WHAT YOU NEED TO KNOW ABOUT MASKS, “N95”s AND OTHER RESPIRATORS

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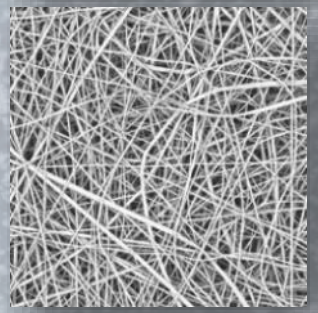
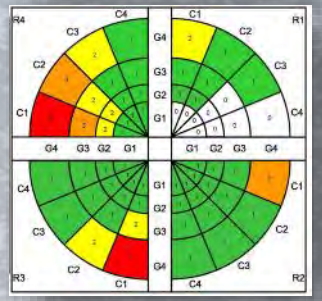
PRESENTATION SUMMARY

Personal Protective Equipment	What is and what isn't a respirator
What to Look for	Respirator types and approvals
What Matters?	Filtration, Fit & Function
User Needs	Choosing and Using the right kind of respirator





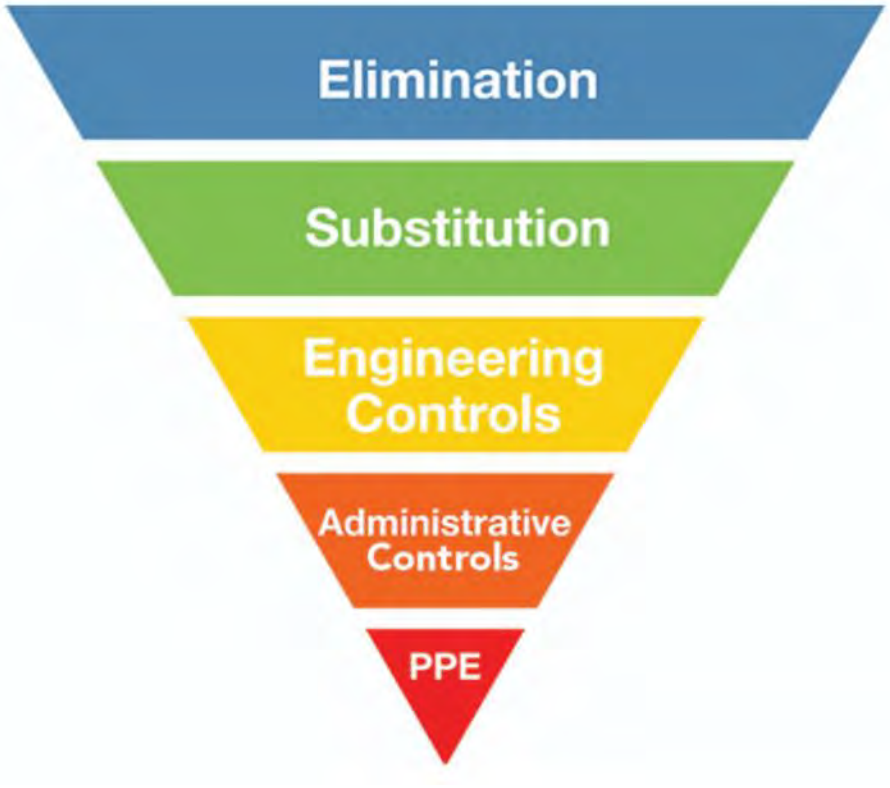
Of necessity for brevity, summaries of information and standards comparisons are provided which do not include all details – for specific information please refer to the relevant documents

FEATURES OF PERSONAL RESPIRATORY PROTECTION IMPLEMENTATION

Workplaces

- Programmes to manage respiratory protection in line with national or other regulations and guidance
- Assessment of the exposure environment, guidance on selection, use and maintenance
- Apply risk assessment, selection protocols based on toxicity and exposure for non- biological hazards, various guidance sources for biological hazards
- Respirators are approved to recognised performance standards through certification systems
- Wear compliance is observable
- Primary focus: wearer protection

Equipment designed and dedicated for protection



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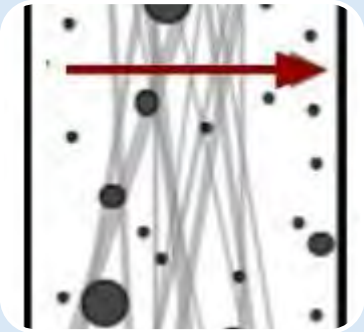
Equipment designed and dedicated for protection

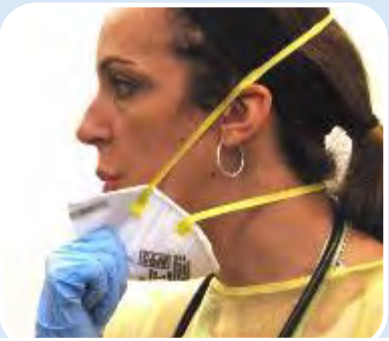
Public

- "Mask mandates" applied as all-or-nothing requirements
- Great variety of products: some standards (though not in Canada) for performance but no requirement for users to select products meeting them
- Manufacturers certify performance generally
- Inconsistent wear compliance
- Focus: wearer protection and source control

Equipment based on various concepts with limited effectiveness

KEY ASPECTS OF RESPIRATORY PROTECTION INFLUENCING EFFECTIVENESS ("3Fs") FOR FILTERING DEVICES





	Filtration	Fit	Function
Key Question	How well does the material used remove particles from the air?	How much air leaks round the perimeter when the product is worn, affecting its protectiveness?	How much does the product affect the wearer's comfort and ability to do their job effectively?
Assoc-iated Factors	Media Efficiency or Penetration (%)	Quality of facial seal, fit testing, fit checking, protection factor	Airflow resistance, skin compatibility, balance, communication, physiological burden, CO_2, heat and moisture build-up

FACE COVERINGS, SURGICAL MASKS, RESPIRATORS ARE DIFFERENT

Microsoft Stock

SJS

3M Canada

Barrier Face Covering

- No good seal to the face
- Any kind of filtration material may be used
- No performance standards until very recently (US, UK, Europe)

Typically:

Filtration
Fit
Function
Splash Protection
Source Control

Surgical Mask

- No good seal to the face
- Filtration is material fluid and biological agent resistant
- Specifications exist but not all types meet them

Typically:

Filtration
Fit
Function
Splash Protection
Source Control

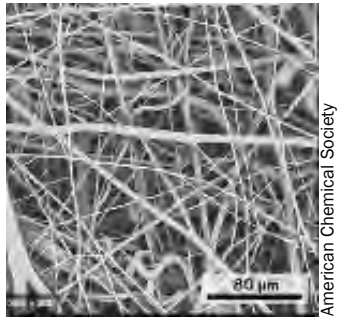
Approved Respirator

- Good seal to the face
- Filtration material required to be highly capable
- Governed by regulations and performance standards

Typically:

Filtration
Fit
Function
Splash Protection
Source Control

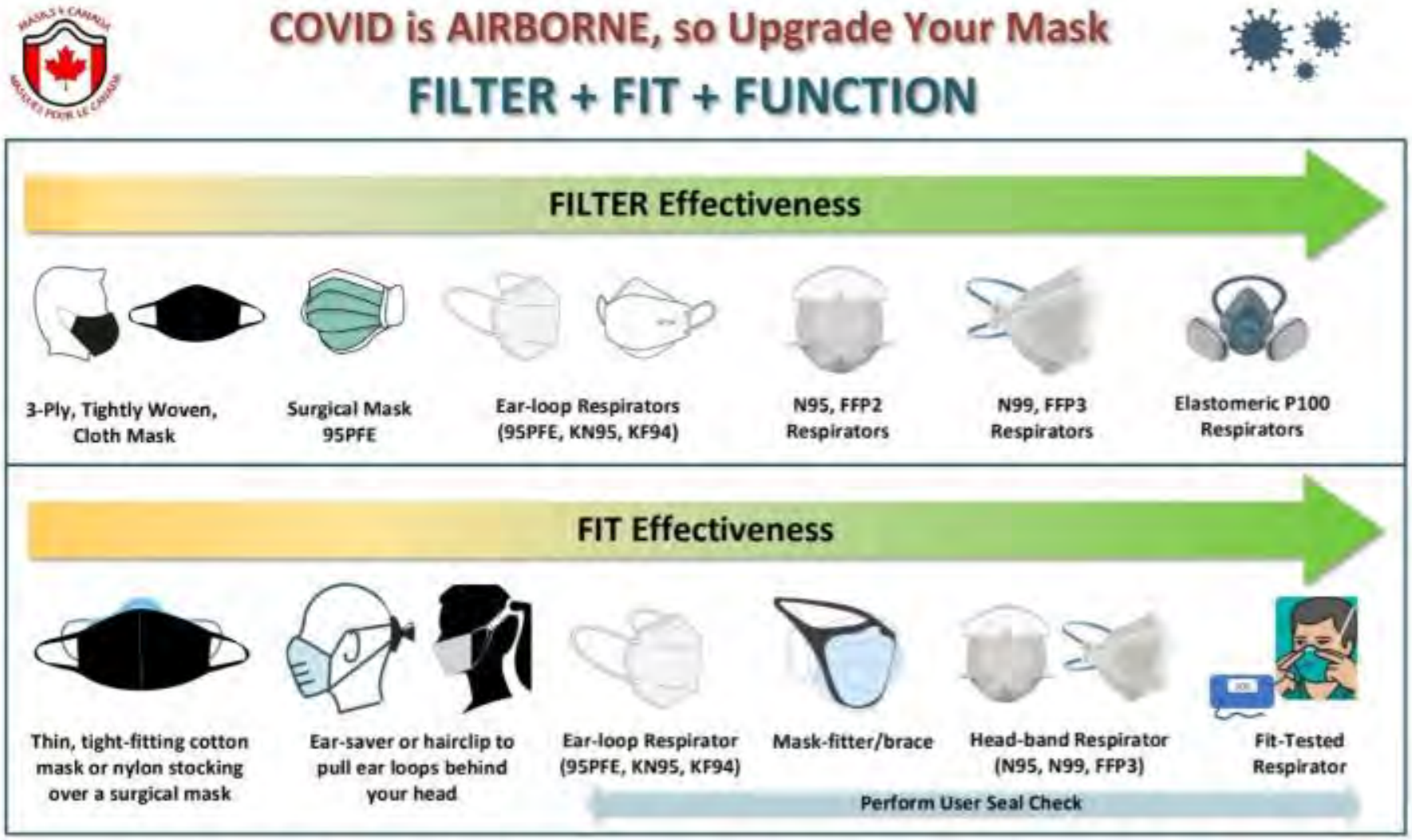
SOME OF THE DIFFERENCES



American Chemical Society

	Barrier Face Covering	Surgical Mask	Non-Approved Respirator	Approved Respirator
Example of Designation	Any	ASTM-Level 3	KN95	NIOSH-N95
Fabric Type	Woven	Non-woven	Non-woven	Non-woven, Electrostatic Media
Layers	Varies	Typically 3	Typically 3	3 or more
Usual Attachment	Ear-loop	Ear-loop	Ear-loop	Around Head
Filtration	Variable but poor	Good	High efficiency	High efficiency
Fit to the Face	Generally poor	Generally poor	Moderate	Good
Application	Source Control	Source Control, Splash Protection	Basic Protection	Workplace Protection

EXAMPLE INFORMATION SHEET FOR PROTECTIVE FACE COVERINGS



Respirators

https://masks4canada.org/

EXAMPLES OF RESPIRATORY PROTECTIVE EQUIPMENT

Respirator:
A component of Personal Protective Equipment (PPE), designed to protect the wearer's respiratory tract against inhalation of hazardous atmospheres

Selection includes balancing desired protection with other factors

Equipment	FFP	HF-APR	PAPR (L)	FF-APR	PAPR (T)	SCBA
Protection Hierarchy Level	1	1	2	3	4	5
Assigned Protection Factor	10	10	25/1,000	100	1,000	10,000
Comfort/Low Physiological Burden	★★	★★	★★★★	★★	★★★	★
Ease of Logistics and simplicity of training/ Maintenance	★★★★	★★★	★★	★★★	★★	★
Non-Stop Usage in typical environment	~2-8 hours (filter limited)	>8 hours (filter limited)	~8 hours (battery limited)	>8 hours (filter limited)	~8 hours (battery limited)	30 min (air supply limited)
Initial Cost Range	$2-3	$30-50	$1,000-1,500	$50-100	$1,000-1,500	>$2,000

Photos: 3M Company/BBC

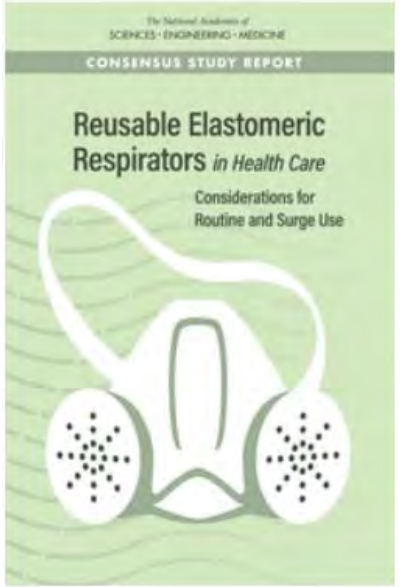
PROTECTION IN HEALTHCARE AND AT HOME? – WHAT ABOUT MEDICAL MASKS

- Source Control - Some
- Protection? Alas:

From ASTM F2101-19: "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*" states:

"This test method evaluates medical face mask materials as an item of protective clothing but does not evaluate materials for regulatory approval as respirators. If respiratory protection for the wearer is needed, a NIOSH-certified respirator should be used. Relatively high bacterial filtration efficiency measurements for a particular medical face mask material does not ensure that the wearer will be protected from biological aerosols, since this test method primarily evaluates the performance of the composite materials used in the construction of the medical face mask and not its design, fit, or facial-sealing properties".

