



Revising the CSA Respirator Standard

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March 2024

Definitions

- Personal Protective Equipment (PPE)
 - A general collective term for device that provide protection including gowns, earplugs, safety glasses, safety boots, face coverings and respirators
- Respirator
 - Specific meaning: equipment that provides respiratory protection and is approved – by testing and qualification of manufacturing operations – to nationally or internationally recognised standards
- Mask
 - General term used for face coverings that includes both respirators and any other face covering



Recap – Some Respiratory Protection Fundamentals

Fit

To work, must be designed to fit



Dräger

Selected with fit testing



3M

Checked each use, fit testing repeated periodically

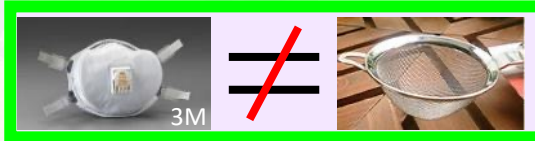
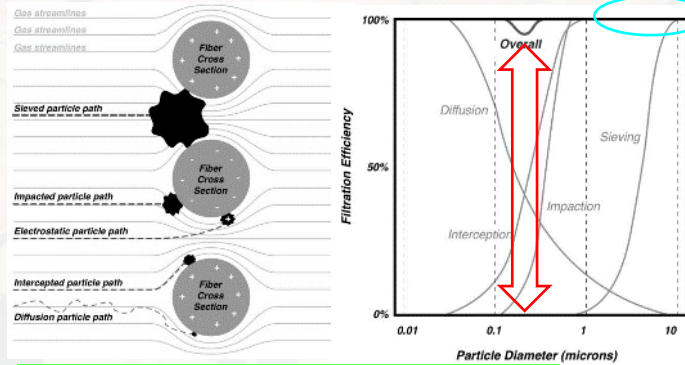


Harvard Medical School



Filtration

Multiple mechanisms,
Laws of physics apply



Multiple types of filter

		Type		
		Negative Pressure	Non-Oil	Oil 1-shift
Efficiency	95	N95	R95	P95
	99	N99	R99	P99
	100	N100	R100	P100
Powered		100N	HE	100P



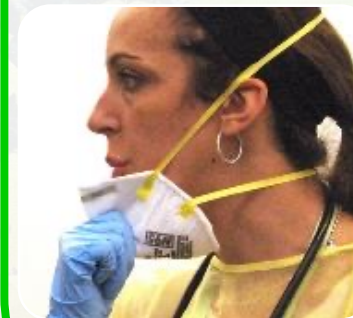
Function

Easy to breathe through,
comfortable to wear?



Today.com

OK for communication and other work functions?



Canadian Occupational Health & Safety Regulation

- **Provincial/Territorial** and **Federal** legislation govern health and safety
 - Regulations may mandate compliance with standards or cite them as a best practice
 - Approval of equipment performance capability by US National Institution for Occupational Safety and Health (NIOSH) is required
- **Standards Council of Canada** (Fed Gov't) certifies Standards Development Organisations (SDOs)
- **Canadian Standards Association (CSA Group)**, is a not-for-profit SDO covering occupational health and safety equipment performance and selection guidance – with standards setting and product testing
- *Note that* **Health Canada** (Fed Gov't) approves medical equipment for use in Canada

Standards Addressing Respiratory Protection

Standard No.	CSA Z94.4	CSA Z94.4.1	CSA Z180.1	CSA/CGSB Z1610	CSA Z1640
Title	Selection, Use and Care of Respirators	Performance of Filtering Respirators	Compressed Breathing Air and Systems	Protection of First Responders from CBRN Events	PPE for Investigating and Dismantling Clandestine Drug Laboratories
Target Community	General workforce	General workforce	General workforce	Emergency responders and medical staff	Law enforcement, firefighters, municipal workers and contractors
Latest Issue Date	2018	2021	2019	2011	2018

Selection/Usage Guidance

Performance Requirements

Pandemic/Respiratory-Related Activities

Start of Pandemic:

- **Respirator shortages** in healthcare; no national filtering facepiece manufacturers
- **Stability of external respirator supplies** to Canada becomes a concern

- **New** Canadian operations want to **manufacture** but need **NIOSH** approval (same as last 50 years)
- **NIOSH** changed **prioritization** to favour US manufacturers

Health Canada creates **Interim Orders**

1. **Permits** healthcare use of respirators with **any type of certification** (March 2020)
2. **Issues a specification to approve certain respirator types** for use in healthcare – product performance requirements, manufacturer quality requirements (August 2020)

- CSA Group tasked to create a **new respirator performance standard** as part of a national certification process – started late 2020, published October 2021

- CSA Group updates its established **standard for selection, use and care of respirators** to accommodate this new standard and Covid-related factors – started late 2022, **in progress**

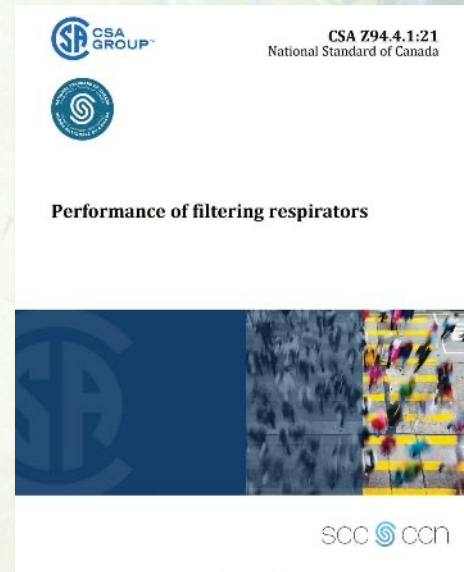
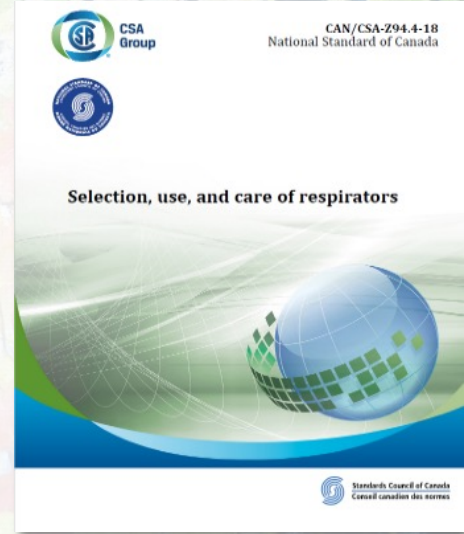
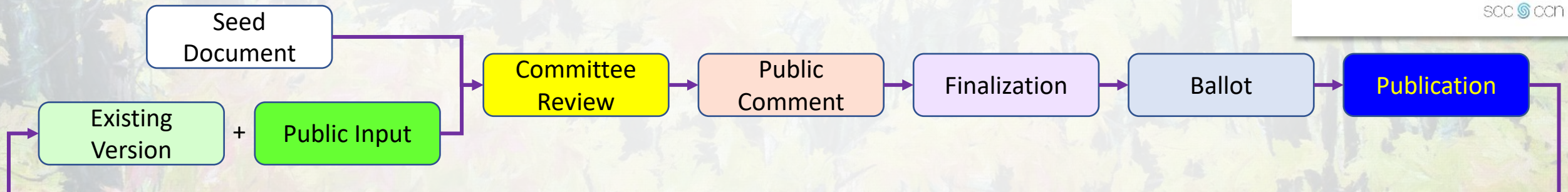


Health
Canada Santé
Canada



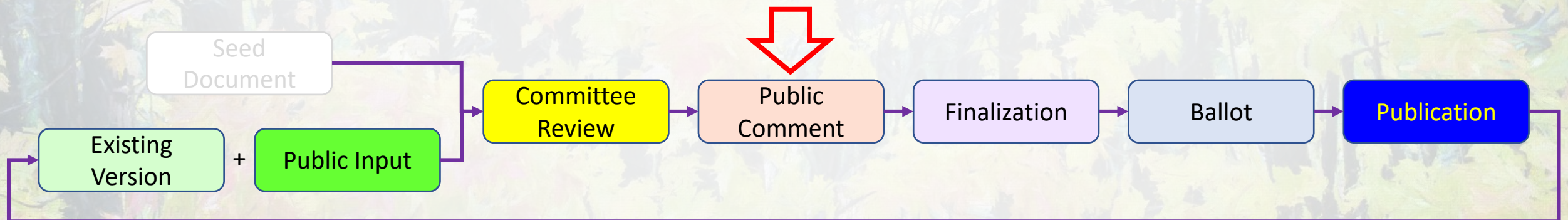
CSA Process

- CSA Group
 - Establishes the need for, develops and markets standards
 - Conducts testing for product certification
- Standards undergo review and periodic updates
- CSA manages standards committees which have a mandatory balanced mix of stakeholders
- Committees meet regularly and may invite experts and other relevant parties to provide input
- Development Stages:



Current Interests

- CSA Z94.4.1 “Performance of Filtering Respirators” developed 2020-2021
 - Supported an urgently needed new Canadian respirator certification system
 - Created by sub-group of CSA Z94.4 committee with added experts
 - CSA established test capability to certify products to the standard
- CSA Z94.4 “Selection, Use and Care of Respirators”
 - First issued 1982, supports workplace use of respirators under legislation, last updated 2018
 - Updating in progress over 2023
 - Multiple working groups, frequent meetings, including invitation of front-line physicians, nurses, hospital support workers, bioaerosol, ventilation and control banding experts
 - **Now at public comment stage**



Canadian standard CSA Z94.4

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

Supports respirator use in workplaces as covered by Federal, Provincial or Territorial Regulation

Covers equipment from disposable facepieces to SCBA

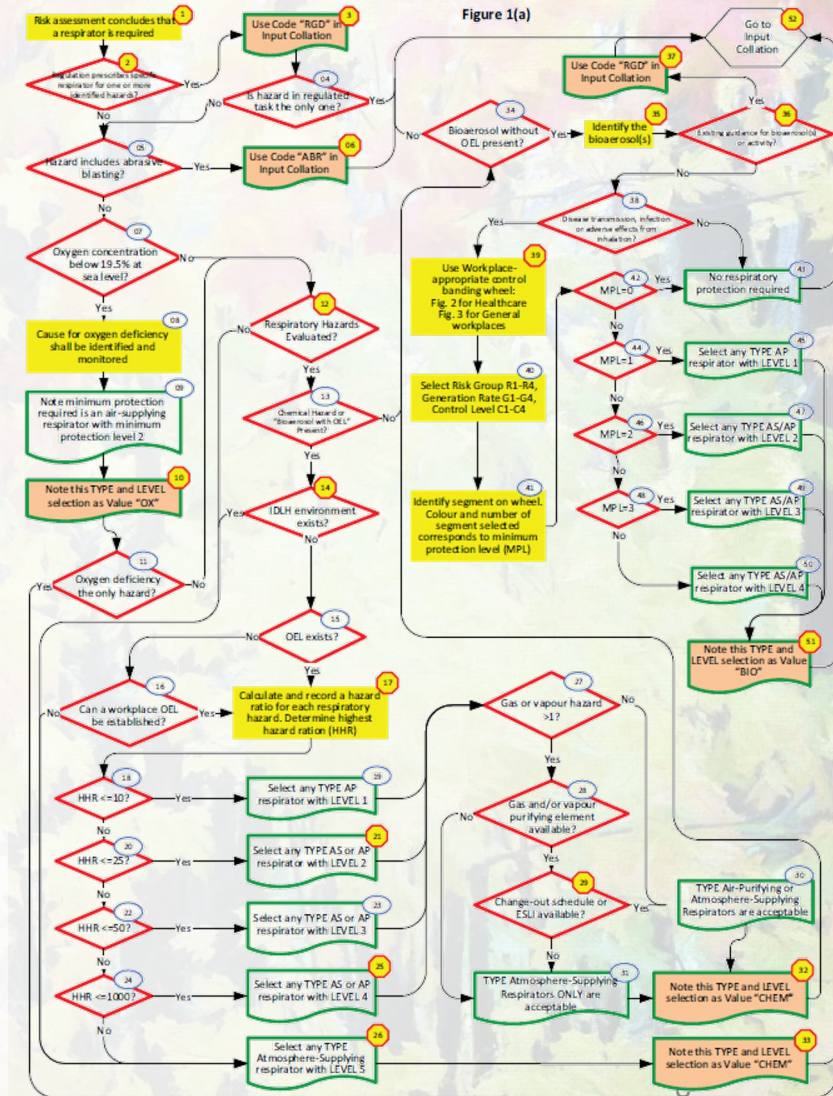
Addresses selection, use and care and is considered a best practice for workplaces to follow

Areas include:

- Respiratory protection programmes
- Medical clearance for prospective wearers
- Hazard and risk assessment
- Selection guidance for appropriate level of protection and type
- Fit testing
- Cleaning, inspection, maintenance and storage of equipment
- Qualifications, training and recordkeeping

CSA Z94.4 was the first standard in the world (2011) to include a systematic guidance protocol for respirator selection for airborne biological hazards

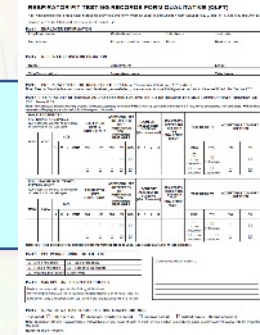
But... the standard has been minimally referenced in guidance from government or medical organisations during the pandemic



CSA Z94.4 Update Work: Key Points – General Needs

Fit Testing

New abbreviated fit test protocol
New form for fit test documentation



Barriers to Accessibility

New section addressing under-served users, special needs and employer strategies for accommodation



Guidance for the Healthcare Community

New section for healthcare user guidance
Highlights relevant parts of the standard
Links to healthcare facility ventilation standard CSA Z317.2
Other considerations for healthcare operations



Proposal

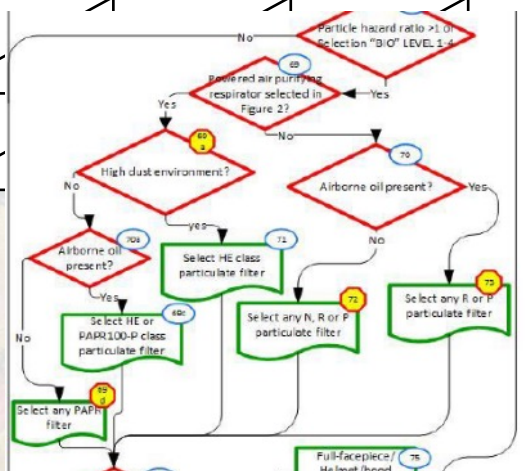
A companion guide to aid healthcare operations in establishing and maintaining respiratory protection programmes and using risk assessment and selection guidance

General Respirator Selection

Incorporates respirator classes CSA Z94.4.1 performance standard, and new NIOSH "PAPR" classes for particle filtering respirators

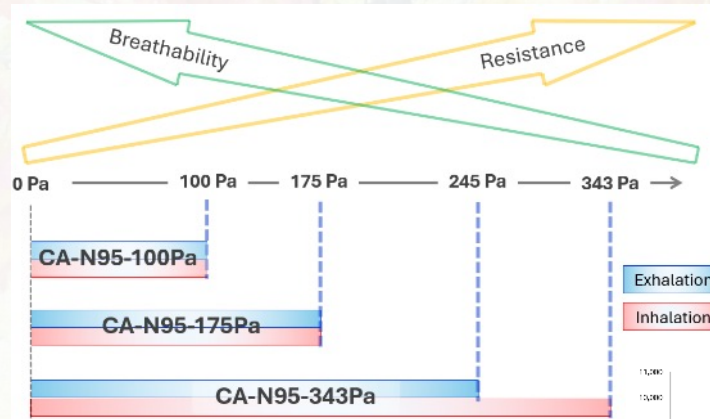
New section on selection considerations beyond protection level

Type		Particle Efficiency (Aerosol at Most Penetrating Particle Size)					
		≥95.00%		≥99.00%		≥99.97%	
		CSA	NIOSH	CSA	NIOSH	CSA	NIOSH
Non-Powered	Non-Oil	CA-N95-100Pa CA-N95-175Pa CA-N95-343Pa	N95	CA-N99	N99	CA-N100	N100
	Non-Oil + "Surgical"	CA-N95F-100Pa CA-N95F-175Pa CA-N95F-343Pa	FDA-cleared + NIOSH tests Surgical N95	CA-N99F		CA-N100F	
	Oil "Resistant"	CA-R95	R95	CA-R99	R99	CA-R100	R100
	"Oil-Proof"	CA-P95	P95	CA-P99	P99	CA-P100	P100
Powered	PAPR Non-Oil			CA-PAPR100-N	PAPR100-N		
	PAPR Oil-Proof			HE CA-PAPR100-P	HE PAPR100-P		



