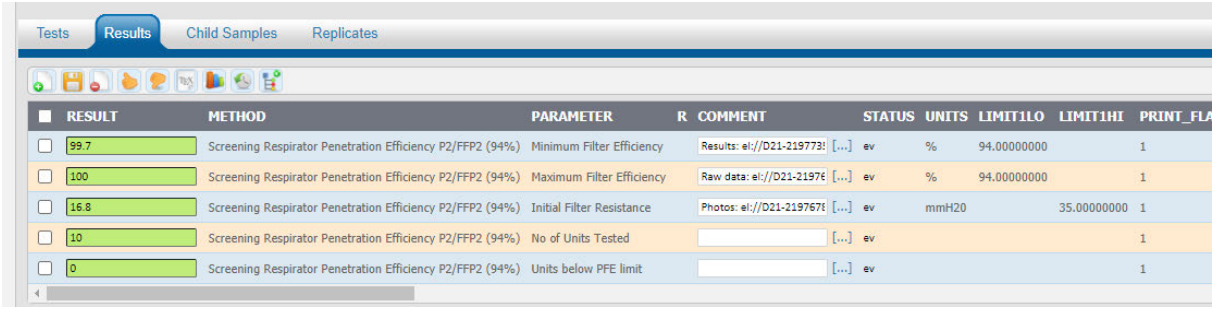
81. Open up QLIMS - transcribe the following data from the test results spreadsheet into the sample's Results tab:

- Minimum Filter Efficiency

- Maximum Filter Efficiency
- Initial Filter Resistance
- Number of Units Tested
- Units below PFE Limit, and

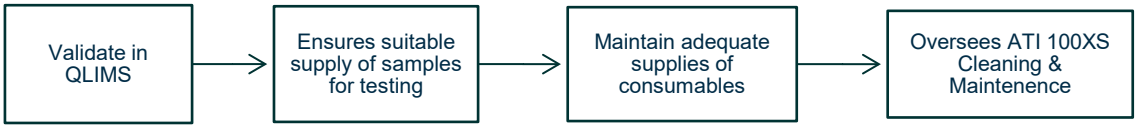
Cut and paste the following TRIM links in the Comments section:

- Results: *TRIM Link*
- Raw data: *TRIM Link*
- Photos: *TRIM Link*



82. Notify the Test Manager of completion (usually email).

83. As soon as possible after completion of testing the **Test Manager** is to**:**



a. review all data, plots and photos and validate test results in QLIMS

b. ensure ATI 100Xs scheduled maintenance and cleaning is carried out as per page 116 of the Operations & Maintenance Manual

c. make sure all consumables and samples used for testing are ready for the next shift, and

d. oversee all PFE testing and manage priorities as needed.

References

- 100Xs Automated Filter Tester Operator Manual
- CFR 42 84 (USA N95)

- AS/NZS 1716:2012 (AUS P2)
- GB2626: 2019 (CHINA KN95)
- EN 149-2001 + A1:2009 (EUROPE FFP2)
- NIOSH – *Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air Purifying Respirators Standard Testing Procedure* TEB-APR-STP-0059 https://wwwn.cdc.gov/PPEInfo/Standards/Info/TEBAPRSTP0059
- https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html
- Industry User Guide 8 - Working with NATA Accredited Personal Protective Equipment (PPE) testing laboratories

ATTACHMENTS

- Example of Results Template
- Example of PFE Performance Validation Sheet
- Photograph of ATI 100XS Automated Filter Tester
- Close up of KN95 respirator compression test fixture in the closed chuck.
- Summary of key differences in performance requirements and testing between the international respirator Standards

ANNEX

A. Particulate Filtration Test Requirements in Accordance with Reg 28(2) (d)

ATI 100Xs Automated Filter Tester with chuck open

Close up of respirator & an adapter in the closed chuck

Example Results Template

Particulate Penetration Efficiency Assessment Results

Sample Details	
LIMS No.	
ARTG No	#N/A
Label name	#N/A
Certification claimed	
Batch No.	#N/A
Expiry date	#N/A

Equipment Used	
ATI Salt Aerosol Automated Filter Tester 100XS	33211
Analytical balance LIMS No.	33203
NaCl 4% batch No.	
NaCl 0.9% batch No.	
Reference filter media sheet batch No.	
Test method used	D20-3958656 - Particulate Penetration Efficiency Assessment - Rapid Screening

Testing			
Operator		Test date	
Room Temp/RH		Probe LIMS	33215

Sample Conditioning			
Enclosure LIMS		Probe LIMS	
Date/Time IN		Temp/RH IN	
Date/Time OUT		Temp/RH OUT	

Example of Results Template

Summary:

In response to the COVID-19 pandemic, the Therapeutic Goods Administration (TGA) is undertaking a post-market review of all face masks included in the Australian Register of Therapeutic Goods (ARTG) to ensure the quality and effectiveness of face masks supplied in Australia, including that they meet the legislative requirements for medical devices and perform as intended.

Testing was performed in accordance with the TGA in-house *Rapid Screening* standard operating procedure D20-3958656 (SOP) to assess the particulate filter efficiency of TGA registered respirators claiming compliance with standards used in other countries.