- Beyond filtering facepieces – well-studied alternatives with reports from the US National Academies of Sciences, Engineering and Medicine
  - Re-usable elastomeric facepieces with replaceable filters
  - Powered air-purifying respirators



https://www.nationalacademies.org/our-work/standing-committee-on-personal-protective-equipment-for-workplace-safety-and-health

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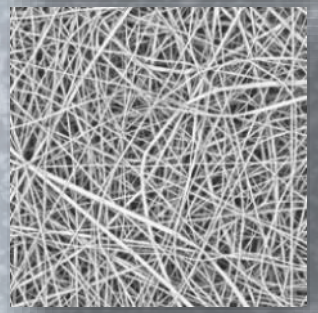
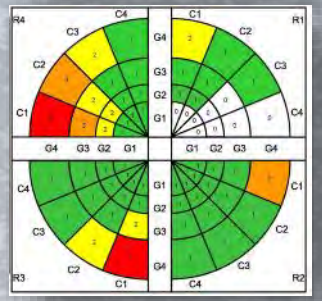




EXAMPLES OF RESPIRATORS USED IN HEALTHCARE AND OTHER WORKPLACES

Filtering Facepiece

Cost $2-3
Changeout 1-2 times/day

3M

Elastomeric Facepiece
(Half-Mask)

Cost: Facepiece ~$30
Filter set ~$30
Filter change 1-3 months
Facepiece 1-2 times/year

https://www.dir.ca.gov/dosh/coronavirus/Hospital-Elastomeric-Respirator-Use-COVID-19-Hines.pdf

Powered Air-Purifying
Respirator (Half-Mask)

Cost: Unit ~$1500
Filter set ~$30
Filter change 2-6 months

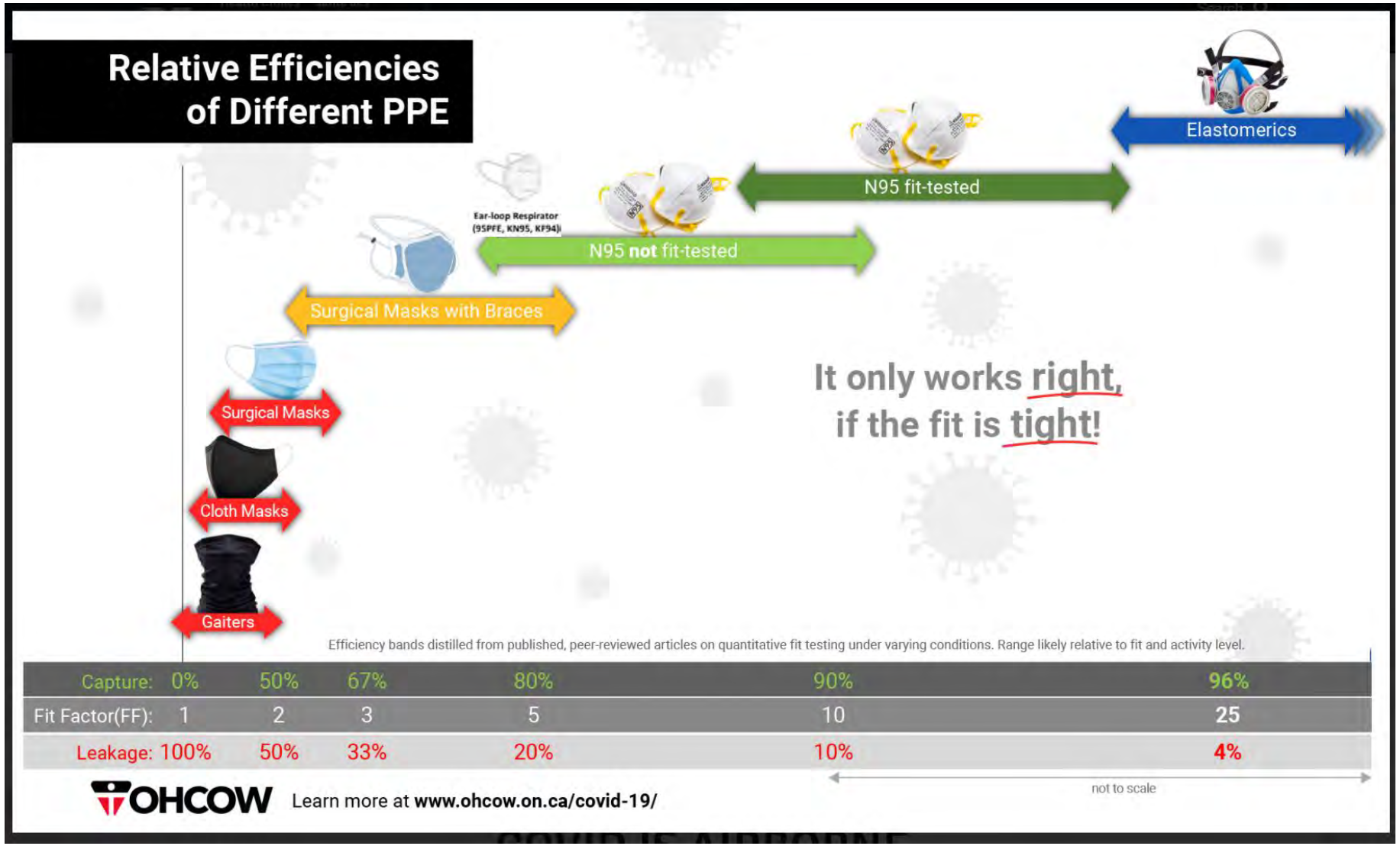
https://cleanspacetechnology.com/cleanspace-halo/

Powered Air-Purifying
Respirator (Hood)

Cost: Unit ~$1500
Filter set ~$30
Filter change 2-6 months

BBC

RELATIVE EFFECTIVENESS OF DIFFERENT FACE COVERINGS



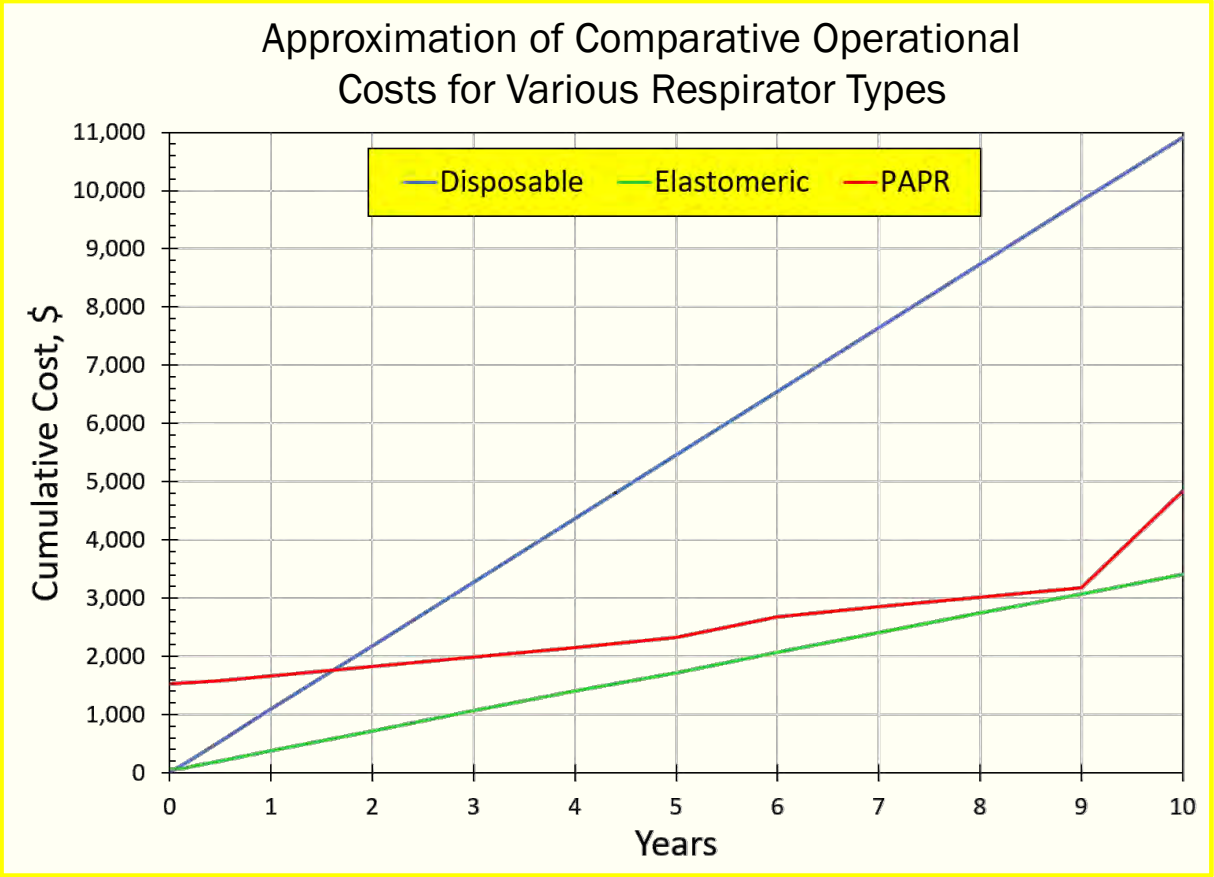
PAPRs, Full-face elastomerics

COST COMPARISONS

- Disposable Filtering Facepieces are cheap, but their costs add up with use – both to user and environment
- Elastomeric and Powered Air devices have higher up-front costs, but can be more cost effective in the long-run
- Sample Calculation and costs over time for a single user

	Disposable	Elastomeric	Powered Air-Purifying Respirator
Non-Consumable Cost	N/A	$30	$1500
...Replacement	N/A	2 / year	1 / 10 years
Consumable Cost	$2	Filter set $30	Filter Set $50
...Replacement	2 / day	Filter 1 / 2 months	Filter 1 / 6 months
Other Costs	Disposal $1 / week	Cleaning/Disposal $2 / week	Clean/Disposal $2 / week Battery 1 / 5 years, $200

- PAPRS have higher initial cost, but
  - Offer better protection, more comfort – better wear compliance, less fatigue
  - Fewer infections in workforce and community



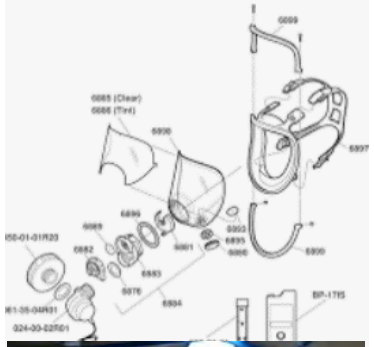
WHAT DOES “APPROVED” MEAN FOR A RESPIRATOR?

- Tested to show demonstrated delivery of a minimum high performance level for filtration and protection
- Manufactured with high standards of quality control and recordkeeping
- Design or component materials cannot be changed by manufacturer without official re-confirmation of performance
- Production sites are audited regularly to ensure ongoing compliance
- Samples are purchased anonymously and tested to verify ongoing compliance
- Approvals cover a “system” – for instance an elastomeric facepiece with specific filters

https://www.3m.com

https://www.cidrap.umn.edu/

https://www.npr.org/



https://www.3m.com

https://redhatsafety.com

https://www.cnn.com

NORTH AMERICAN APPROVALS

- Canada historically accepted respirators approved by the US National Institute for Occupational Safety and Health (NIOSH, to standard "42 CFR 84")
  - Users and manufacturers have strong familiarity with its classifications and requirements
- New manufacturers starting operations early in the pandemic inundated NIOSH, but non-US applications had lower priority than US ones
- Health Canada created an "Interim Specification" in August 2020 for certain types of respirator for healthcare use, approximating NIOSH requirements with some additions
- NEW! CSA created the new standard CSA Z94.4.1-21 during 2021 as part of an approvals system to replace the Health Canada approvals system
  - Currently only for particle filtering respirators, future expansion to all types
  - Approvals apply in parallel with NIOSH approvals
- The CSA standard incorporates "surgical" respirators evaluated with an additional fluid resistance test by FDA in the US into the same system, and for N95 respirators designates the breathability with an additional number
- See reference list for web links to the documents

So in addition to "N95" and other classifications, you may see –examples are (there are many more types):

NIOSH 42 CFR 84	Health Canada Specification	CSA Z94.4.1-21
N95	95PFE	CA-N95-100Pa CA-N95-175Pa CA-N95-343Pa
"Surgical" N95 (NIOSH approval+ FDA clearance)	95PFE-L1 or –L2	None
	95PFE-L3	CA-N95F-100Pa CA-N95F-175Pa CA-N95F-343Pa
P100	None	CA-P100
Powered Air HE	None	HE

PRODUCTS FROM NON US/CANADA APPROVALS IN CIRCULATION

Organisation	Standard	Classes	Comment
Europe (European Committee for Standardization)	EN 149 (2001, updated 2009)	FFP2 and FFP3 (FFP1 not suitable)	Comparable with NIOSH P95, P100 Filtering facepieces
China (Standards Administration of China)	GB2626 (2019) KN95	KN95, KN100 (KN90 not suitable)	Generally ear loop style and less well-fitting
Korea (Ministry of Employment and Labour)	KMOEL - 2017-64 (2017)	KF94, (1st Class)	Generally ear loop style and less well-fitting

DEGREES OF DISCREPANCY

MISLEADING

Uses “N95” or similar classification in name or description but it is not a NIOSH approved product and does not claim to be

https://canadastrongmasks.ca/

FAKE APPROVAL

Uses NIOSH symbols or another product’s approval number to claim approval when not approved

https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

COUNTERFEIT

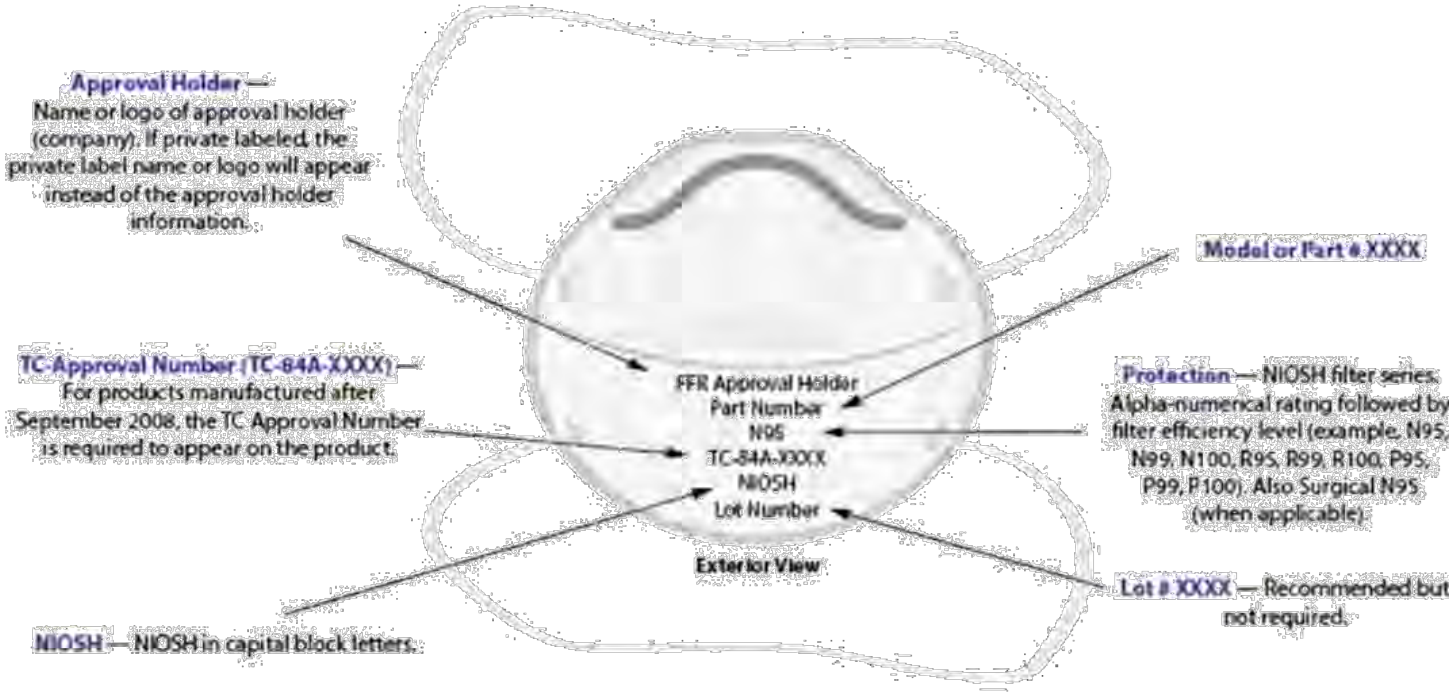
Purports to be another company’s approved product but may not perform adequately

https://multimedia.3m.com/mws/media/1934 7480/3m-counterfeit-communication-letter.pdf