NIOSH [2020]. Filtering facepiece respirators with an exhalation valve: measurements of filtration efficiency to evaluate their potential for source control. Portnoff L, Schall J, et. al. DHHS (NIOSH) Publication No. 2021-107. DOI: <https://doi.org/10.26616/NIOSHPUB2021107external icon>

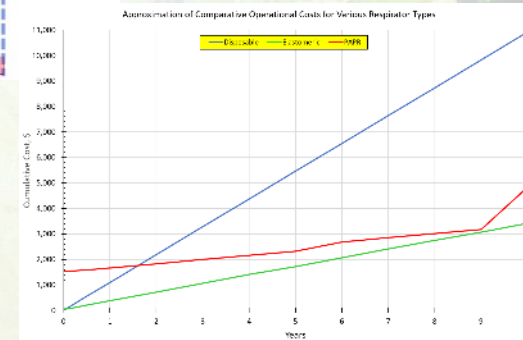
Breathability



Comfort, Fluid Resistance



Single-use or re-usable respirators



Exhalation Valves

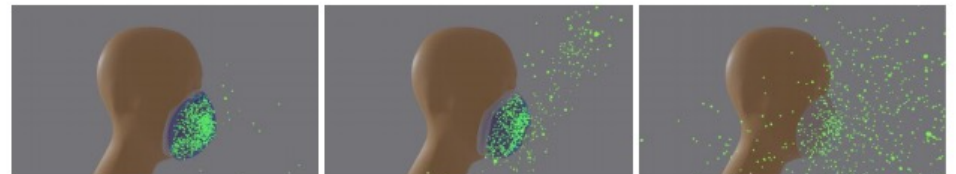


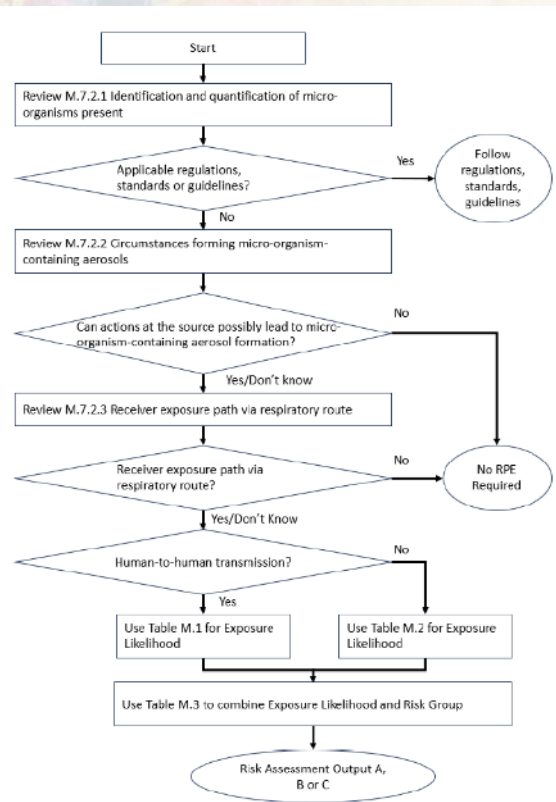
Figure 1. Simulations of particle exhalation through an FFR without an exhalation valve (left), an FFR with an exhalation valve (center), and a barrier face covering (right). Density of particles near the face represents particles remaining inside the mask. Illustrations by NIOSH

Risk Assessment for Biological Aerosols

Proposed change from descriptive text to a systematic control banding method using “Source-Pathway-Receiver” model with 3-level graded output

Changes recognising latest research and new factors such as

- Comparative impact of “Aerosol Generating Procedures” versus speaking, coughing on aerosol generation
- Respirator user susceptibility



Source → Pathway → Receiver

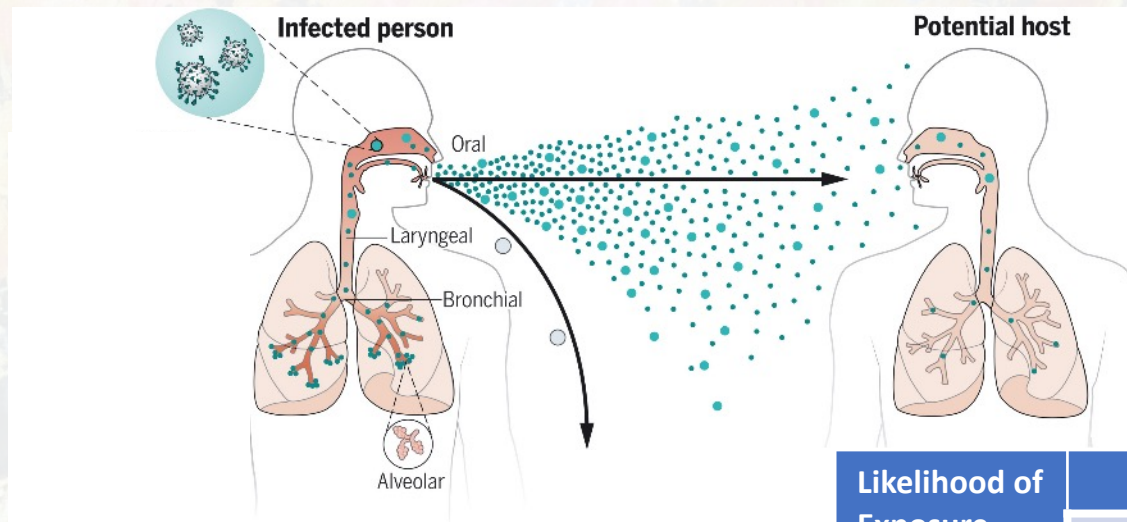


Image Source: <https://www.science.org/doi/10.1126/science.abd9149>

Airborne transmission of respiratory viruses, Science, August 27, 2021, Vol. 373, No. 6558. Image reproduced with permission.

Table M.2 – Contributors and scaling of likelihood of exposure: Botanical and Physical Sources

No.	Contribution to Likelihood of Exposure	See Clause	Low	Medium	High
Source Factors					
1	Number and types of sources in workspace – include additional waste disposal	M.4.3b	Single source of aerosols	Several sources of aerosols	Multiple sources
2	Frequency of operation of generating activities	M.4.3d	Infrequent operation when workers present	Occasional operation when workers present	Continuous or frequent operation when workers present
3	Generation rate of potentially infectious bioaerosol(s) of work or process activities	M.4.3a	Generation rates G1, G2	Generation rate G3	Generation rate G4
	Abnormal generation	M.4.3e	No abnormal conditions	Occasional activities with	Frequent activities with

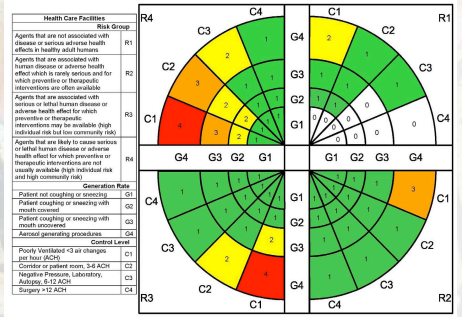
Likelihood of Exposure Rank	Micro-organism Risk Group					
	R1	R2L	R2H	R3L	R3H	R4
L1	A	A	A	B	B	B
L2	A	B	B	B	C	C
L3	B	B	C	C	C	C

Respirator Selection for Biological Aerosols

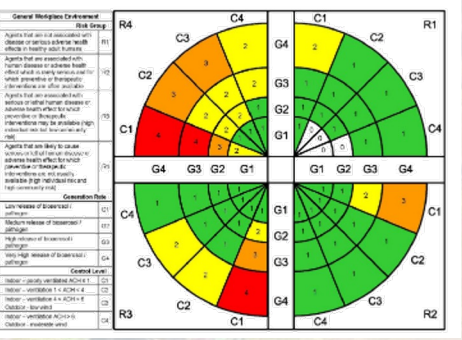
- ### Changes to Selection Inputs
- Enhanced micro-organism risk group scale
 - New generation input rationale
 - Single but expanded control level scale

- ### Changes to Selection Outputs
- Revision of algorithm determining protection levels
 - Range of protection levels for typical healthcare needs simplified