The post-market rapid assessment program was specifically developed to expeditiously quantify the filtration efficiency of respirators. The in-house rapid screening test methodology is based on a **modified** version of the 42 CFR Part 84 Approval of Respiratory Protective Devices. Whilst most of the test parameters listed in the SOP are consistent with NIOSH Standard Test Procedure TEB-APR-STP-0059 (STP-0059), this modified test differs for pre-conditioning, test duration and filter mass loading. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059. The values reported are only to provide an indication of filter efficiency to ensure masks perform as intended.

Respirator filters were tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The aerosol was dried, charge neutralised and passed through the test article at a flow rate of 85 ± 4 litres per minute. Each respirator was tested for five minutes after maximum penetration was reached or ten minutes and the findings recorded.

This assessment used convenience sampling, a non-probability sampling technique whereby samples were drawn from a population based on their availability. Respirator filter specimens were then selected at random from the sample provided.

Prior to penetration testing, specimens underwent a visual inspection to qualitatively assess build and marking quality. The initial inhalation resistance and maximum particle penetration (%) for each individual respirator was then determined.

An ATI 100Xs Salt Aerosol Automated Filter Tester was used capable of efficiency measurements of up to 99.9995%. The tester produces a particle size distribution with a count median diameter of 0.075 ± 0.02 um and a geometric standard deviation <1.86. The mass median diameter is approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size.

Unless stated otherwise, specimens were tested under normal laboratory environmental conditions in the condition received. Data relating to the initial resistance does not take into account any bias due to specific mounting fixture used for testing.

Example of Results Template

Particulate Penetration Efficiency Assessment Results

Rapid Screening

The minimum filter efficiency requirement for respirators must be greater than or equal to the certification standard claimed for each item tested. Test data indicate the minimum and maximum filter efficiency for the sample batch was as follows:

Minimum Filter Efficiency =	0.0%	Masks Tested =	0
Maximum Filter Efficiency =	0.0%	Total Fails =	0
Maximum Initial Resistance =	0.0	Certification claimed = 0	

Filter No	Initial Airflow Resistance (mmH_2O)	Max Particle Penetration (%)	Filtration Efficiency (%)	Test Result
1			not tested	not tested
2			not tested	not tested
3			not tested	not tested
4			not tested	not tested
5			not tested	not tested
6			not tested	not tested
7			not tested	not tested

Example of PFE Validation Sheet

ATI 100Xs PFE Performance Validation Sheet

Date		Settings	Load Time	8s
Time			Sample Time	2s
Operator			Flow Rate	85 l/min

Aerosol Concentration		ug/l

		Penetration	Resistance	Flow	Lot Number
# of filter sheets	4				
	3				
	2				
Performance within limits (Y/N)					

Note: If 'No', re-calibrate instrument and repeat validation with four new sheets. Green Line verification charts D21-2422561.

Table 1: Particular filtration efficiency requirement and testing in commonly referenced respirator standards.

Standard (Designation)	Filtration Level	NaCl Aerosol Dimension	Aerosol Concentration	Flow Rate	Sample Size
AS/NZS 1716:2012 (P2)	≥ 94%	Mass median diameter (MMD): 0.3-0.6 µm	5-15 mg/m^3, constant within 5%	95 L/min	Unspecified
42 CFR 84 (N95), NIOSH TEB-APR-STP-0059	≥ 95%	Count median diameter (CMD): 0.075±0.020 µm, geometric standard deviation ≤ 1.86 (MMD: ~0.175 - 0.302 µm)	≤200 mg/m^3	85 L/min	20
EN 149:2001+A1:2009 (FFP2)	≥ 94%	References EN 13274-7. EN 13274-7: 2008, MMD of ~0.6 µm. EN 13274-7: 2019, CMD of 0.06 – 0.10 µm, geometric standard deviation 2.0 – 3.0. (MMD: 0.25 – 3.74 µm)	EN 13274-7: 2008: 4-12 mg/m^3 EN 13274-7: 2019: 4-12 mg/m^3, ±3% for 5 min, ±10% during the test	95 L/min	9
GB 2626:2019 (KN95)	≥ 95%	CMD: 0.075±0.020 µm, geometric standard deviation ≤ 1.86 (MMD: ~0.175 - 0.302 µm)	≤200 mg/m^3	85 L/min	20
GB 19083: 2010 (Grade 1)	≥ 95%	CMD: 0.075±0.020 µm, geometric standard deviation ≤ 1.86 (MMD: ~0.175 - 0.302 µm)	≤200 mg/m^3	85 L/min	6
AS ISO 16900.3:2015		CMD of 0.06 – 0.10 µm, geometric standard deviation 1.4 – 1.8. (MMD: 0.08 – 0.28 µm)	8-35 mg/m^3, ±10% during the test	Unspecified	Unspecified

Summary of key differences in performance requirements and testing between the international respirator Standards