NIOSH does not approve products with ear loops or products for children - so a “Child-size N95” is not NIOSH approved

WHAT TO LOOK FOR

- Approved respirators have a NIOSH “TC” number – for filtering facepieces, this is in the form “TC-84A-”+4 digit number
- Approved respirators can be searched on the “Certified Equipment List”: https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html
- CDC Counterfeit respirator information: https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html
- Government of Canada: https://recalls-rappels.canada.ca/en
- Also, you can visit corporate anti-counterfeit websites – example: https://www.3m.com/3M/en_US/worker-health-safety-us/covid19/covid-fraud/



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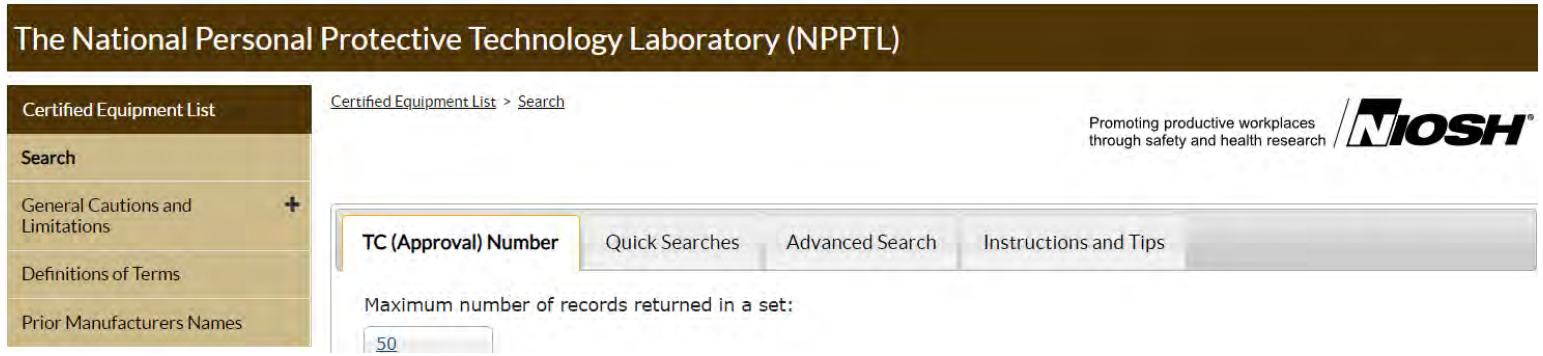

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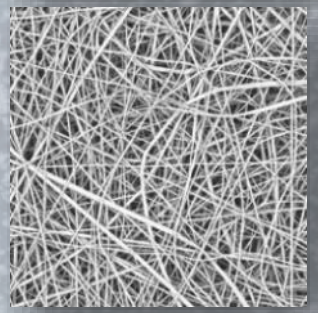

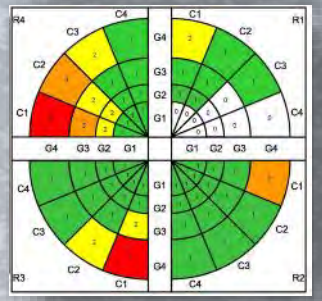

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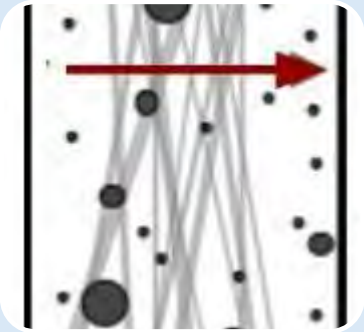

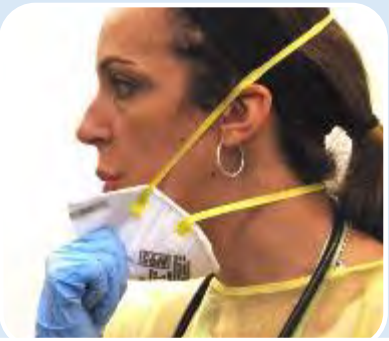

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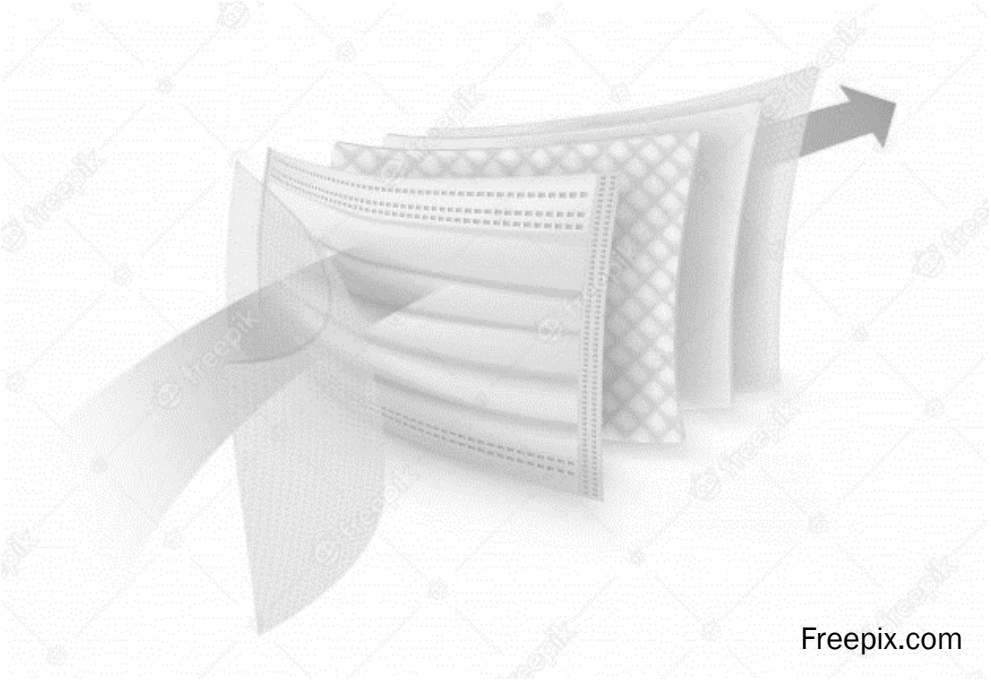
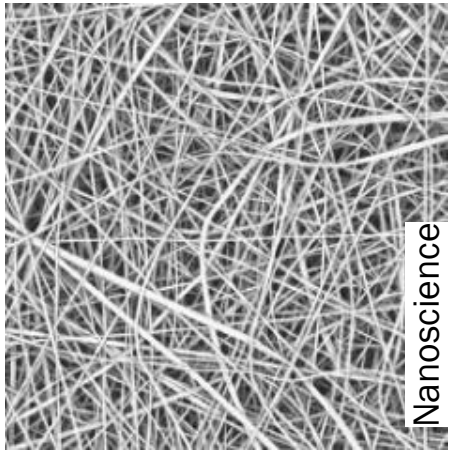
FILTRATION OF PARTICULATE MATTER

- Effective performance in respirator filters comes from:
  - Multiple layers, including a fibrous non-woven web (usually glass or polymer)
  - Multiple mechanisms for particle removal
  - Some more effective for larger particles, others for smaller particles
- Fibrous media can be treated to improve attraction of the smallest particles: “Electret” media -
  - Fibres have areas of locally dispersed electrical charge
  - Enhanced removal of smaller particles by induced charge attraction
  - Additional treatments ensure that charges are stable and withstand long-term storage and heavy dust loading



Freepix.com



Nanoscience

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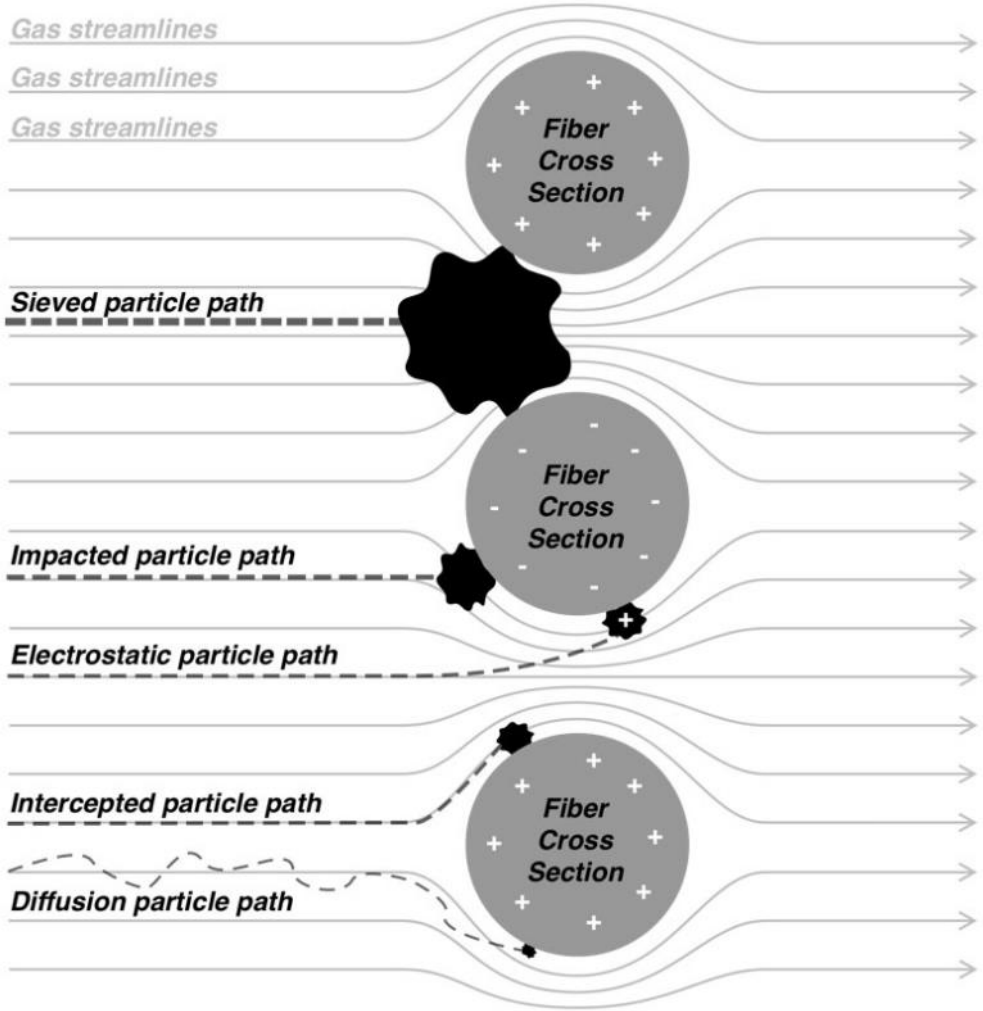
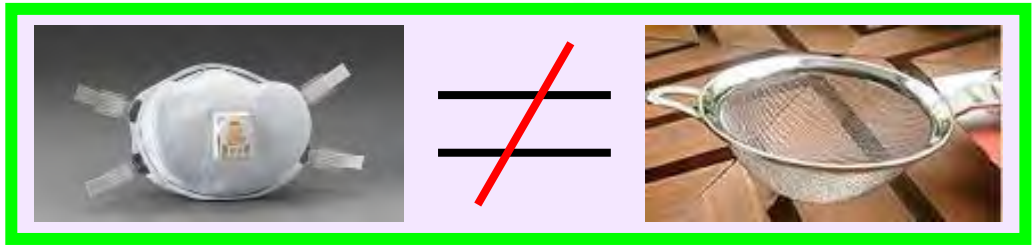
https://www.apsf.org/article/hepa-filters-do-we-really-know-enough-breathing-circuit-filters-in-the-era-of-covid-19/