Healthcare



General Workplace



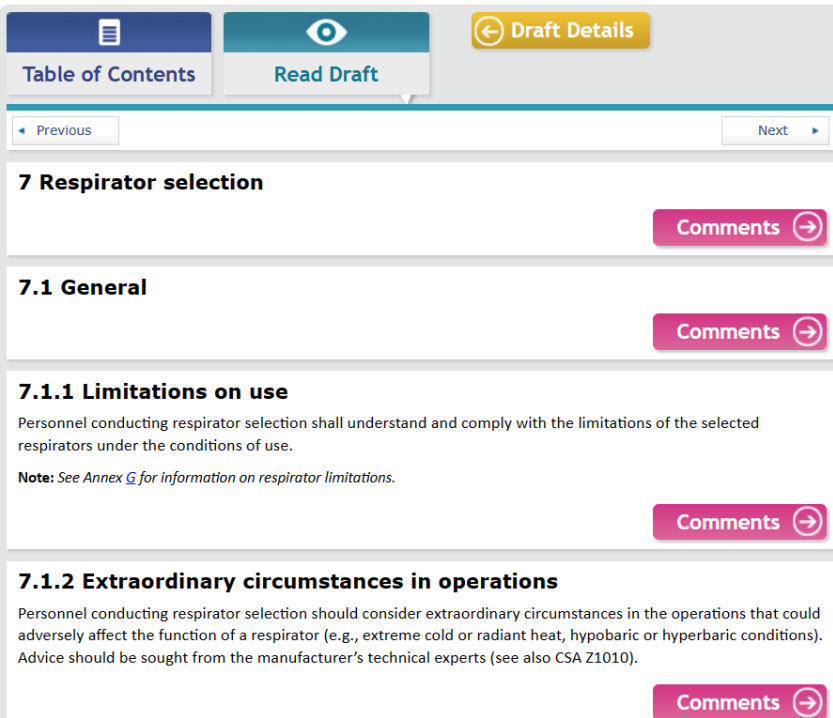
R	Starting Biosafety Risk Group	Base Description	Qualifying factors*			
R1	RG1	Not associated with disease or serious adverse health effects in healthy adult humans	Use only if high probability of no adverse effects on exposed workers			
R2L	G	Healthcare Workplace	Public Workplace	General Workplace		
		Patients, co-workers, non-patients wearing effective source controls	Low density of public or co-workers present, generally using source controls	Operations in enclosed systems with precautions to minimize leakage		
R2H	G1	Patients, co-workers, non-patients wearing effective source controls	C	ACH Range	Healthcare Workplace Example	General/Public Workplace
			C1	>12 ACH	Surgical suite, local extraction hood	Extraction hoods
			C2	6-12 ACH	Negative pressure room, laboratory, autopsy	Outdoor moderate wind or higher
			C3	4-6 ACH	Patient Room	Indoor with good ventilation, windows open
R3L	G2	Aerosol generation procedure	C1	>12 ACH	Surgical suite, local extraction hood	Outdoor moderate wind or higher
			C2	6-12 ACH	Negative pressure room, laboratory, autopsy	Indoor with good ventilation, windows open
R3H	G3	Patients, co-workers, non-patients wearing effective source controls	C2	6-12 ACH	Negative pressure room, laboratory, autopsy	Outdoor light wind
			C3	4-6 ACH	Patient Room	Indoor workplace, typical factory or office space
R3H	G4	Generation containing sawing in s toilet flush	C3	4-6 ACH	Patient Room	Outdoor still air
			C4	1-3 ACH	Corridor	Indoor storage room
R4	RG4	Causes disease	C5	≤1 ACH	Not applicable	Unventilated building

Risk and control band	Description	Generation band			
		G1	G2	G3	G4
R1	Not known to cause infection: may cause adverse effects				
C1	Very High Ventilation (>12 ACH)	0	0	0	0
C2	High Ventilation 6-12 ACH	0	0	0	1
C3	Medium Ventilation 4-6 ACH	0	1	1	1
C4	Low Ventilation 1-3 ACH, Close Contact	0	1	1	1
C5	Unventilated <=1 ACH	0	1	1	2
R2L	Rarely serious, prevention/therapy available				
C1	Very High Ventilation (>12 ACH)	0	1	1	1
C2	High Ventilation 6-12 ACH	0	1	1	1
C3	Medium Ventilation 4-6 ACH	0	1	1	1
C4	Low Ventilation 1-3 ACH, Close Contact	1	1	1	1
C5	Unventilated <=1 ACH	1	1	2	3
R2H	Rarely serious, prevention/therapy available, extended precautions				
C1	Very High Ventilation (>12 ACH)	1	1	1	1
C2	High Ventilation 6-12 ACH	1	1	1	1
C3	Medium Ventilation 4-6 ACH	1	1	1	1
C4	Low Ventilation 1-3 ACH, Close Contact	1	1	1	1
C5	Unventilated <=1 ACH	1	1	2	3
R3L	Serious/Lethal, prevention/therapy possible				
C1	Very High Ventilation (>12 ACH)	1	1	1	1
C2	High Ventilation 6-12 ACH	1	1	1	1
C3	Medium Ventilation 4-6 ACH	1	1	1	1
C4	Low Ventilation 1-3 ACH, Close Contact	1	1	1	2
C5	Unventilated <=1 ACH	1	2	3	4
R3H	Serious/Lethal, prevention/therapy possible, extended precautions				
C1	Very High Ventilation (>12 ACH)	1	1	1	1
C2	High Ventilation 6-12 ACH	1	1	1	2
C3	Medium Ventilation 4-6 ACH	1	1	1	2
C4	Low Ventilation 1-3 ACH, Close Contact	1	1	2	2
C5	Unventilated <=1 ACH	1	2	3	4
R4	Serious/Lethal, prevention/therapy not readily available				
C1	Very High Ventilation (>12 ACH)	1	1	1	1
C2	High Ventilation 6-12 ACH	1	1	1	2
C3	Medium Ventilation 4-6 ACH	1	2	2	3
C4	Low Ventilation 1-3 ACH, Close Contact	1	2	3	4
C5	Unventilated <=1 ACH	2	3	4	4

Frequent fatalities reported in nitherto healthy individuals

Document Finalization

- Public Review continues to **18th March 2023**



- Co
in
- Ci
m
- Pu
En
- W
co
when draft is finalized
- CSA accepts comments throughout the life of the standard

Public Comment website:

<https://publicreview.csa.ca/Home/Details/5176>

After you register, the website provides facilities to provide comments on each section

If needed for comparison, the current version (CSA Z94.4-18) can be viewed at:

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



Thank you and Questions

Simon Smith is a volunteer committee member with CSA
and does not represent the organisation officially

Any unattributed photos taken by the author

New Standard CSA Z94.4.1 “Performance of Filtering Respirators

- Respirator classes comparable with NIOSH types, with “CA-” appended
- Performance requirements aligned with NIOSH requirements **with some additions**
- **Deletions** for areas covered by the CSA certification process



NIOSH Requirements for Particle Filtering Respirator performance as in applicable clauses in 42 CFR 84

IMPORTANT:
Certification to the CSA performance standard is not a grant of NIOSH approval nor a substitute for it outside of Canada

Classifications

Airflow resistance classes for CA-N95

Fluid resistant “Surgical” respirators

Requirements

Quantitative Fit Test

Shelf Life

Cleaning Statement

Securing Mechanisms

Vision

Biocompatibility

Mfr Assessment of Reliability

Non-preconditioned efficiency tests

Measurements versus general statements

Applying uncertainty of measurement

Non-Performance Requirements in 42 CFR 84

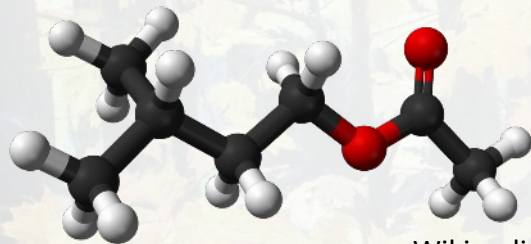
- Application process
- Administration
- Manufacturer quality control & documentation

These are addressed by other components of the Canadian Certification System

Fit testing

NIOSH

- Qualitative isoamyl acetate (“banana oil”) test for respirator approval, except for filtering facepieces
- NIOSH has conducted extensive research and contributed to a new ASTM Standard (F3407-20) for a quantitative fit method for half-facepieces, but this is not yet part of the approvals protocol



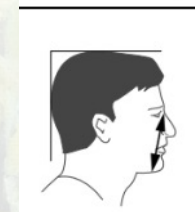
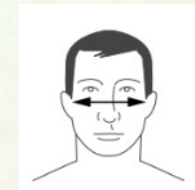
Wikipedia