Aspects		P2 (AS/NZS 1716:2012)	KN95 (GB 2626:2019)	FFP2 (EN 149:2001+A1:2009)	N95 (42 CFR 84)	Grade 1 (GB 19083: 2010)	AS ISO 16900.3:2015 (testing standard)	Additional comment
Particle filtration efficiency	Filtration level	≥ 94%	≥ 95%	≥ 94%	≥ 95%	≥ 95		
	NaCl aerosol dimension	Mass median diameter (MMD): 0.3-0.6 µm	CMD: 0.075±0.020 µm, geometric standard deviation ≤ 1.86	References EN 13274-7. EN 13274-7: 2008, MMD of ~0.6 µm. EN 13274-7: 2019, CMD of 0.06 – 0.10 µm, geometric standard deviation 2.0 – 3.0.	CMD: 0.075±0.020 µm, geometric standard deviation ≤ 1.86	CMD: 0.075±0.020 µm, geometric standard deviation ≤ 1.86	CMD of 0.06 – 0.10 µm, geometric standard deviation 1.4 – 1.8.	Different aerosol dimension definitions have been used. The GB 2626 / 42 CFR 84 specification translates to a MMD of about 0.24 µm. It's not necessarily the case that smaller particles are more difficult to filter[5].
	Aerosol concentration	5-15 mg/m³, constant within 5%	≤200 mg/m³	EN 13274-7: 2008: 4-12 mg/m³ EN 13274-7: 2019: 4-12 mg/m³, ±3% for 5 min, ±10% during the test	≤200 mg/m³	≤200 mg/m³	8-35 mg/m³, ±10% during the test	
	Flow rate	95 L/min	85 L/min	95 L/min	85 L/min	85 L/min	Unspecified	
Breathability (inhalation)	Max pressure drop	≤ 70 Pa at 30 L/min, ≤ 240 Pa at 95 L/min	≤ 210 Pa	≤ 70 Pa at 30 L/min, ≤ 240 Pa at 95 L/min	≤ 343 Pa	≤ 343 Pa		
	Flow rate	30 L/min and 95 L/min	85 L/min	30 L/min and 95 L/min	85 L/min	85 L/min		

[5] https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/

Annex A – Particulate Filtration Test Requirements in Accordance with Reg 28(2) (d)

A (surgical) respirator is a personal respiratory protective device designed to protect the wearer from airborne particles[6][7][8]. Adequate filtration capability is a key performance metric to achieve the intended purpose of such devices. Therefore, for (surgical) respirators to be registered on the Australian Register of Therapeutic Goods (ARTG), they need to be tested for particulate filtration efficiency (PFE) to demonstrate compliance with the Essential Principles (EP) Clause 3, *Medical devices to be suitable for intended purpose*.

The majority of (surgical) respirators on ARTG claim PFE of 94% - 95%, and this Annex is focused on the PFE test of this class. For (surgical) respirators of different PFE classes, the test framework remains similar but the detailed acceptable test conditions may be evaluated on a case-by-case basis according to the devices' claims.

Respirator PFE can be tested using sodium chloride (NaCl) aerosol or oil mist based aerosols. As healthcare settings generally are not expected to be oily environment, (surgical) respirators on the ARTG are expected to be tested for PFE with NaCl aerosols.

There are various Australian and international respirator standards prescribing the PFE requirements and test methods. These classifications have similar PFE performance requirements[9] and respirators meeting these standards can thus be expected to function similarly. The *Particulate Penetration Efficiency Assessment – Rapid Screening* assessment is based on an in-house developed modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059.

The methods outlined in the standards below (
Table 1) are deemed comparable to this SOP and also suitable for determining if respirator PFE performance is adequate to demonstrate compliance with the applicable provisions of the essential principles in accordance with Reg 28(2)(d) of the *Therapeutic Goods Regulations 1990*. Methods in other respirator standards may also be considered suitable tests if justifications are provided that they yield comparable or more stringent PFE results than the *Particulate Penetration Efficiency Assessment – Rapid Screening* assessment.

Notes: The filtration efficiency level, the NaCl aerosol size and the flow rate are particularly important in comparing PFE tests. For most respirator filters, particles with diameters of about 0.3 µm are most penetrating. Therefore, the PFE test should feature NaCl aerosol with a mass median aerodynamic diameter of about 0.3 µm to represent the worst case scenario. Typically higher flow rates result in higher particle penetration, and thus lower filtration efficiency measurements. The Australian and European respirators standards specify the PFE test with a slightly higher flow rate than the US and Chinese standards: 95 L/min vs 85 L/min, but also require a slightly lower minimum acceptable filtration efficiency level: 94% vs 95%.

Adequate sample size is essential to ensure that the test results are representative of the overall PFE performance of the lot under test. Respirator standards typically either do not specify sampling requirements or have not provided justifications for the sample size chosen. The sample size per lot in the PFE test must be at least 10 or the sample size requirement of the referenced standard, **whichever is larger**, in order for the PFE test to be deemed suitable in accordance with Regulation 28(2)(d).

[6] https://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19
[7] AS/NZS 1716:2012
[8] https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks
[9] https://multimedia.3m.com/mws/media/1793275O/3m-anz-2020-comparison-of-ffp2-kn95-and-n95-and-other-filtering-facepiece-respirator-classes.pdf