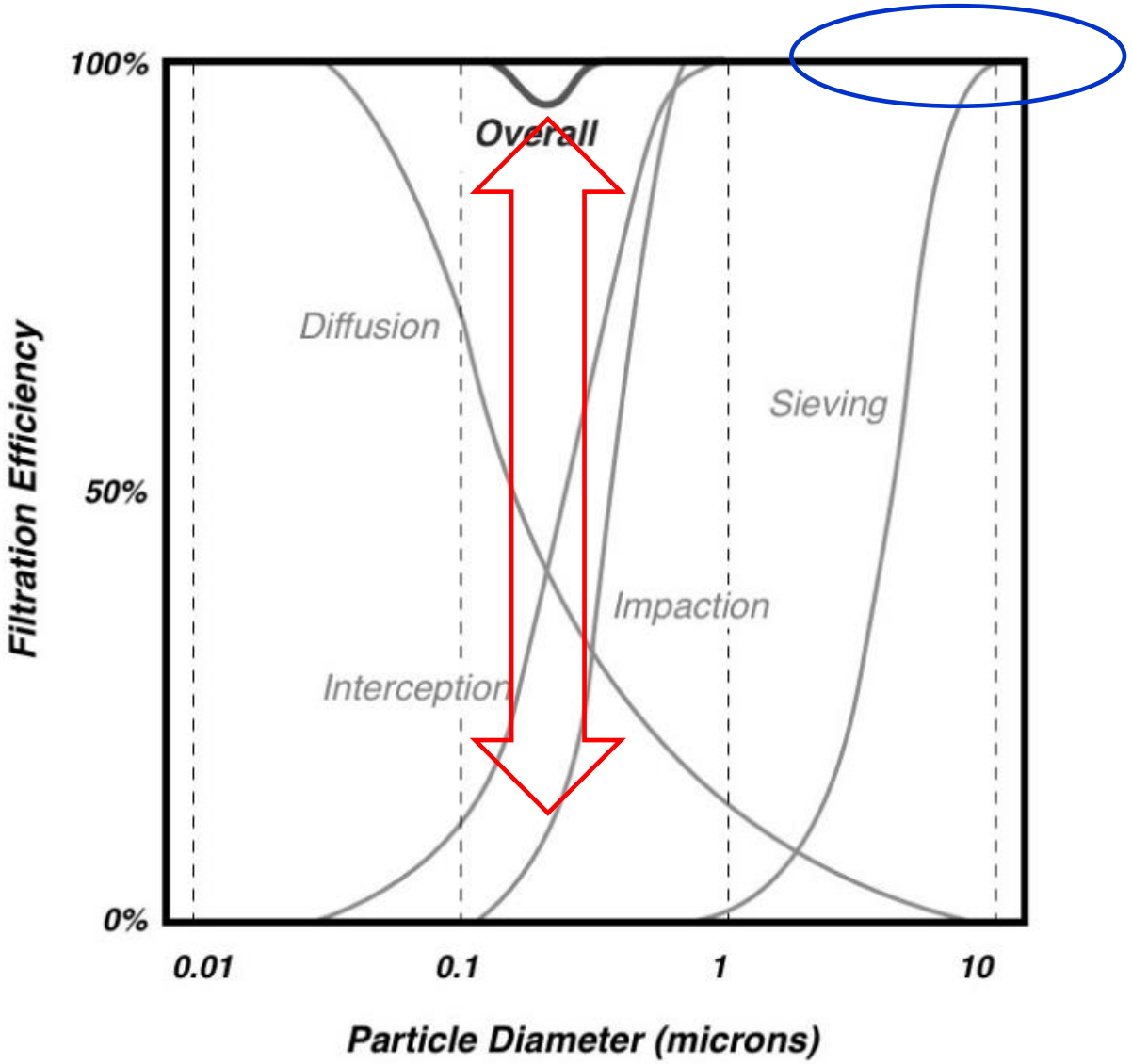




NOT like a fishing net or tea strainer!

FILTRATION OF PARTICULATE MATTER

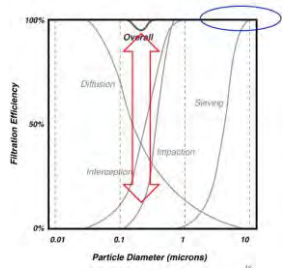
- Filtration mechanisms combine so there is a "most penetrating particle size" - in the range 0.2 to 0.3 microns aerodynamic diameter
- Respiratory protection filters are tested with uniformly-sized particles in this range
- Research shows no difference in filtration between "living" and "inert" particles
- The "95" in "N95" represents 95% efficiency at the most penetrating size
- Sizes of particles expelled on respiration mean that filtration efficiency for them is close to 100% for a N95-class filter



N, R, P & 95, 99, 100?

N	Not oil-resistant	Don't use with oil-based aerosols
R	Oil-Resistant	Use one shift with oil-based aerosols
P	Oil-Proof	Use indefinitely with oil-based aerosols

- Letter classifications are to do with oil resistance – **not an issue in healthcare**
- An "R"-type covers what an "N" can do, and a "P"-type covers what an "N" and "R" can do
- "95", "99" and "100" (actually 99.97%) are % Penetration at the most penetrating particle size
- For particles of concern which carry a virus, removal efficiency by the media is close to 100% for all of these
- So by using R or P, and 99 or 100 you are adding cost and possibly airflow resistance without much additional protection over a N95-type filter
- "P100" filters more likely associated with an elastomeric facepiece, but not always
- And…. "N95" is a test standard, NOT a product, but alas this is lost in popular understanding



N95

P100

- Powered air – till April 2020, just class of particle filter, "HE" – comparable with P100 capability but at high flow rates
- Two new classes "PAPR100-N" and "PAPR100-P" added, these should lead to smaller, lighter products,

FIT TESTING AND FIT CHECKING – TO MINIMIZE FILTER BY-PASS (PART OF A RESPIRATORY PROTECTION PROGRAMME)

Qualitative Fit Test

3M Company

For initial selection and routine re-testing

- Subject dons respirator as normal
- Hood over head
- Bitter or sweet aerosol introduced into hood
- Taste indicates leakage

Quantitative Fit Test

TSI Incorporated

- Subject wears respirator with probe to sample interior
- Sensitive particle analyser compares ratio of airborne dust outside to inside facepiece
- Ratio is measured during movement breathing and speech exercises

User Seal Check

Each donning

Harvard Medical School

- Subject dons mask and blocks air paths
- Sharp inhalation and exhalation, feel for air leakage around face-seal

FIT CONSIDERATIONS

Sizing	Some respirators are “one size fits all” Others come in different sizes Check and use the most appropriate size for your face
Approval Type	Respirators to Chinese and Korean standards – such as KN95 and KF94 are designed to fit an Asian head shape which may not be suitable for everyone

Attachment Type

Headbands

- Example classifications – N95, N99, FFP2
- A minimum of two headbands provides a strong force holding the respirator to the face giving a good seal

Ear Loops

- Example classifications – KN95, KF94
- Ear loops provide less force to the face, poorer seal
- NIOSH will not approve ear loop respirators

“FUNCTION” IN RESPIRATORY PROTECTION

Health and Comfort

- Fatigue
- Heat/moisture build-up
- Comfort and skin irritation

Communication

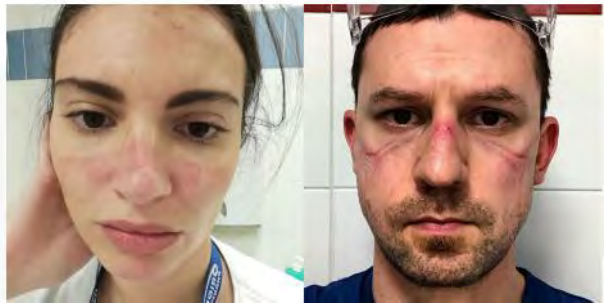
- Reduction in clarity or volume of speech
- Impedance of hearing

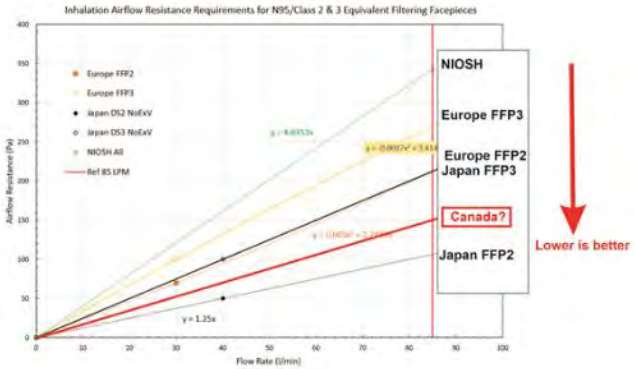
Ability to perform work

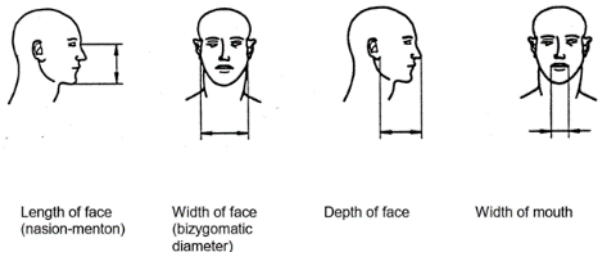
- Interference with movement
- Dislodging by movement
- Interference with vision
- Compatibility with other PPE

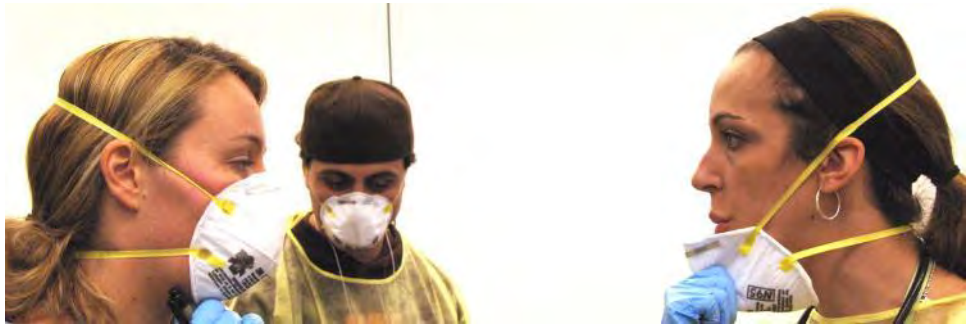
Other Factors

- Shelf-Life
- Decontamination, extended use, re-use
- Mechanical robustness of strap and structure



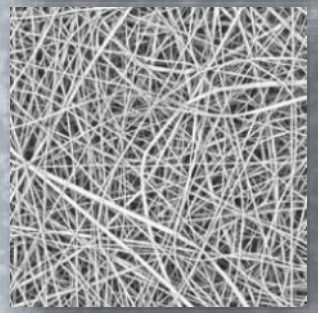


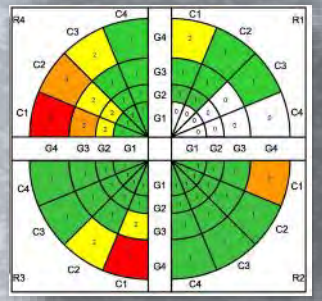




PRESENTATION SUMMARY

Personal Protective Equipment	What is and what isn't a respirator
What to Look for	Respirator types and approvals
What Matters?	Filtration, Fit & Function
User Needs	Choosing and Using the right kind of respirator



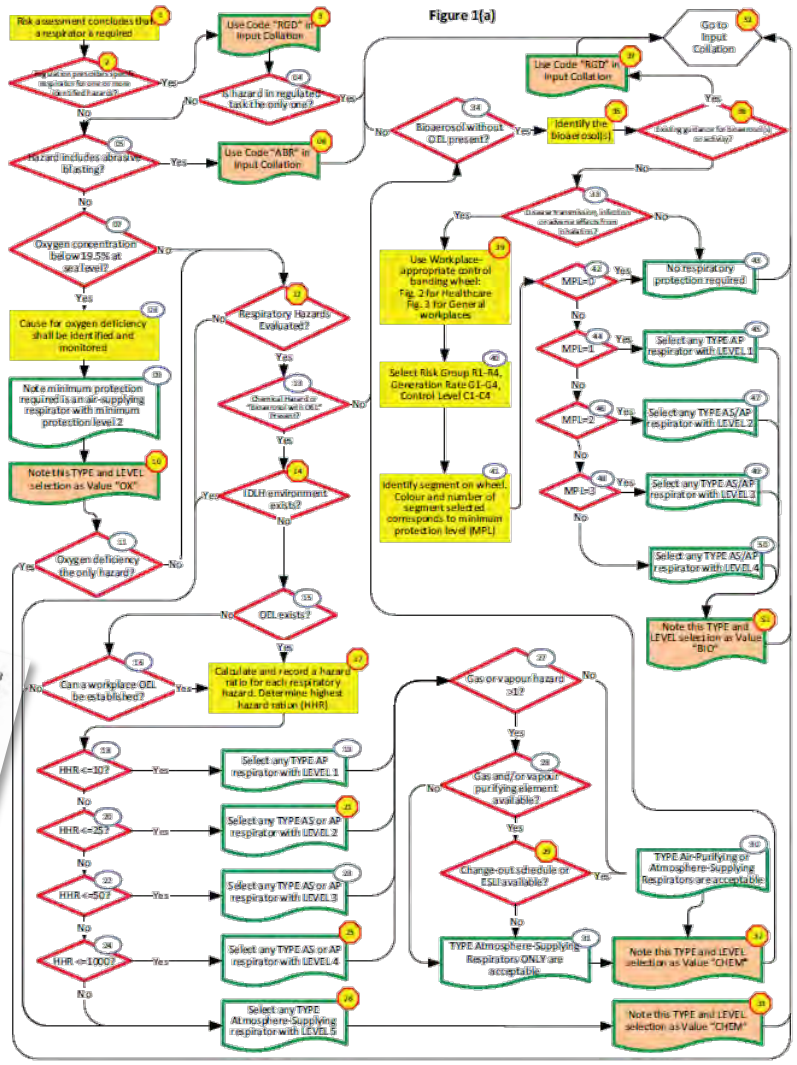


RESPIRATOR SELECTION – NATIONAL STANDARD OF CANADA CSA Z94.4-18

Note that the Manitoba Workplace Safety and Health Regulation specifies the 2011 edition of CSA Z94.4, but all the selection criteria and use/maintenance requirements are the same for the 2018 edition

- Selection is one part of a respiratory protection programme
- Assess all potential hazards
  - Assess oxygen deficiency, particulate and gas/vapour hazards
- Non-biological hazards with exposure limits
  - Measure concentration, determine hazard ratio and aerosol type (oil/non-oil-based) if necessary
  - Select respirator type based on hazard ratio
- Biological hazards – no defined exposure limits
  - "Expert Opinion" guidance (from government or recognised authorities e.g. medical organisations)
  - Control Banding selection guidance from Canadian Standard CSA Z94.4-18

    https://community.csagroup.org/docs/DOC-121294



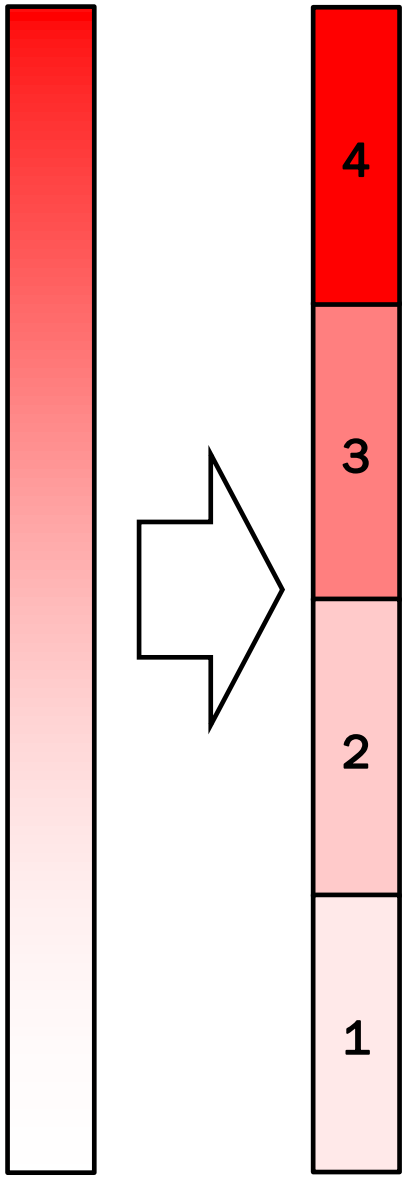
APPROACHES FOR RESPIRATOR SELECTION FOR BIOLOGICAL HAZARDS

Method	Advantages	Disadvantages
Guidelines Expert Opinion	Often authoritative sources Well recognised	May cover specific circumstances but also leaves gaps Different sources' guidance may be inconsistent with each other or with occupational hygiene principles … and who are the experts?
Quantitative Modelling (e.g. ANSI Z88.12)	Supports wide range of scenarios Accuracy	Needs numeric data as inputs which may be hard to obtain Acceptable "Probability of Infection"?
Control Banding	Relatively simple Covers range of scenarios	Relies on qualitative assessment of some inputs May lead to over-simplification or wrong assumptions by users