Isoamyl acetate – from NIOSH qualitative fit test

CSA Z94.4.1

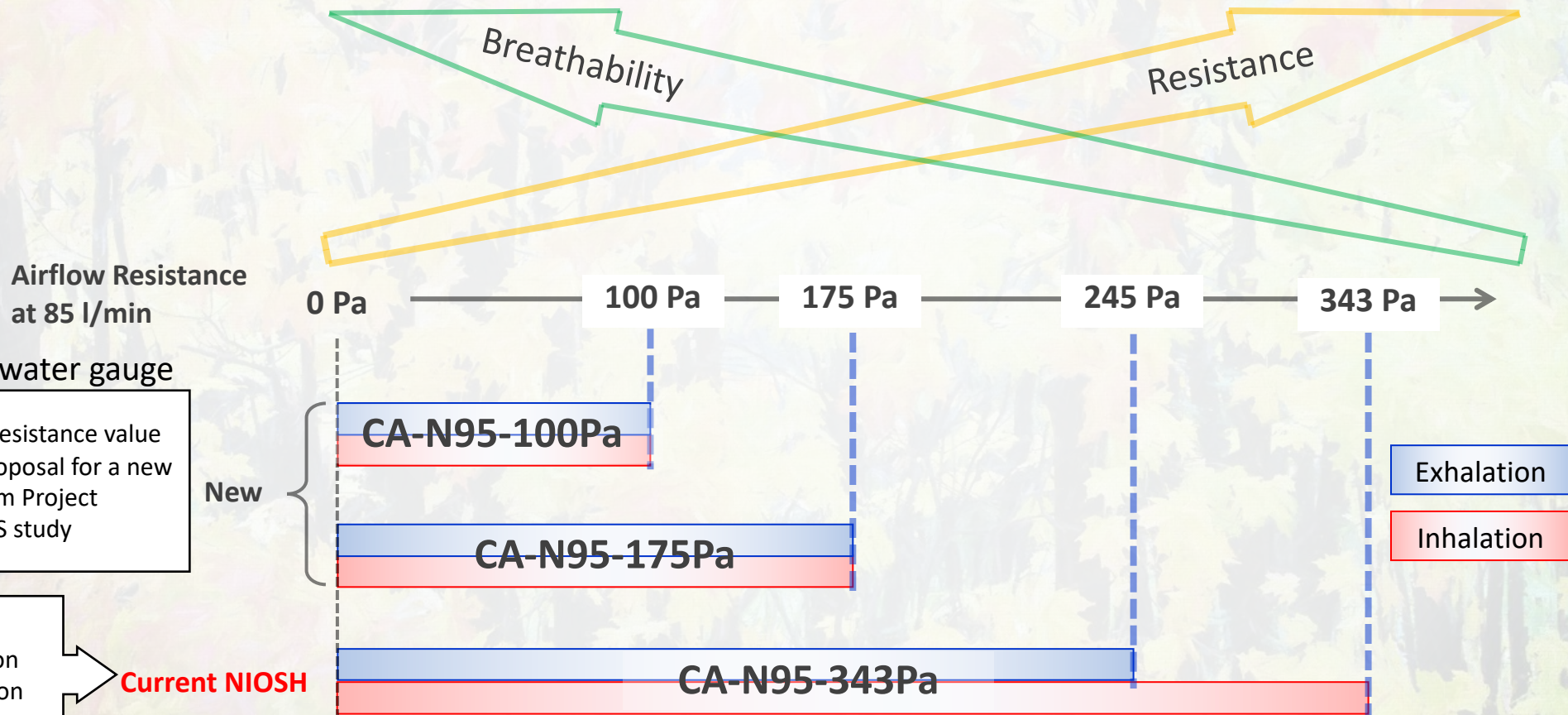
- New protocol for tight-fitting respirators based on the quantitative fit testing method in the CSA Selection, Use and Care standard CSA Z94.4-18 Annex C
- Bivariate panel, Minimum 25 test subjects with 2 to 5 per cell across size range and minimum 30% of one sex
- Standard breathing, movement and speaking exercises in a chamber with controlled particle concentration

Face Length (mm)	Face Width (mm)		
	120.5	134.5	146.5
138.5		9	10
128.5	6	7	8
118.5	3	4	5
108.5	1	2	
98.5			



Comfort and Breathability

- Ergonomic and comfort assessment introduced along with fit test measurement
- Breathability identification added to CA-N95/CA-N95F respirators in three classification levels, based on maximum observed resistance value of the set of respirators submitted



Airflow Resistance at 85 l/min

0 Pa — 100 Pa — 175 Pa — 245 Pa — 343 Pa →

1 Pa = 0.102 mm water gauge

Note that the 100 Pa resistance value corresponds with a proposal for a new respirator concept from Project "BREATHE", a major US study

New

Exhalation
Inhalation

NIOSH sets
35 mm water inhalation
25 mm water exhalation
at 85 l/min

Current NIOSH

CA-N95-343Pa

“Surgical” respirators

NIOSH+FDA

- “Surgical” designation is added only to N95-type respirators
- FDA sets requirements according to ASTM standard methods originally established for surgical masks:
 - **Biocompatibility to ISO 10993**
 - **Biological filtration**
 - **Flammability resistance to U.S. Standard 16 CFR 1610.7**
 - **Fluid resistance to ASTM F1862**
- ASTM F1862 fluid resistance test has three levels (derived from human blood pressure ranges) – test involves squirting simulated blood at the respirator and visual examination of penetration
- For surgical respirators, it is not specified which level must be met (though recently to show pressure)

CSA Z94.4.1

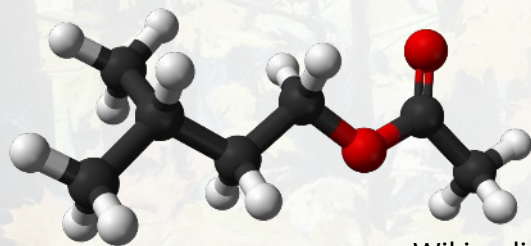
- “Surgical” designation can be added to All N-type respirators (with “F” appended to classification)
- **Biocompatibility to ISO 10993 is required for ALL respirators covered by the standard, not just “surgical”**
- **No biological filtration efficiency requirement, as the N-type efficiency test is worst case**
- **Same flammability resistance requirement**
- **Fluid resistance testing to ASTM F1862 Level 3**
 - CSA Z94.4.1 includes the highest (worst case) of the ASTM levels only
 - Rationale is to keep selection decisions as simple as possible

Note: Health Canada included biocompatibility, fluid and flammability resistance for “surgical” categories of respirator in its 2020 specification

Fit testing and Comfort

NIOSH

- Qualitative isoamyl acetate (“banana oil”) test for respirator approval, except for filtering facepieces
- NIOSH has conducted extensive research and contributed to a new ASTM Standard (F3407-20) for a quantitative fit method for half-facepieces, but this is not yet part of the approvals protocol
- No comfort assessment requirement in 42 CFR 84



Wikipedia

Isoamyl acetate – from NIOSH qualitative fit test

CSA Z94.4.1

- New protocol for tight-fitting respirators based on the quantitative fit testing method in the CSA Selection, Use and Care standard CSA Z94.4-18 Annex C
- Bivariate panel, Minimum 25 test subjects with 2 to 5 per cell across size range and minimum 30% of one sex
- Standard breathing, movement and speaking exercises in a chamber with controlled particle concentration
- Assessment of comfort by test subjects is adopted from CSA Z94.4-18; excessive discomfort rating results in failure

Face Length (mm)	Face Width (mm)		
	120.5	134.5	146.5
138.5	6	9	10
128.5		7	8
118.5	3	4	5
108.5	1	2	
98.5			



Shelf Life

- Shelf life is the the time a respirator or respirator component can be stored without performance deterioration below the applicable requirements of the standard prior to use – when stored in accordance with information supplied by the manufacturer
- **NIOSH has no shelf life requirement** for non-CBRN respirators in its standard, though many manufacturers set one
- **CSA Z94.4.1 introduces a shelf life requirement for:**
 - Filters
 - Integrated respirators – types where the filter is permanently attached or incorporated into the respirator – which includes filtering facepieces
- **The proposed standard specifies:**
 - That manufacturers validate the provided shelf life in some way, and provide documentation of the validation method
 - Marking requirements for shelf life
 - Information from the manufacturer addressing shelf life
- **The proposed standard does NOT specify:**
 - Requirements for a shelf life duration
 - Methods for validating shelf life
 - Evaluation of the validation methods submitted
 - Methods for shelf life extension
- **Manufacturers may optionally set a shelf life for other components**
- Shelf life may be expressed as either:
 - A manufacture date plus a pre-use storage duration
 - An expiration date (to nearest month)



Cleaning

- The pandemic brought into effect the need for re-use of respirators designed as single-use
- Various methods were developed with chemical, heat/steam or radiation-based processes for decontamination
- There was extensive discussion on cleaning and re-use during document development, but it was concluded that a respirator performance standard could not require manufacturers to anticipate every method that might be developed, nor to set re-use criteria for products not designed for re-use

The cleaning requirements are:

- The manufacturer shall identify at least one cleaning method for re-usable respirators and, where applicable, components.
- The manufacturer may additionally identify at least one sanitization or disinfection method.
- If there are commonly available cleaning, sanitization, or disinfection methods that are known to have an adverse effect on the respirator performance or integrity, immediately or with repeated use, these shall be identified.
- **Note:** *For respirators designed and/or intended for use in a healthcare environment, other requirements for sanitization or disinfection might apply and should be observed by the manufacturer*

Securing mechanisms for respiratory interface

NIOSH

- “...All facepieces must be equipped with head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face”.
- Facepiece head harnesses, except those employed on filtering facepiece respirators must be adjustable and replaceable.