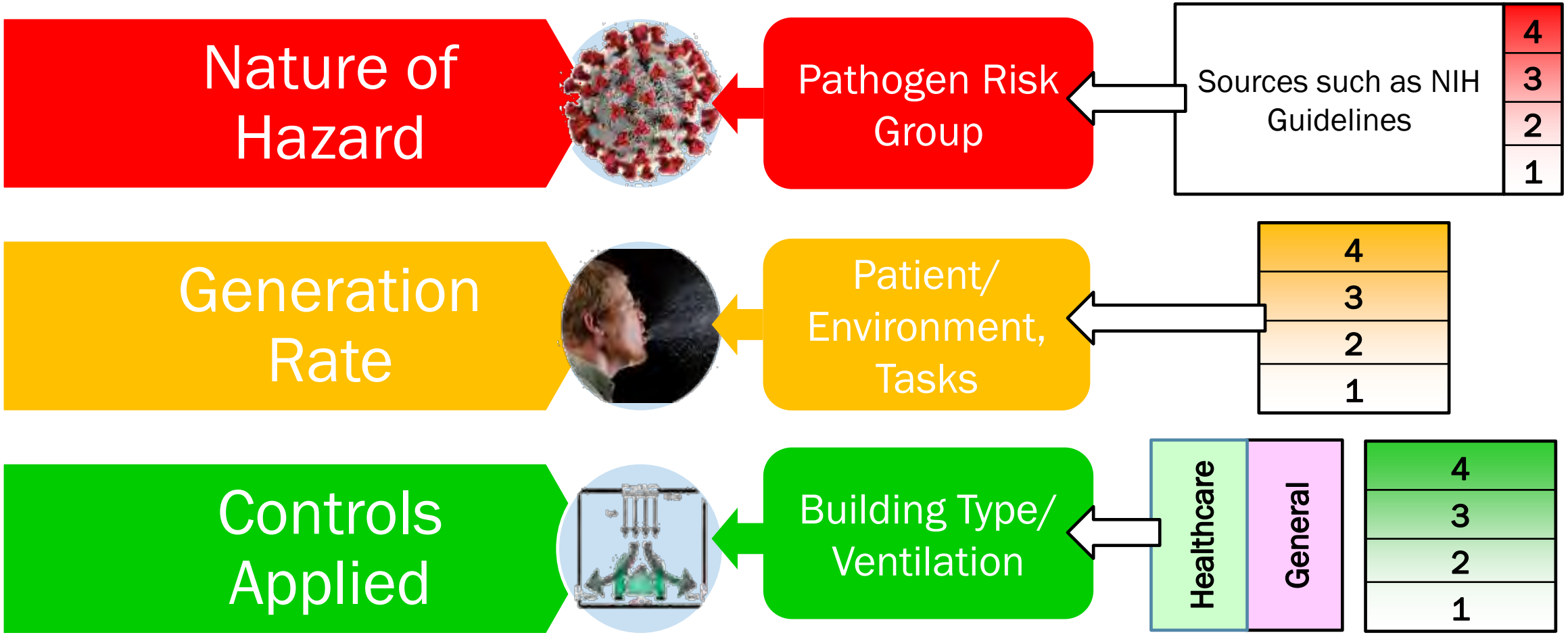
WHAT IS CONTROL BANDING?

- Originally developed for use in the pharmaceutical industry to create safety protocols for novel chemicals
- Aids decision making when precise information is not known, but the general level of a contributing factor is available
- Risk factors are assigned into a “band” within the overall range – usually there are between 3 and 6 bands
- An algorithm is devised to convert banded inputs for several factors in the exposure environment to an output defining safe practices or equipment selection
- A qualified person can use this simple and effective tool to reduce the complexity and improve the applicability of selection decisions
- Applied in CSA Z94.4-18 for respirator selection for bioaerosol exposures
- For more information, refer to AIHA, Guidance for Conducting Control Banding Analyses:

https://online-ams.aiha.org/amsssa/ecssashop.show_product_detail?p_mode=detail&p_product_serno=879



CONTROL BANDING – ADAPTATION TO RESPIRATORY PROTECTION FOR BIOLOGICAL AEROSOLS - INPUTS



Images: www.bbc.com/news/, https://phil.cdc.gov/details.aspx, https://pubmed.ncbi.nlm.nih.gov/16501436/

OUTPUT: HIERARCHY OF RESPIRATORY PROTECTION

For filtering respirators: recommendation is at or above the 0-4 level identified in process output

0
Respiratory Protection not presumed necessary

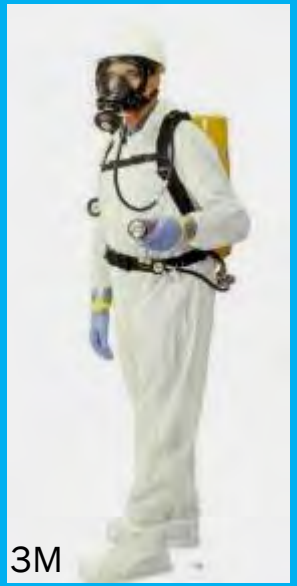
1
Fitted filtering facepiece

1
Half-facepiece air-purifying respirator

2
Loose-fitting powered air-purifying respirator

3
Full-facepiece air-purifying respirator

4
Tight-fitting powered air-purifying respirator



5
Self-Contained Breathing Apparatus

OVERALL CONTROL BANDING SELECTION PROCESS IN CSA Z94.4

Seven-stage process conducted by a qualified professional following overall risk assessment and consideration of other types of hazard

Step	Action
1	Identify the bioaerosol
2	Confirm that a risk of transmission of disease, infection or adverse effects is produced from inhalation of bioaerosol
3	Select applicable control banding wheel (Healthcare or General Workplace)
4	Determine the bioaerosol risk group (R1 to R4)
5	Determine the generation rate (G1 to G4)
6	Determine the control (ventilation) level (C1 to C4)
7	Identify the protection level in the segment in the applicable wheel at the intersection R, G and C values and select respirator based on this

CLASSIFICATION OF BIOHAZARDS BY RISK GROUP

Risk Group	Health impacts (transmissibility, infectivity and adverse health effects of the biohazard)
Risk Group 1 (R1)	Agents that are not associated with disease or serious adverse health effects in healthy adult humans
Risk Group 2 (R2)	Agents that are associated with human disease or adverse health effect which is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3 (R3)	Agents that are associated with serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions may be available (high individual risk but low community risk)
Risk Group 4 (R4)	Agents that are likely to cause serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

Some Examples

Biohazard	Factor Used
Chickenpox, Measles	R2
Influenza viruses A,B,C (except as below)	R2
SARS-Covid2	R3
Hantaviruses	R3
Histoplasmosis	R3
Tuberculosis	R3
Influenza viruses H1N1, H2N2, H5N1	R3

Classifications correspond with the US National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules" (April 2019) – see reference list.

GENERATION INPUTS

Rank	Qualitative Example
Healthcare	
G1	Patient not coughing or sneezing
G2	Patient coughing or sneezing with mouth covered
G3	Patient coughing or sneezing with mouth uncovered
G4	Aerosol generating procedure
General Workplace	
G1	Low - Vacuuming with a HEPA filter
G2	Medium - Soaking then shovelling pigeon droppings
G3	High – Misting then shovelling pigeon droppings
G4	Very High – Dry Sweeping pigeon droppings

CONTROL (VENTILATION) INPUTS

Rank	ACH	Qualitative Example
Healthcare		
C1	<3	Storage Area
C2	3-6	Patient Room/Corridor
C3	6-12	Autopsy
C4	12-25	Surgery
General Workplace		
C1	<1	Indoor/Poor Ventilation
C2	1-4	Indoor Natural Ventilation
C3	4-6	Indoor Mechanical Ventilation/Outdoor Low Wind
C4	>6	Outdoor Moderate Wind

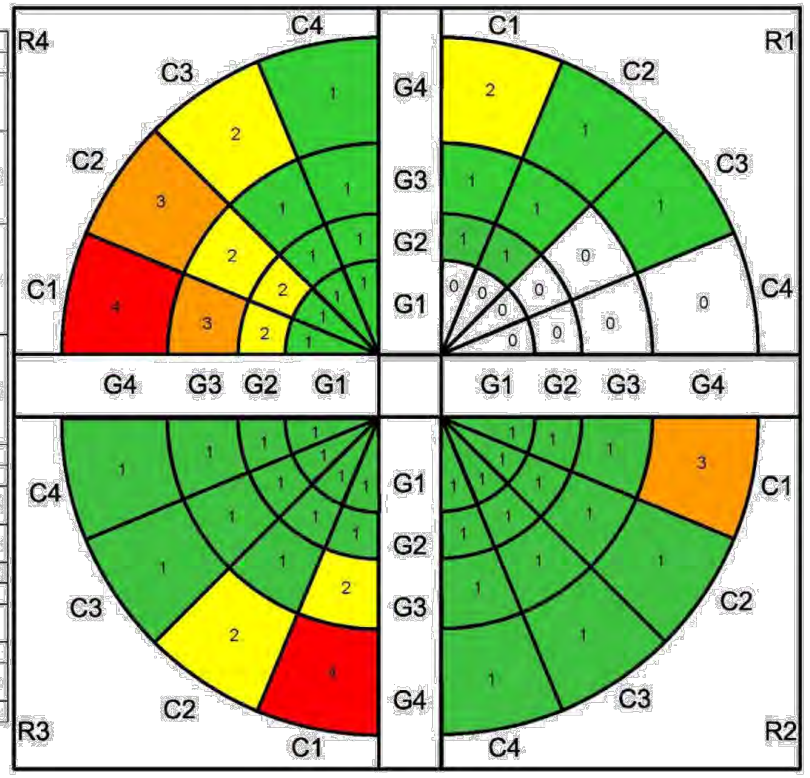
ACH = Air Changes per Hour

REPRESENTATION OF OUTPUT

- Presented as a circular diagram for compactness
  - Quadrant based on risk rating, chord on generation rate, sector on ventilation rate
  - Number/colour indicates protection level required
- Output generally agrees with expert opinion but fills gaps, and considers impact of ventilation

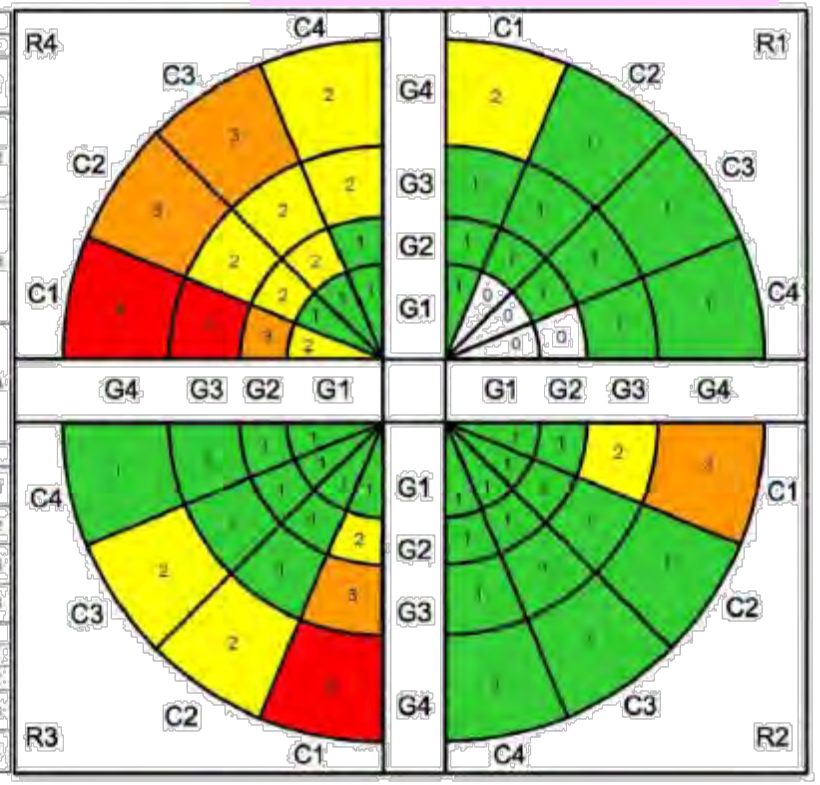
Healthcare

Health Care Facilities	
Risk Group	
Agents that are not associated with disease or serious adverse health effects in healthy adult humans	R1
Agents that are associated with human disease or adverse health effect which is rarely serious and for which preventive or therapeutic interventions are often available	R2
Agents that are associated with serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions may be available (high individual risk but low community risk)	R3
Agents that are likely to cause serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)	R4
Generation Rate	
Patient not coughing or sneezing	G1
Patient coughing or sneezing with mouth covered	G2
Patient coughing or sneezing with mouth uncovered	G3
Aerosol generating procedures	G4
Control Level	
Poorly Ventilated <3 air changes per hour (ACH)	C1
Corridor or patient room, 3-6 ACH	C2
Negative Pressure, Laboratory, Autopsy, 6-12 ACH	C3
Surgery >12 ACH	C4



General Workplace

General Workplace Environment	
Risk Group	
Agents that are not associated with disease or serious adverse health effects in healthy adult humans	R1
Agents that are associated with human disease or adverse health effect which is rarely serious and for which preventive or therapeutic interventions are often available	R2
Agents that are associated with serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions may be available (high individual risk but low community risk)	R3
Agents that are likely to cause serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)	R4
Generation Rate	
Low release of bioaerosol / pathogen	G1
Medium release of bioaerosol / pathogen	G2
High release of bioaerosol / pathogen	G3
Very High release of bioaerosol / pathogen	G4
Control Level	
Indoor - poorly ventilated ACH ≤ 1	C1
Indoor - ventilation 1 < ACH < 4	C2
Indoor - ventilation 4 < ACH < 6 Outdoor - low wind	C3
Indoor - ventilation ACH > 6 Outdoor - moderate wind	C4



Standard document includes sample scenarios

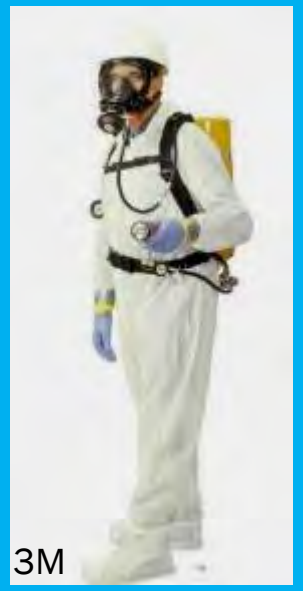
OUTPUT: CSA Z94.4 HIERARCHY OF RESPIRATORY PROTECTION

For filtering respirators: recommendation is at or above the 0-4 level identified in process output

0
Respiratory Protection not presumed necessary

1
Fitted filtering facepiece

1
Half-facepiece air-purifying respirator



5
Self-Contained Breathing Apparatus

2
Loose-fitting powered air-purifying respirator

3
Full-facepiece air-purifying respirator

4
Tight-fitting powered air-purifying respirator

EXAMPLE SCENARIO : COVID-19 INTUBATION IN PATIENT ROOM

A team is intubating a patient that has been diagnosed with Covid-19. Due to space shortages, the emergency action is being undertaken in a patient room.