CSA Z94.4.1

- Respirator mounted on a headform or equivalent fixture, each strap of the harness, buckles, and other adjusting means shall withstand the following forces per attachment point in the direction of pulling when the respirator is donned for 10 seconds:
- **Single-Use Respirators: 10 N**, following EN 140
- **Re-usable half-facepiece respirators: 50 N**, following EN 140
- **Re-usable full-facepiece respirators: 100 N** following EN 136
- No breaks or sliding of the straps, buckles or attachment lugs
- During and after force is applied, test fails on breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation (such as loss of elasticity) remaining after 4 h or other obvious loss of function

Note: the Health Canada specification applied the single-use requirement to all types

Vision (Actually no change in Canada)

NIOSH

- “Respiratory inlet coverings must be designed and constructed to provide adequate vision which is not distorted by the eyepieces”

CSA Z94.4.1

- Incorporates relevant parts of CSA Z94.3 “Eye and face protectors” for vision characteristics – adherence to which is already a requirement in Canada
- Requires quantitative assessment of visual distortion

Biocompatibility

NIOSH

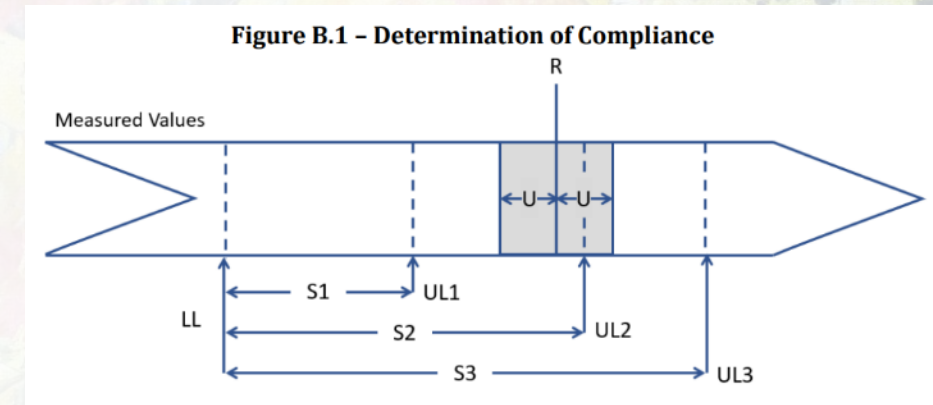
- “Respirator components which come into contact with the wearer’s skin shall be made of non-irritating materials”

CSA Z94.4.1

- Applies requirements in ISO 10993 “Biological evaluation of medical devices” to all respirators

Other points

- Failure Mode Effects Analysis is required as part of product development
- Application of process for uncertainty of measurement – where measurement precision overlaps with the pass/fail margin
- Use of non-preconditioned samples for N-type filter efficiency measurement (arises from National Research Council studies)
- Hydration device flow rate (based on ISO requirements)
- Airflow resistance range calculation to determine use of pro-rated test flow rates in respirators with multiple filters (based on ISO/EN requirements)
- Flow checking device to be provided for PAPRs (not in NIOSH but a universal industry practice)



Comparison with NIOSH Respirator Classes

Additional classes with low airflow resistance and fluid resistant categories

Type		Particle Efficiency (Aerosol at Most Penetrating Particle Size)					
		≥95.00%		≥99.00%		≥99.97%	
		CSA	NIOSH	CSA	NIOSH	CSA	NIOSH
Non-Powered	Non-Oil	CA-N95-100Pa CA-N95-175Pa CA-N95-343Pa	N95	CA-N99	N99	CA-N100	N100
	Non-Oil +"Surgical"	CA-N95F-100Pa CA-N95F-175Pa CA-N95F-343Pa	FDA-cleared + NIOSH tests Surgical N95	CA-N99F		CA-N100F	
	Oil "Resistant"	CA-R95	R95	CA-R99	R99	CA-R100	R100
	"Oil-Proof"	CA-P95	P95	CA-P99	P99	CA-P100	P100
Powered	PAPR Non-Oil					CA-PAPR100-N	PAPR100-N
	PAPR Oil-Proof					HE CA-PAPR100-P	HE CA-PAPR100-P

The Future?

Content of the Standard

CSA Standards are created, regularly reviewed and updated by an expert committee of stakeholders – closer to European or Australian approaches than NIOSH – so the standard could change over time

- Proposals for discussion for the next update, work possibly starting 2025
 - Add Scope 2 – gas and vapour filtering respirators (with Scope 3 CBRN and atmosphere-supplying respirators in future updates)
 - Additional particle filter efficiency and breathability classes
 - Respirator re-use and recycling
 - Bioburden (cleanliness) test requirement for “F”-type “surgical” respirators
 - Communication
 - Practical performance tests to demonstrate respirator capability for particular occupations
- Test methods
 - Review particle tests
 - Dedicated test methods in place of cited NIOSH “Standard Test Protocols”

Alignment

- Update CSA Z94.4 “Selection, Use and Care of Respirators” to reference Z94.4.1 and align terminology

Certification Practicalities

- CSA has set up a test capability for non-powered particle filtering respirators
- But for powered air and future gas/vapour requirements, testing by third-party laboratories will be required – again a more European approach than NIOSH

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>
 - NIOSH-approved respirators can be searched on the Certified Equipment List:
<https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html>
 - Searchable list of CSA Approved products (for respirators approved to the new standard, use class number “7204-03”):
<https://www.csagroup.org/testing-certification/product-listing/> (note no products listed at time presentation)
 - 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>

Aspect	Detail	NIOSH	CSA
All Types Performance	General and construction requirements	Requirements	Requirements
	Wearer compatibility and safety	General	Specific
	Compliance with other standards		Specific
	Respiratory Interfaces	General	General
	Integrated eye protection	General	Specific
	Fit, Fit factor requirements, Fit testing	Qualitative	Quantitative
	Valves – inhalation and exhalation	Specific	Specific
	Special Marking	General	Specific
		Specific	Specific
		General	General
No re	General – Statement about the feature with no measured criteria	Specific	Specific
	Specific – sets a performance requirement measuring physical characteristics	Specific	Specific
Po purifying respirators	Qualitative – test based on a subjective sensation by wearer		Specific
	Quantitative – test based on measurement	Specific	Specific
	Particle filtration efficiency, loading	Specific	Specific
	Noise and Communication	Specific	Specific
	Warning devices	Specific	Specific
	Flow checking device		Requirements
All Types Additional	Shelf life		Requirements
	Cleaning of re-usable respirators		Requirements
	Assessment of reliability		Requirements
	Marking and Information supplied by the manufacturer	Requirements	Requirements

Requirements – criteria defined for aspects which must be present which are general or with details set by the manufacturer

General – Statement about the feature with no measured criteria

Specific – sets a performance requirement measuring physical characteristics

Qualitative – test based on a subjective sensation by wearer

Quantitative – test based on measurement

Aspect	Detail	NIOSH	CSA			
	General and construction requirements	Requirements	Requirements			
All Types Performance	<div style="border: 1px solid black; padding: 10px;"> <h3 style="text-align: center; color: blue;">Key Aspects for a Filtering Facepiece</h3> <div style="text-align: right; color: yellow; font-weight: bold;">NIOSH "Specifics" Highlighted</div> <p>The diagram illustrates three types of respirators with specific callouts: <ul style="list-style-type: none"> Filtration Efficiency: Callout to the top of a white respirator. Airflow Resistance: Callout to a blue respirator. Markings: Callout to the back of a white respirator. Fluid & Flammability Resistance for "Surgical" Types: Callout to the bottom of a blue respirator. Strap Strength: Callout to the strap of a blue respirator. Fit: Callout to the top of a black respirator. Biocompatibility: Callout to the top of a white respirator. Valve Performance: Callout to the valve of a white respirator. </p> </div>			Specific	Specific	
				Specific	General	Specific
				Specific	Specific	Quantitative
				Specific	Specific	Specific
				Specific	Specific	Specific
				General	Specific	Specific
				Specific	Specific	Specific
				Specific	Specific	Specific
				Specific	Specific	Specific
				Specific	Specific	Specific
Non-powered respirators						
Powered air-purifying respirators						
	Warning devices	Specific	Specific			
	Flow checking device		Requirements			
All Types Additional	Shelf life		Requirements			
	Cleaning of re-usable respirators		Requirements			
	Assessment of reliability		Requirements			
	Marking and Information supplied by the manufacturer	Requirements	Requirements			

<https://sellercentral.amazon.com/>

Risk and Generation Band Changes

Risk Level R	Starting Biosafety Risk Group	Base Description	Qualifying factors*
R1	RG1	Not associated with disease or serious adverse health effects in healthy adult humans	Use only if high probability of no adverse effects on exposed workers
R2L	RG2	Associated with rarely serious occurrence of human disease or adverse health effects	Preventive/therapeutic intervention available, applied and effective Low community spread
R2H	RG2	Associated with rarely serious occurrence of human disease or adverse health effects	Preventive/therapeutic intervention inadequate or unavailable Identified receiver sensitization Medium/high community spread Serious health effects noted in some cases in worker population
R3L	RG3	Associated with serious or lethal human disease or adverse health effects	Preventive/therapeutic intervention available, applied and effective Low community spread No fatalities in hitherto healthy individuals
R3H	RG3	Associated with serious or lethal human disease or adverse health effects	Preventive/therapeutic intervention inadequate or unavailable Medium/high community spread Fatalities reported in hitherto healthy individuals
R4	RG4	Causes serious or lethal human disease or adverse health effects	Preventive/therapeutic intervention inadequate or unavailable High probability of infection Frequent fatalities reported in hitherto healthy individuals

G	General Description	Contributors
G1	Minimal aerosolization	Not close contact, local ventilation, low source density (i.e. small size or number of sources in volume)
G2	Low aerosolization	Close contact, general ventilation only, low source density
G3	Moderate aerosolization	Close contact, general ventilation only, high source density
G4	High/Very High aerosolization	Close contact, general ventilation only, high source density

Examples provided for workplaces

G	General Description	Healthcare Example	Public Workplace Example	General Workplace Example
G2L	Low aerosolization	Single patient inactive with mouth covered Non-patients not wearing effective source controls Patient close to extraction ventilation Far-field exposure	Low density of public /co-workers present generally using source controls	Open operations with minimal generation or disturbance and effective source extraction (e.g. a HEPA vacuum cleaner)

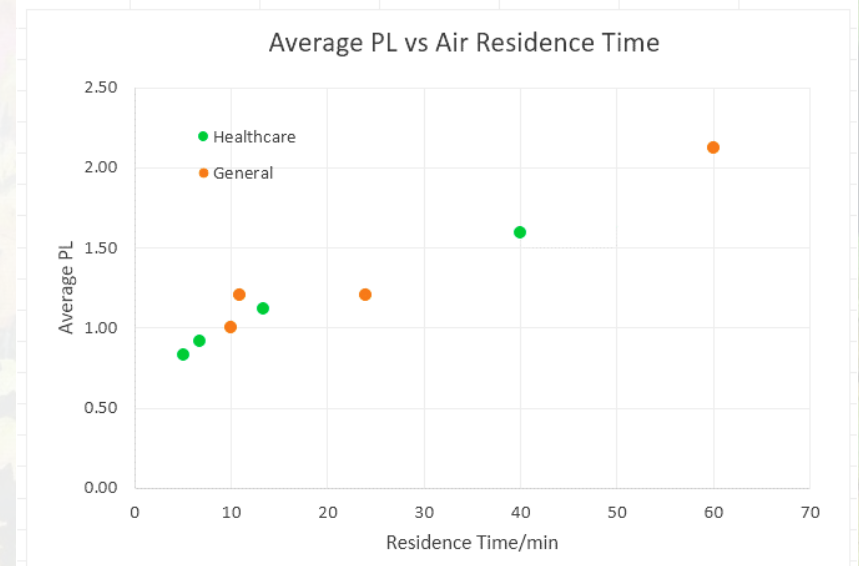
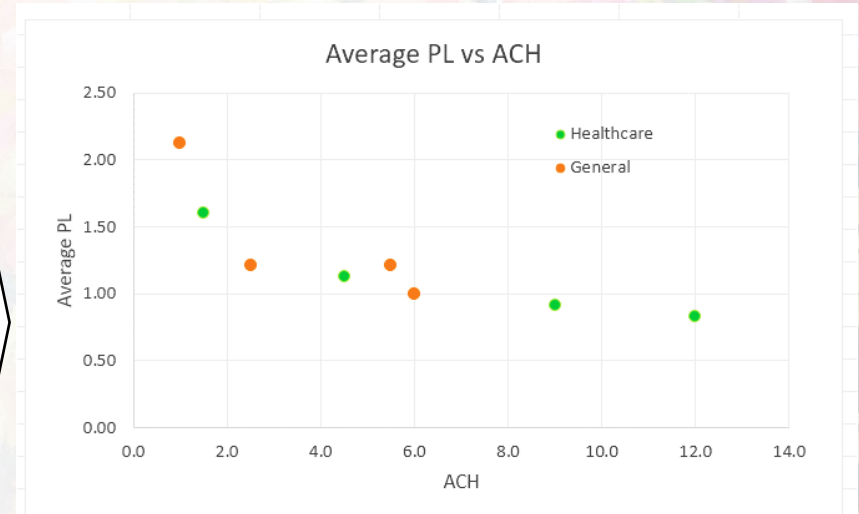
*Any one of the qualifying factors listed should trigger "H" level assignment

Analysis of Existing Guidance

Interpretation current Healthcare wheel into Excel spreadsheet

R/C	Agent Type		CSA Z94.4-18			
R1	Not known to cause infection: may cause adverse effects	1	G1	G2	G3	G4
C1	Poorly Ventilated (<3 ACH)	3	0	1	1	2
C2	Corridor/Patient room (3-6 ACH)	6	0	1	1	1
C3	Negative Pressure/Laboratory/Autopsy (>6-12 ACH)	12	0	0	0	1
C4	Surgery (>12 ACH)	25	0	0	0	0
R2	Rarely serious, prevention/therapy available	2				
C1	Poorly Ventilated (<3 ACH)	3	1	1	1	3
C2	Corridor/Patient room (3-6 ACH)	6	1	1	1	1
C3	Negative Pressure/Laboratory/Autopsy (>6-12 ACH)	12	1	1	1	1
C4	Surgery (>12 ACH)	25	1	1	1	1
R3	Serious/Lethal, prevention/therapy possible	3				
C1	Poorly Ventilated (<3 ACH)	3	1	1	2	4
C2	Corridor/Patient room (3-6 ACH)	6	1	1	1	2
C3	Negative Pressure/Laboratory/Autopsy (>6-12 ACH)	12	1	1	1	1
C4	Surgery (>12 ACH)	25	1	1	1	1
R4	Serious/Lethal, prevention/therapy not readily available	4				
C1	Poorly Ventilated (<3 ACH)	3	1	2	3	4
C2	Corridor/Patient room (3-6 ACH)	6	1	2	2	3
C3	Negative Pressure/Laboratory/Autopsy (>6-12 ACH)	12	1	1	1	2
C4	Surgery (>12 ACH)	25	1	1	1	1

- Assign “average” flow to ventilation band (some arbitrariness)
- Average all protection levels outputs for the matrix of R/G combinations
- Upper plot – average protection level vs flow based on average ACH
- Lower plot – average protection level vs reciprocal of flow expressed as air “residence” time



Reorganise by ventilation band, and add proposed R and G levels

C/R	Agent Type		CSA Z94.4-18							
C1	Poorly Ventilated (<3 ACH)	1	G1		G2		G3		G4	
			L	H	L	H	L	H	L	H
R1	Not known to cause infection: may cause adverse effects	R1	0	0	1	1	1	1	2	2
R2	Rarely serious, prevention/therapy available	R2L	1	1	1	1	1	1	3	3
R2	Rarely serious, prevention/therapy available, Extra Prec.	R2H	1	1	1	1	1	1	3	3
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	1	2	2	4	4
R3	Serious/Lethal, prevention/therapy possible Extra Prec.	R3H	1	1	1	1	2	2	4	4
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	1	2	2	3	3	4	4
C2	Corridor/Patient room (3-6 ACH)	2								
R1	Not known to cause infection: may cause adverse effects	R1	0	0	1	1	1	1	1	1
R2	Rarely serious, prevention/therapy available	R2L	0	0	1	1	1	1	1	1
R2	Rarely serious, prevention/therapy available, Extra Prec.	R2H	0	0	1	1	1	1	1	1
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	1	1	1	2	2
R3	Serious/Lethal, prevention/therapy possible Extra Prec.	R3H	1	1	1	1	1	1	2	2
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	1	2	2	2	2	3	3