Step	Action	Result
1	Identify	Covid-19
2	Confirm transmission	Yes
3	Select CB wheel	Healthcare
4	Risk group	R3: Covid-19
5	Generation Rate	G4: Aerosol Generating Procedure
6	Control level	C2: 3-6 ACH (patient room)
7	Identify segment	

Scenario Summary:

Healthcare Wheel

Risk group **R3**

Generation level **G4**

Control level **C2**

Minimum Protection Level Advised:

2

Loose-fitting powered air-purifying respirator

Level 2:
Assigned Protection Factor Required is 25 or greater

Health Care Facilities	
Risk Group	
Agents that are not associated with disease or serious adverse health effects in healthy adult humans	R1
Agents that are associated with human disease or adverse health effect which is rarely serious and for which preventive or therapeutic interventions are often available	R2
Agents that are associated with serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions may be available (high individual risk but low community risk)	R3
Agents that are likely to cause serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)	R4
Generation Rate	
Patient not coughing or sneezing	G1
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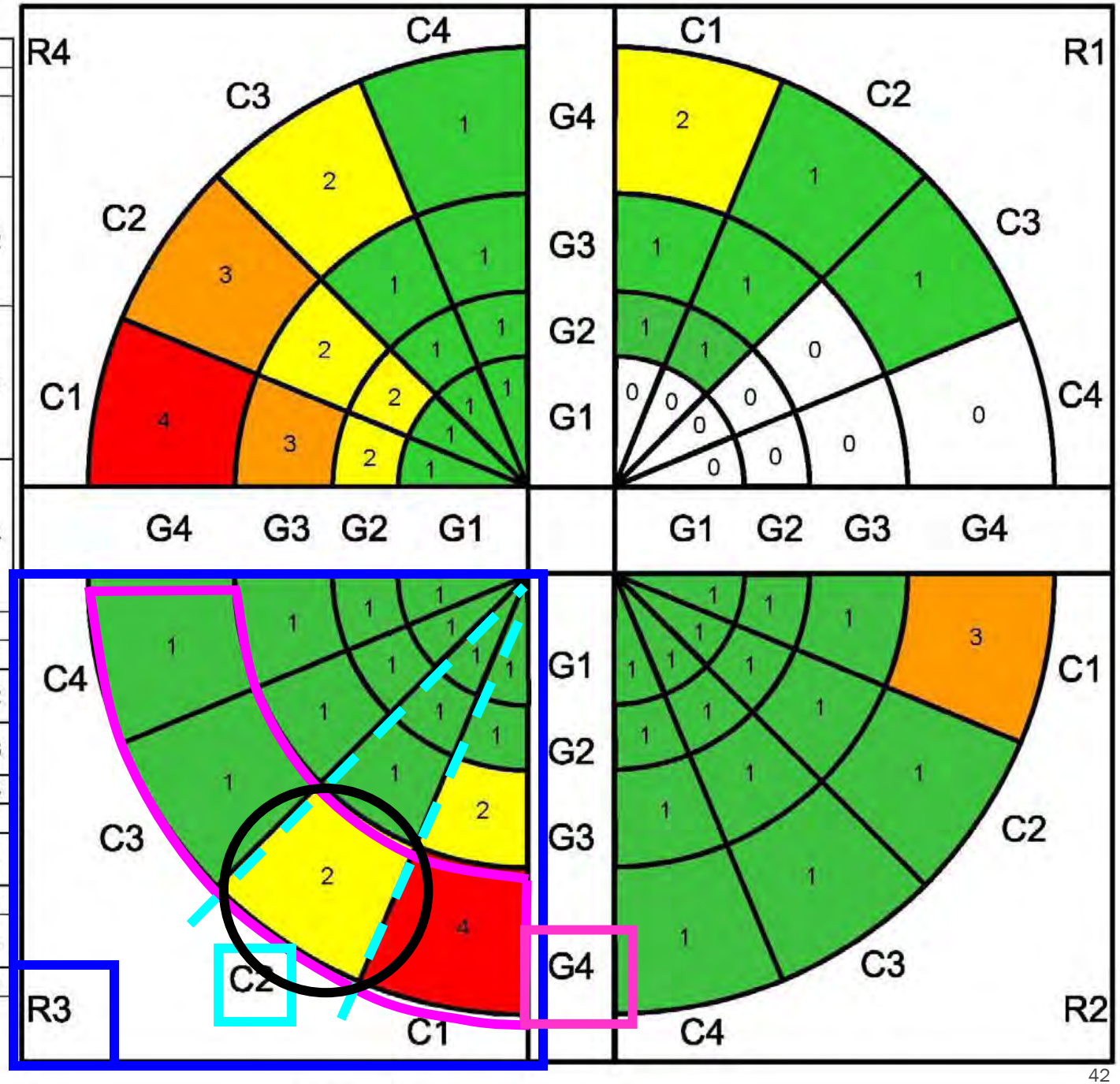

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Step	Action	Result
1	Identify	Covid-19
2	Confirm transmission	Yes
3	Select CB wheel	Healthcare
4	Risk group	R3: Covid-19
5	Generation Rate	G4: Aerosol Generating Procedure
6	Control level	C2: 3-6 ACH (patient room)
7	**Identify segment**	**R3 G4 C2 = Yellow = Minimum APF of 25**

Output: APF of 25 or above

- Powered air purifying respirator. CDC proposes filtering facepiece or above. California OSHA proposes powered air-purifying respirator or above

GUIDANCE FOR QUEBEC

- The Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) has created a similar guidance protocol for Quebec which is available as an on-line tool

Partial sample of input

SELECT THE RISK GROUP

Determine the RG to which the bioaerosols present in the workplace belong. In the presence of several bioaerosols belonging to different RGs, select the highest RG (worst case scenario).

- ○ **RG 1:** Low risk for individuals and communities (non-infectious microorganisms that may present immunological or toxin-related risks under certain conditions)
- ○ **RG 2:** Moderate risk for individuals, low for communities (infectious microorganisms that cause generally mild infections for which preventive measures and treatments exist; not likely to spread in communities)
- ◉ **RG 3:** High risk for individuals, low for communities (infectious microorganisms that cause generally serious infections for which preventive measures and treatments may exist; not likely to spread in communities)
- ○ **RG 4:** High risk for individuals and communities (infectious microorganisms that cause very serious infections for which preventive measures and treatments do not exist; very likely to spread in communities)

SELECT THE CONTROL LEVEL

Select your workplace control level or the one most similar to it. Examples of different work situations are given.

- ○ **ACH ≤ 2**; no ventilation; confined spaces
- ○ **2 < ACH ≤ 6**; general ventilation
- ◉ **6 < ACH ≤ 12**; negative pressure room; general laboratory ventilation; isolation room; ventilation by displacement
- ○ **ACH > 12**; work under a laboratory chemical hood; some hospital departments (bronchoscopy, operation room)
- ○ **Work in biological safety cabinets (BSC)**

SELECT THE GENERATION RATE

Select your workplace generation rate or the one most similar to it. Examples of different work situations are given.

- ○ **Very high:** Uncontrolled aerosolization of the biological contaminant; proximity to emission sources; medical procedures producing aerosols
- ◉ **High:** High aerosolization of the biological contaminant; care given to an infectious patient coughing or sneezing with mouth uncovered
- ○ **Moderate:** Moderate aerosolization of the biological contaminant; long distance from the source; infectious patient coughing or sneezing with mouth covered
- ○ **Low:** Low aerosolization of the biological contaminant; personnel assigned to other care tasks
- ○ **None:** No aerosolization of the biological contaminant

Output

		Exposure level				
		Very low	Low	Medium	High	Very high
Risk group (RG)	1	None	APF 10	APF 10	APF 10	APF 25
	2	None	APF 10	APF 10	APF 25	APF 50/100 [1]
	3	None	APF 10	APF 25	APF 50/100 [1]	APF ≥ 1000
	4	APF ≥ 1000	APF ≥ 1000	APF ≥ 1000	APF ≥ 1000	APF ≥ 1000

[1] The APF of 50 from the NIOSH is equivalent to the APF of 100 in the Guide des appareils de protection respiratoire utilisés au Québec

TAKE-AWAYS

- The virus is in the air
- Filtration, Fit and Function all matter
- “Masks” are not all the same
  - We need multiple layers to protect us from airborne particles
  - Respirators are the most efficient way to protect you AND others
  - Until you get a respirator, make sure what you’re using has a tight fit
  - Respirators>Surgical Masks with brace>Surgical Masks
- Systematic Selection Guidance is available

REFERENCE LIST

- CSA Z94.4-18 “Selection, Use and Care of Respirators” viewable version: https://community.csagroup.org/docs/DOC-121294
- CSA Z94.4.1-21 “Performance of Filtering Respirators” viewable version: https://view.csagroup.org/K6UbmP
- IRSST Respirator selection for biological aerosols control banding on-line tool: https://www.irsst.qc.ca/bioaerosol/default.aspx?
- Health Canada Guidance: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators/safety-performance-specifications.html
- ISO Standards addressing respiratory protection: https://www.iso.org/committee/291088/x/catalogue/p/1/u/0/w/0/d/0

All of these are available in English and French

- Electronic version of NIOSH Standard 42 CFR 84: https://www.ecfr.gov/cgi-bin/text-idx?SID=1e52f48c2b606c31f3df95baa80cc78e&mc=true&node=pt42.1.84&rgn=div5
- Approved respirators can be searched on the NIOSH Certified Equipment List: https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html
- CDC Counterfeit respirator information: https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html
- US National Institutes of Health “Guidelines for Research Involving Recombinant DNA Molecules”: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
- Studies from the National Academies of Sciences, Engineering and Medicine on various aspects of respirator testing and use provide useful background: https://www.nationalacademies.org/our-work/standing-committee-on-personal-protective-equipment-for-workplace-safety-and-health