Observe that ranges in the two “wheels” appear on a common line, overlapping

Proposal for revised algorithm

- No separation of workplace type in tables, but applicable ventilation ranges provided in text
- Modify to PL allocations make an even pattern
 - Note this is a change from calculation method used earlier
- Use five ventilation bands to cover both former ranges
 - Can cover other workplace types as guidance needs only to interpret applicable C range
- Modified outputs in some cases to simplify selection in common healthcare scenarios
- New “average” line consistent with current inputs/outputs

C1	Unventilated Indoor Space	<=1 ACH	G1 G2 G3 G4							
			L	H	L	H	L	H	L	H
R1	Not known to cause infection: may cause adverse effects	R1	0	0	1	1	1	1	2	2
R2	Rarely serious, prevention/therapy available	R2L	1	1	1	1	1	2	2	3
R2	Rarely serious, prevention/therapy available, Extra Precautions	R2H	1	1	1	1	2	2	3	3
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	2	2	3	3	4
R3	Serious/Lethal, prevention/therapy possible Extra Precautions	R3H	1	1	2	2	3	3	4	4
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	2	2	3	3	4	4	4

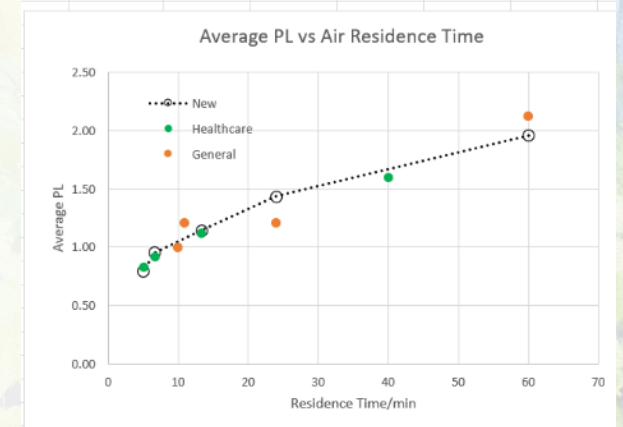
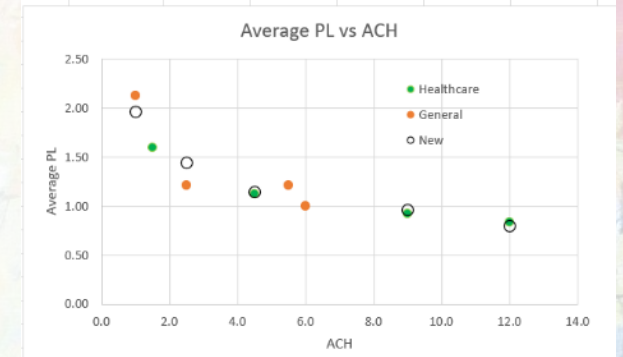
C2	Low	1-3 ACH	G1 G2 G3 G4							
			L	H	L	H	L	H	L	H
R1	Not known to cause infection: may cause adverse effects	R1	0	0	1	1	1	1	1	2
R2	Rarely serious, prevention/therapy available	R2L	1	1	1	1	1	1	1	2
R2	Rarely serious, prevention/therapy available, Extra Precautions	R2H	1	1	1	1	1	1	2	2
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	1	1	2	2	2
R3	Serious/Lethal, prevention/therapy possible Extra Precautions	R3H	1	1	1	1	2	2	2	2
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	1	2	2	3	3	4	4

C3	Mid	4-6 ACH	G1 G2 G3 G4							
			L	H	L	H	L	H	L	H
R1	Not known to cause infection: may cause adverse effects	R1	0	0	1	1	1	1	1	1
R2	Rarely serious, prevention/therapy available	R2L	0	0	1	1	1	1	1	1
R2	Rarely serious, prevention/therapy available, Extra Precautions	R2H	1	1	1	1	1	1	1	1
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	1	1	1	2	2
R3	Serious/Lethal, prevention/therapy possible Extra Precautions	R3H	1	1	1	1	1	1	2	2
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	1	2	2	2	2	3	3

C4	High	6-12 ACH	G1 G2 G3 G4							
			L	H	L	H	L	H	L	H
R1	Not known to cause infection: may cause adverse effects	R1	0	0	0	0	0	0	1	1
R2	Rarely serious, prevention/therapy available	R2L	0	0	1	1	1	1	1	1
R2	Rarely serious, prevention/therapy available, Extra Precautions	R2H	1	1	1	1	1	1	1	1
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	1	1	1	2	2
R3	Serious/Lethal, prevention/therapy possible Extra Precautions	R3H	1	1	1	1	1	1	2	2
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	1	1	1	1	2	2	2

C5	Very High	>12 ACH	G1 G2 G3 G4							
			L	H	L	H	L	H	L	H
R1	Not known to cause infection: may cause adverse effects	R1	0	0	0	0	0	0	0	0
R2	Rarely serious, prevention/therapy available	R2L	0	0	1	1	1	1	1	1
R2	Rarely serious, prevention/therapy available, Extra Precautions	R2H	1	1	1	1	1	1	1	1
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	1	1	1	1	1
R3	Serious/Lethal, prevention/therapy possible Extra Precautions	R3H	1	1	1	1	1	1	1	1
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	1	1	1	1	1	1	1

Proposal and Current Comparison



Example Difference Analysis

Proposal

Current

Differences

C1	Unventilated Indoor Space	<=1 ACH	G1 G2 G3 G4								G1 G2 G3 G4								G1 G2 G3 G4							
			L	H	L	H	L	H	L	H	L	H	L	H	L	H	L	H	L	H	L	H	L	H	L	H
R1	Not known to cause infection: may cause adverse effects	R1	0	0	1	1	1	1	2	2	0	0	1	1	1	1	2	2	0	0	0	0	0	0	0	0
R2	Rarely serious, prevention/therapy available	R2L	1	1	1	1	1	2	2	3	1	1	1	1	2	2	3	3	0	0	0	0	-1	0	-1	0
R2	Rarely serious, prevention/therapy available, Extra Precautions	R2H	1	1	1	1	2	2	3	3	1	1	1	1	2	2	3	3	0	0	0	0	0	0	0	0
R3	Serious/Lethal, prevention/therapy possible	R3L	1	1	1	2	2	3	3	4	1	1	2	2	3	3	4	4	0	0	-1	0	-1	0	-1	0
R3	Serious/Lethal, prevention/therapy possible Extra Precautions	R3H	1	1	2	2	3	3	4	4	1	1	2	2	3	3	4	4	0	0	0	0	0	0	0	0
R4	Serious/Lethal, prevention/therapy not readily available	R4	1	2	2	3	3	4	4	4	2	2	3	3	4	4	4	4	-1	0	-1	0	-1	0	0	0

Output: CSA Z94.4 Hierarchy of Respiratory Protection

For filtering respirators: algorithm output recommendation is a respirator at or above the Protection Level (PL) 0-4 for types as shown



S.J. Smith

0
Respiratory
Protection
not
presumed
necessary



3M

1
Fitted
filtering
facepiece



Dräger

1
Half-
facepiece
air-
purifying
respirator



3M

2
Loose-
fitting
powered
air-
purifying
respirator



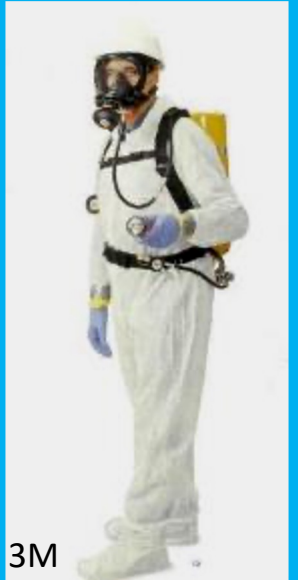
3M

3
Full-
facepiece
air-
purifying
respirator



3M

4
Tight-
fitting
powered
air-
purifying
respirator



3M

5
Self-
Contained
Breathing
Apparatus