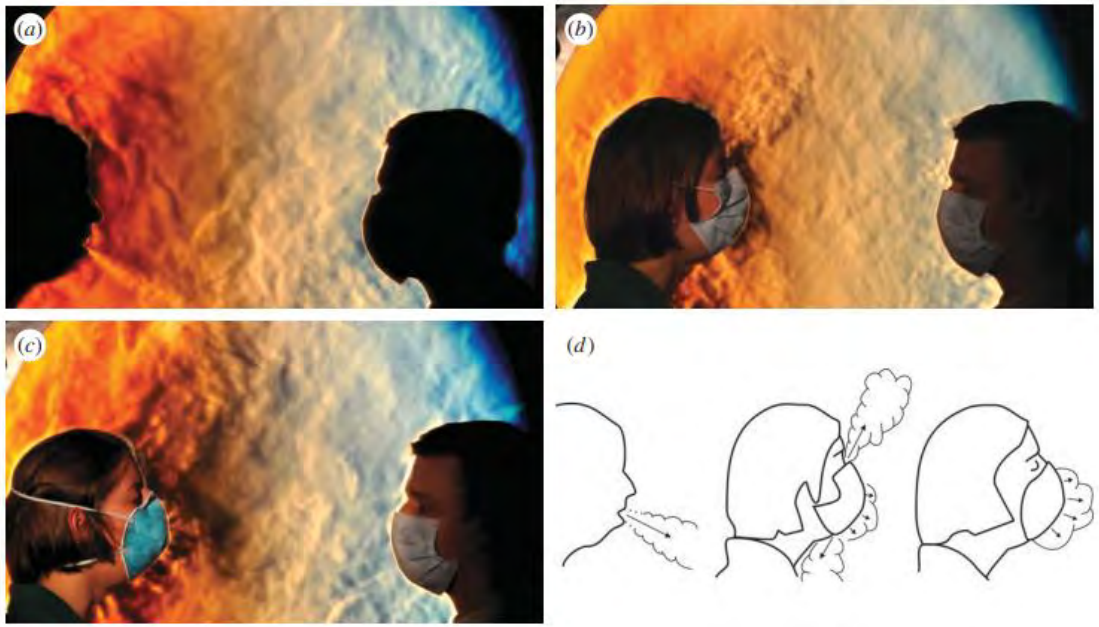
THANK YOU

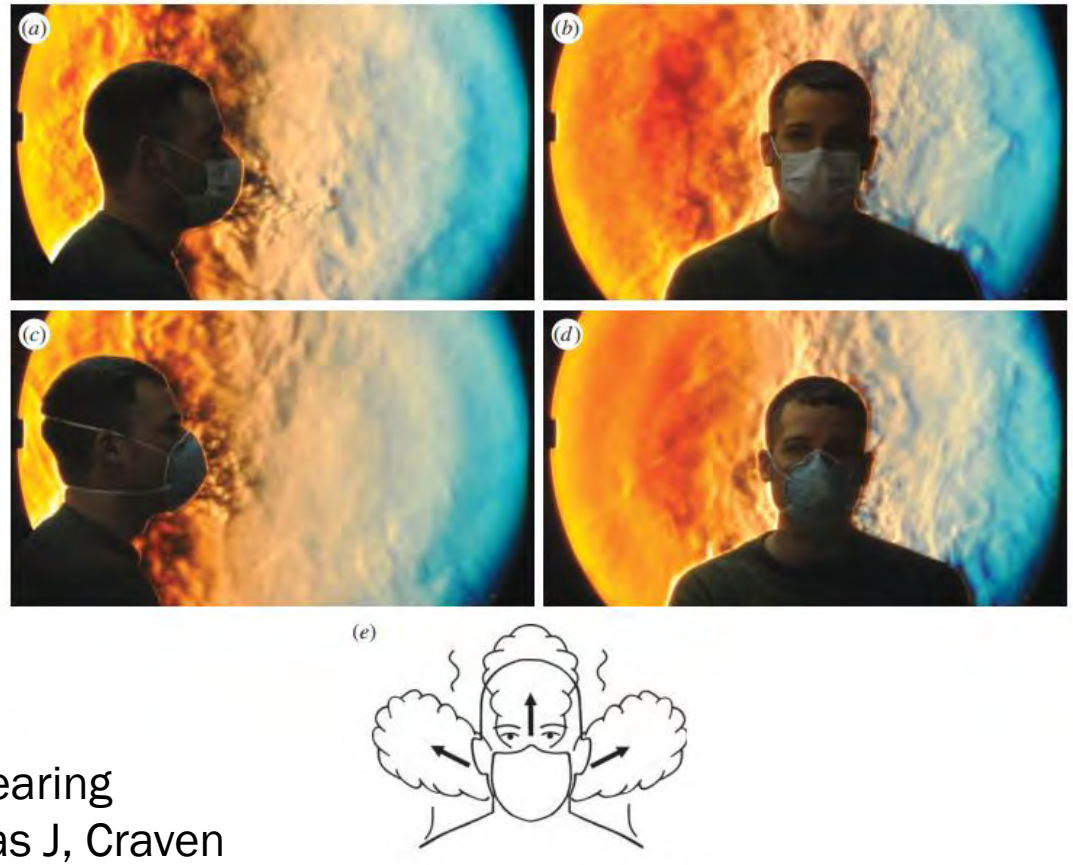
Simon Smith

sjsmith@kos.net

Unattributed images were taken by the author

EXHALATION DISPERSION – SOURCE CONTROL EXAMPLES





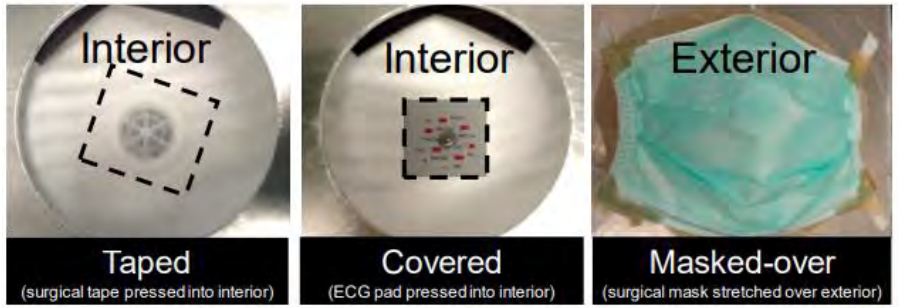
"A schlieren optical study of the human cough with and without wearing masks for aerosol infection control", Tang Julian W, Liebner Thomas J, Craven Brent A, Settles Gary S, Journal of the Royal Society Interface, 6 p.S727-S736 (2009)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2843945/pdf/rsif20090295.pdf

EXHALATION VALVES ON MASKS – RECENT NIOSH STUDY

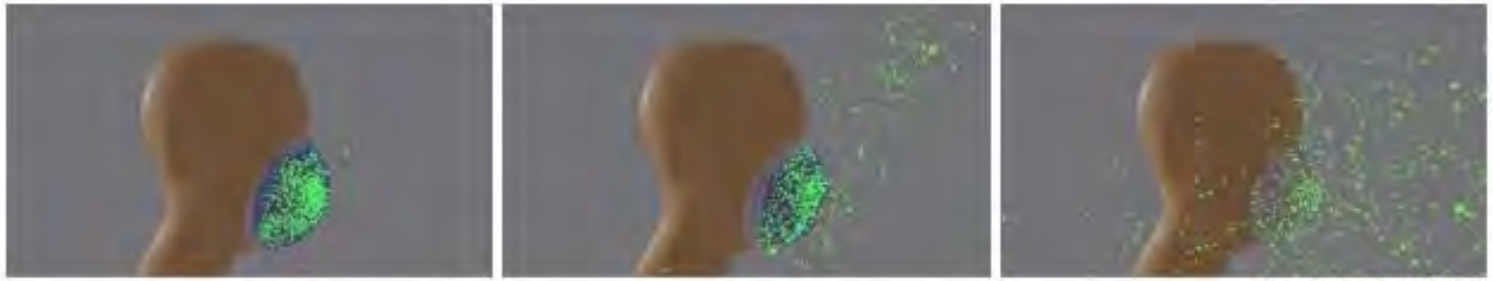
Draeger Safety

https://www.flare.com/health/how-to-make-a-mask-for-coronavirus/f

Impact of Covering

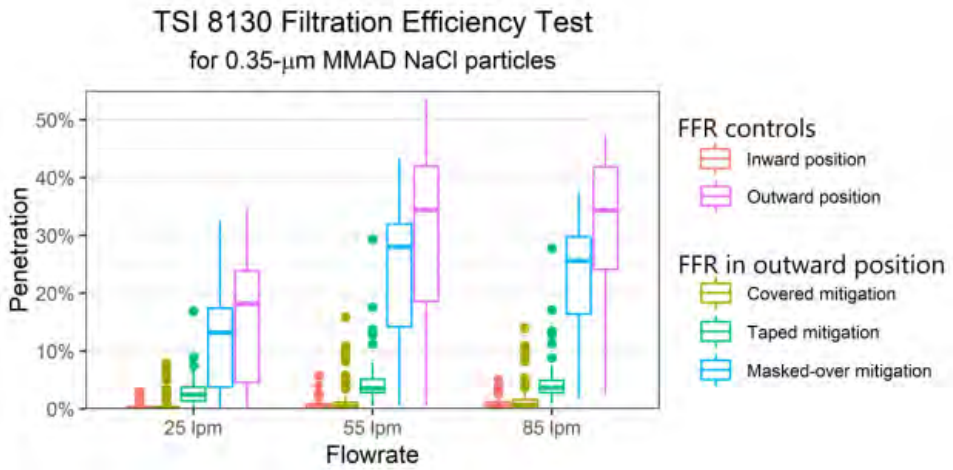


Photos by NIOSH



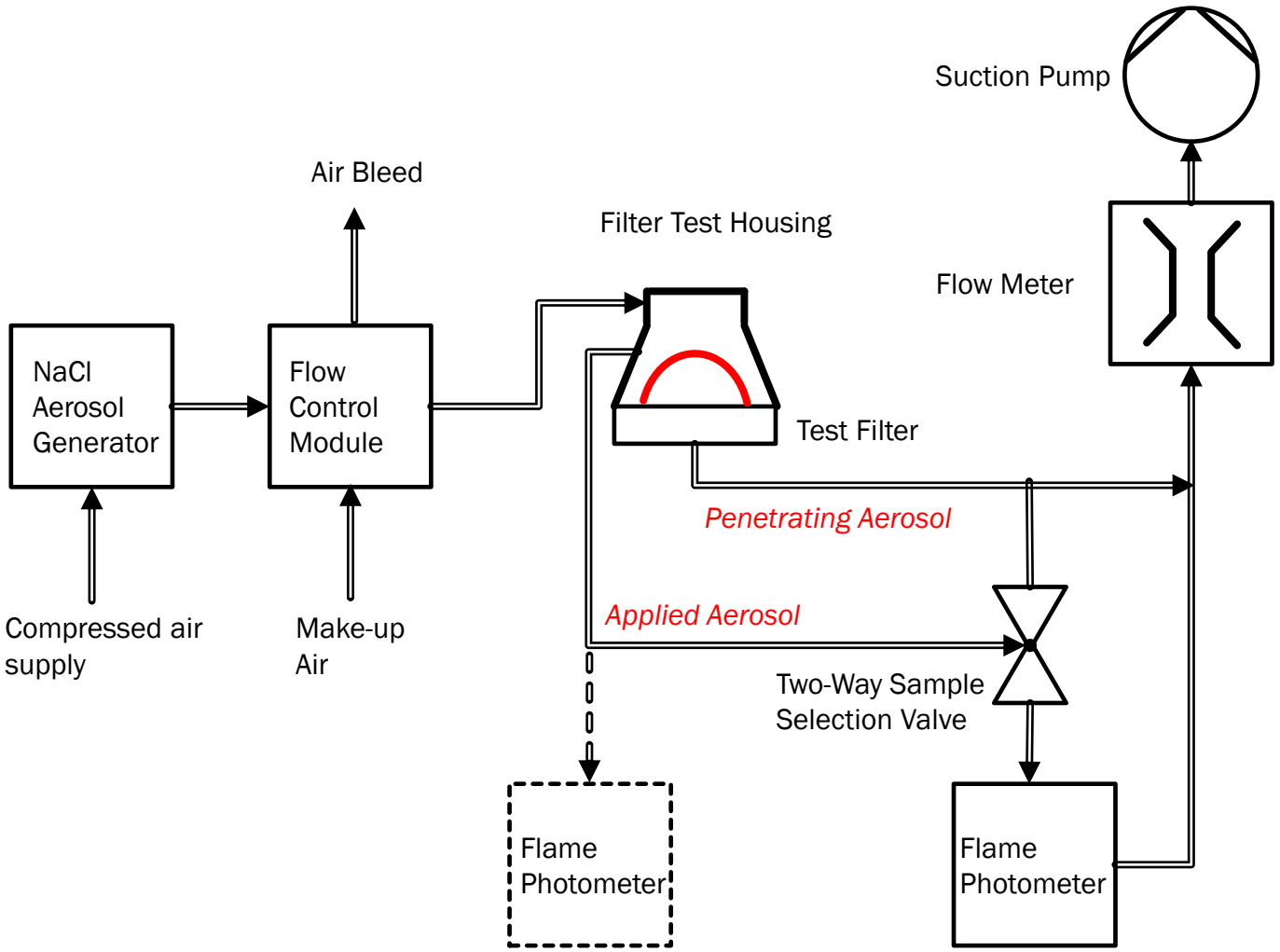
Illustrations by NIOSH

Figure 1. Simulations of particle exhalation through an FFR without an exhalation valve (left), an FFR with an exhalation valve (center), and a barrier face covering (right). Density of particles near the face represents particles remaining inside the mask.

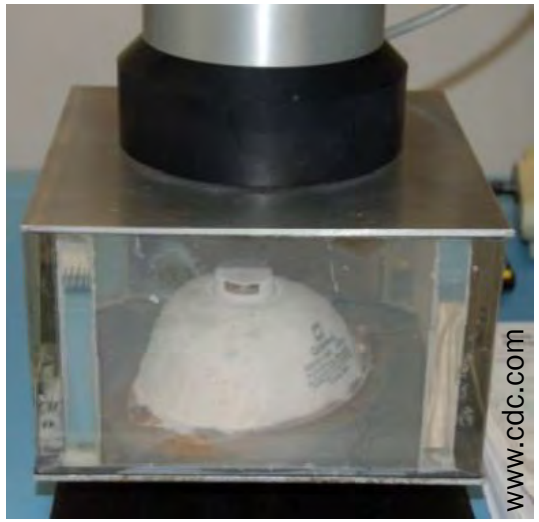


NIOSH [2020]. Filtering facepiece respirators with an exhalation valve: measurements of filtration efficiency to evaluate their potential for source control. By Portnoff L, Schall J, Brannen J, Suhon N, Strickland K, Meyers J. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2021-107. DOI: https://doi.org/10.26616/NIOSHPUB2021107external icon

FILTER EFFICIENCY TESTING

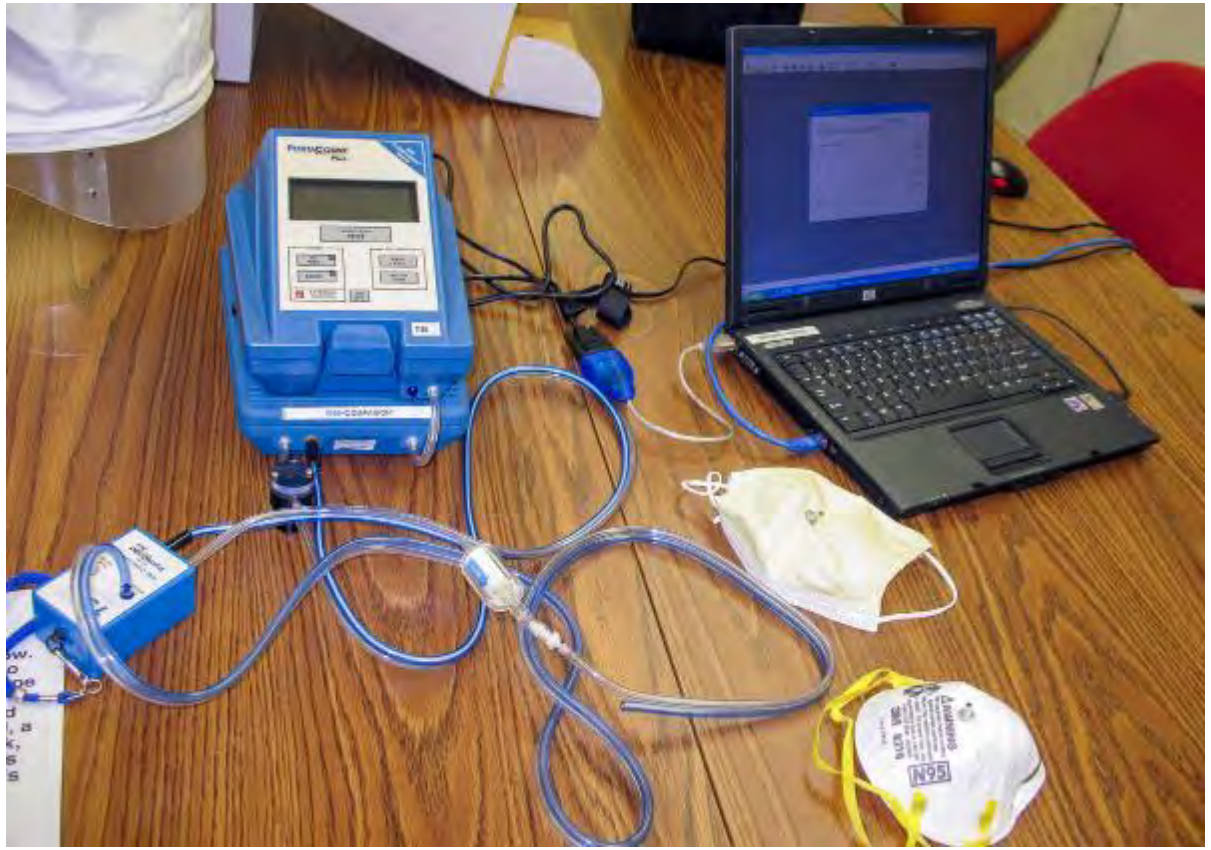


- Features of Filter Tests
  - Pre-Conditioning – elevated humidity/temperature or physical impact
  - Testing with monodisperse aerosol at most penetrating particle size
  - Instantaneous particle penetration (% efficiency)
  - Airflow resistance measurement possible
  - Particle loading (exposure to aerosol over time) with efficiency measurement



FIT: WHAT AFFECTS FIT OF A FILTERING FACEPIECE OR OTHER RESPIRATOR

- Design of mask (technology, standards and head-shape)
- Airflow resistance of filter media – higher resistance may exacerbate leakage
- Flexibility of facepiece
- Nose clip/cushioning or sealing materials
- Straps – adjustment, placement, effectiveness
- Proper donning and adjustment
- Facial hair growth



Additionally – changes over time:

- Loss of flexibility/seal due to heat, humidity and secretions
- Effects of decontamination for re-used equipment - on filtration, strength and flexibility
- Ageing of construction materials
- Studies on stockpiles show straps fail first

Summary of Major World-Wide Filtering Respirator Standards and Guidance (Addressing Particle Protection)

Organisation	Recognised in	Respirator performance standards (includes requirements, testing & marking) Latest revision year indicated		Selection, use and care standards (or nearest equivalent) (includes user testing and appropriate use)	
		Standard	Description	Standard	Description
Australia/New Zealand Standards (AS/NZS)	Australia & New Zealand	AS/NZS 1716 (2012)	Respiratory Protective Devices	AS/NZS 1715 (2012)	Selection, use and maintenance of respiratory protective equipment
Associação Brasileira de Normas Técnicas (ABNT)	Brazil	ABNT NBR 13698 (2011)	Respiratory protective devices - Filtering half mask to protect against particles	ABNT NBR 12543 (2017)	Respiratory protective devices - Terminology
Canadian Standards Association (CSA)	Canada	CSA Z94.4.1 (2021)	Performance of Filtering Respirators	CSA Z94.4 (2018)	Selection, use and care of respirators
Standardization Administration of China	China	GB 2626 (2019)	Non-powered air-purifying particle respirators	GB/T 18664 (2002)	Selection, use and maintenance of Respiratory protective equipment
		GB 30864 (2014)	Powered air-purifying respirators		
European Committee for Standardization (CEN)	UK, European Union, European Free-Trade Association, Russia. South Africa	EN 136 & EN 140 (1998)	Elastomeric facepiece	EN 132 (1999)	Definitions of terms & pictograms
		EN 143 (2000)	Filters for respirators	EN 529 (2005)	Recommendations for selection, use, care and maintenance
		EN 149 (2009)	Filtering facepiece		
		EN 12941 (2008)	Loose fitting PAPR		
		EN 12942 (2008)	Tight-fitting PAPR		
		EN 14387 (2008)	Gas filters & Combined filters		
Japanese Industrial Standards Committees (JIS)[1]	Japan	JIS T 8151 (2018)	Particulate respirators	JIS T 8150 (2006)	Guidance for selection, use and maintenance of respiratory protective devices
		JIS T 8157 (2018)	Powered air purifying respirator for particulate matter		
Japan Ministry of Health, Labour and Welfare (JMHLW)		Notification 214-2018	Standard for Dust Mask		
Korean Agency for Technology and Standards (KATS)[2]	Korea	KS M 6673 (2008)	Dust respirators	KS P 1101 (2010)	Guidance for selection, use and maintenance of respiratory protective devices
		KS M 6764 (2009)	Filter for dust respirators		
		KS P 8416 (2008)	Dust respirators for fine particles		
		KS P 8417 (2008)	Powered air purifying respirators		
Korean Ministry of Employment and Labour (KMOEL)		KMOEL Notification 2017-64 (2017)	Dust respirators		
Norma Oficial Mexicana (NOM)	Mexico	NOM-116-STPS-2009	Particulate FFP and replaceable filters	Annex to NOM-116-STPS-2009	Guide for selection of air purifying respirators for hazardous dusts
U.S. National Institute for Occupational Safety & Health (NIOSH)	USA, Canada[3]	42 CFR 84 (1995)	All types of respiratory protective device	29 CFR 1910.134 (1998) (USA only)	Respiratory Protection

[1] In Japan, JIS standards are not mandatory, while JMHLW notifications are mandatory
[2] In Korea, KATS standards are not mandatory, while KMOEL notifications are mandatory
[3] In Canada, there are multiple jurisdictions: NIOSH approvals are generally accepted but those of other agencies may also be applicable in some jurisdictions

COMPARISON OF STANDARDS FOR FILTERING FACEPIECES USED IN HEALTHCARE AND INDUSTRY

(BASED ON PERFORMANCE REQUIRED IN THE RESPECTIVE STANDARDS)

One document for all RPE types

Separate document for each RPE type

Country/Domain (with standards setting agency)	Applicable Standard (Year)	Filtering Facepiece Classification Examples		
		Classes Usual for Healthcare (HC) Use	Classes not usual in HC but Acceptable for HC use (Equivalent to/Greater than N95 Capability)	Classes not usual in HC and Not Recommended for HC use (Lower than N95-equivalent Capability)
Australia/New Zealand (Standards Australia/Standards New Zealand)	AS/NZS 1716 (2012)	P2, P3		P1
Brazil (Associação Brasileira de Normas Técnicas)	ABNT NBR 13698 (2011)	PFF2 S, PFF3 S	PFF2 SL, PFF3 SL	PFF1 S, PFF1 SL
China (Standards Administration of China)	GB2626 (2019)	KN95	KN99, KN100, KR95, KR99, KR100, KP95, KP99, KP100	
Europe (European Committee for Standardization)	EN 149 (2001, updated 2009)	FFP2, FFP3		FFP1
Japan (Ministry of Health, Labour and Welfare)	JMHLW Notification 214 (2018)	DS2, DS3	DL2, DL3	DS1, DL1
Korea (Ministry of Employment and Labour)	KMOEL - 2017-64 (2017)	KF94 (1st Class)	Special	KF80 (2nd Class)
Mexico (Comisión Nacional de Normalización)	NOM-116-STPS-2009	N95	N100, R95, R100, P95, P100	N90, R90, P90
United States (National Institute for Occupational Safety and Health)	42 CFR 84 (1995)	N95	N99, N100, R95, R99, R100, P95, P99, P100	

Comparison of US Respirator (N95) and Surgical Mask Filtration Requirements

Copied from: "A comparison of facemask and respirator filtration test methods", Samy Rengasamy, Ronald Shaffer, Brandon Williams, Sarah Smit, Journal of Occupational and Environmental Hygiene, 14(2) p.92-103 (2019).

Test Method	Source Documents	Aerosol Type	Particle Size	Particle Charge	Particle Concentration	Aerosol Detector	Flow Rate (Face Velocity)	Test Time	Max Efficiency	Sample Type (Size)
NIOSH NaCl	42 CFR part 84	NaCl	0.075 µm CMD (GSD <1.86)	Neutralized	<200 mg/m^3	Light Scattering photometer	85 L/min (Face Velocity varies between respirators	Maximum penetration	99.999%	Respirator (Entire mask)
FDA-PFE	1) FDA Guidance Document (SM 501(k)) 2) ASTM F 1215-89 (withdrawn) 3) ASTM F2100 4) ASTM F2299	Polystyrene latex spheres (FDA Guidance Document)	0.1 um (FDA Guidance Document)	Un-neutralized (FDA Guidance Document)	Generate 10^7 - 10^8 particles/m^3 and dilute as needed (ASTM F2299)	Optical particle counter (ASTM F2299	0.5-25 cm/sec (ASTM F2299	1-5 min Initial efficiency (ASTM F2299)	99.9% Increase aerosol concentration to achieve greater efficiencies (ASTM F2299)	Surgical mask (Entire mask) (FDA Guidance Document)
ASTM-PFE	ASTM F2299	Latex spheres	0.1 to 5.0 µm (Mono-disperse aerosol; MPS)	Neutralized	Generate 10^7 - 10^8 particles/m^3 and dilute as needed	Optical particle counter	0.5-25 cm/sec	1-5 min Initial efficiency	99.9% Increase aerosol concentration to achieve greater efficiencies	Surgical mask (50-150 mm diameter circle)
FDA-BFE	1) FDA Guidance Document (SM 501(k) 2) ASTM F2100 3) ASTM F2101	Staphylo-coccus aureus (ASTM F2101	3.0±0.3 µm (MPS) (ASTM F2101	Undefined (ASTM F2101	2200 ± 500 viable particles per test (ASTM F2101)	Six-Stage Viable Particle Cascade Impactor (ASTM F2101)	28.3 L/min (Face velocity not defined) (ASTM F2101	2 min aerosol exposure per test (ASTM F2101)	99.9% (ASTM F2101)	Surgical mask (Entire mask) (FDA Guidance Document)
ASTM-BFE	ASTM F2101	Staphylo-coccus aureus	3.0±0.3 µm (MPS)	Undefined	2200 ± 500 viable particles per test	Six-Stage Viable Particle Cascade Impactor	28.3 L/min (Face velocity not defined)	2 min aerosol exposure per test	99.9%	Surgical mask (Mask material) (Test material area not defined; but should be reported)
VFE	VFE Not a Standard test method	PhiX174 virus	33.0±0.3 µm MPS (adapted from ASTM F2101)	Undefined	1700 – 2000 plaque forming units per test (adapted from ASTM F2101)	Six-Stage Viable Particle Cascade Impactor (adapted from ASTM F2101)	28.3 L/min (Face velocity < 4.7 cm/sec) (per Nelson Labs)	Not Defined	99.9% (adapted from ASTM F2101)	Entire mask or 10 × 10 cm mask material (per Nelson Labs)

Selected Details of standards for filtering facepiece (FFP) respirators and filters for reusable respirators (EFR)

Domain	Respiratory Protective Equipment Classification (FFP and reusable filter)	Minimum efficiency of filter performance[1]		FFP Maximum total inward leakage[2]	FFP Maximum inhalation airflow resistance[3]		FFP Maximum exhalation airflow resistance		FFP/EFR Maximum CO_2 build-up
		Value	Flow (L/min)		Value (Pa)	Test Flow (L/min)	Value (Pa)	Test Flow (L/min)	
Australia	P1 respirator / P1 filter	80%	95	22%	110/340	30/95	120	85	1%
	P2 respirator / P2 filter	94%		8%	120/370	30/95			
	P3 respirator / P3 filter	99%		2%	170/570	30/95			
Brazil	PFF1 S / PFF1 SL respirator / P1 filter[4]	80%	95	Not specified	60/210	30/95	120	85	1%
	PFF2 S / PFF2 SL respirator / P2 filter	94%			70/240	30/95			
	PFF3 S / PFF3 SL respirator / P3 filter	99%			100/300	30/95			
China	KN95 / KR95 / KP95[5]	95%	85	8%	350	85	250	85	1%
	KN99 / KR99 / KP99	99%							
	KN100 / KR100 / KP100	99.97%							
Europe	FFP1 respirator / P1 filter[6]	80%	95	22%	60/210	30/95	300	160	1%
	FFP2 respirator / P2 filter	94%		8%	70/240	30/95			
	FFP3 respirator / P3 filter	99%		2%	100/300	30/95			
Japan	DS1 / DL1 respirator / RS1 / RL1 filter[7]	80%	85	Inward Leakage measured, included in user Instructions	60/45	40	60/45[8]	40	1%
	DS2 / DL2 / RS2 / RL2 filter	95%			70/50	40	70/50	40	
	DS3 / DL3 / RS3 / RL3 filter	99.9%			150/100	40	80/60	40	
Korea	KF80 (2nd Class)[9]	80%	95	22%	60/210	30/95	300	160	1%
	KF94 (1st Class)	94%		8%	70/240	30/95			
	Special	99.9%		2%	100/300	30/95			
Mexico	N90 / R90 / P90[10]	90%	85	Not specified	343	85	245	85	Not Specified
	N95 / R95 / P95	95%							
	N100 / R100 / P100	99.97%							
USA & Canada	N95 / R95 / P95[11]	95%	85	No requirement in this standard, though max. 10% in practice	343	85	245	85	Not Specified
	N99 / R99 / P99	99%							
	N100 / R100 / P100	99.97%							

[1] Minimum efficiency at most penetrating particle size – typically 0.2-0.3 micron mass median diameter
[2] Maximum total inward leakage reported as arithmetic mean of panel of tests except for Australia where it includes mean of panel of tests and individual tests.
[3] Dual values indicate testing at two flow rates, single values indicate testing at one flow rate
[4] Brazil: S appended to type – tested with sodium chloride; SL appended – tested with both sodium chloride and either paraffin oil or dioctyl phthalate
[5] KN-type – tested with sodium chloride, not suitable for oil-containing atmospheres; KR & KP types tested with dioctyl phthalate indicating suitability for oil-containing atmospheres
[6] Europe and Australia: all types tested with both sodium chloride and paraffin oil
[7] Japan – D types disposable, R types reusable; DS/RS-type – tested with sodium chloride, not suitable for oil-containing atmospheres; DL/RL types tested with dioctyl phthalate indicating suitability for oil-containing atmospheres
[8] First value is for FFP with exhalation valves, second value for FFP without exhalation valves.
[9] Korea: all types tested with both sodium chloride and paraffin oil
[10] Mexico: N-type – tested with sodium chloride, not suitable for oil-containing atmospheres; R & P types tested with paraffin oil or corn oil indicating suitability for oil-containing atmospheres; same classes for respirators and filters
[11] USA/Canada: N-type – tested with sodium chloride, not suitable for oil-containing atmospheres; R & P types tested with dioctyl phthalate indicating suitability for oil-containing atmospheres; same classes for respirators and filters