## Continuidad del negocio ante el COVID-19: ¿Mascarilla o respirador?





### **3** Science. Applied to Life.<sup>™</sup>





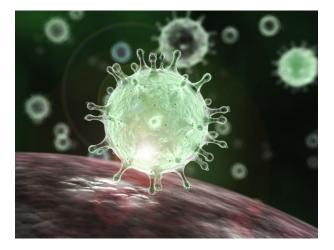






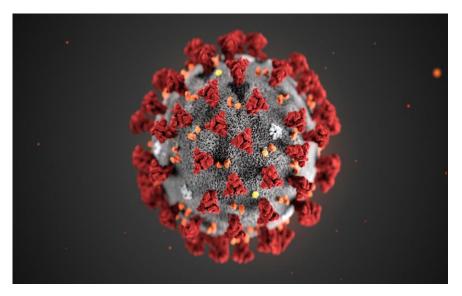
# 2019 Novel Coronavirus

- Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals, including camels, cats and bats.
- The now identified novel coronavirus, first reported on December 31, that is causing an outbreak in Wuhan. Following lab tests that ruled out SARS-CoV, MERS-CoV, avian influenza, adenovirus, and influenza, Chinese authorities announced that they had isolated a novel coronavirus on January 7.



# COVID-19

 On February 11, 2020 the World Health
 Organization announced an official name for the disease that is causing the 2019 novel coronavirus outbreak (SARS-CoV-2), COVID-19.

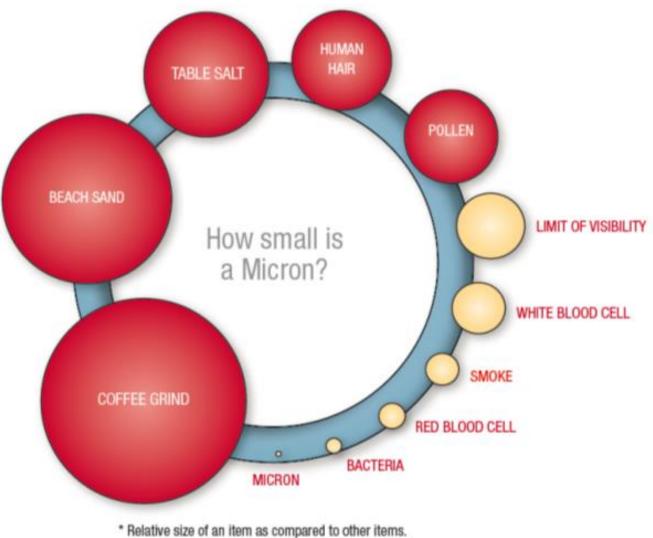


# Bioaerosols

- Microorganisms or particles, gases, vapors or fragments of biological origin that are in the air.
- Bioaerosols are everywhere in the environment.
- Some bioaerosols, when breathed in, can cause diseases including pneumonia, asthma, rhinitis and respiratory infection.
- Some bioaerosols can also infect the eyes and via ingestion.

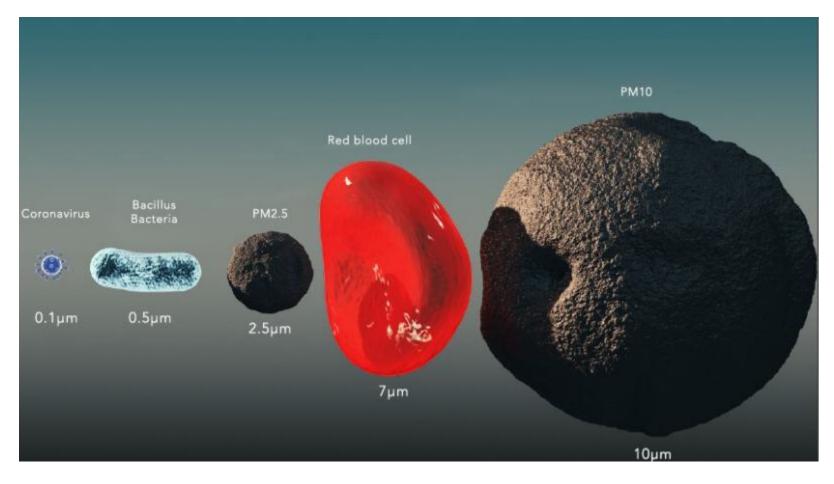


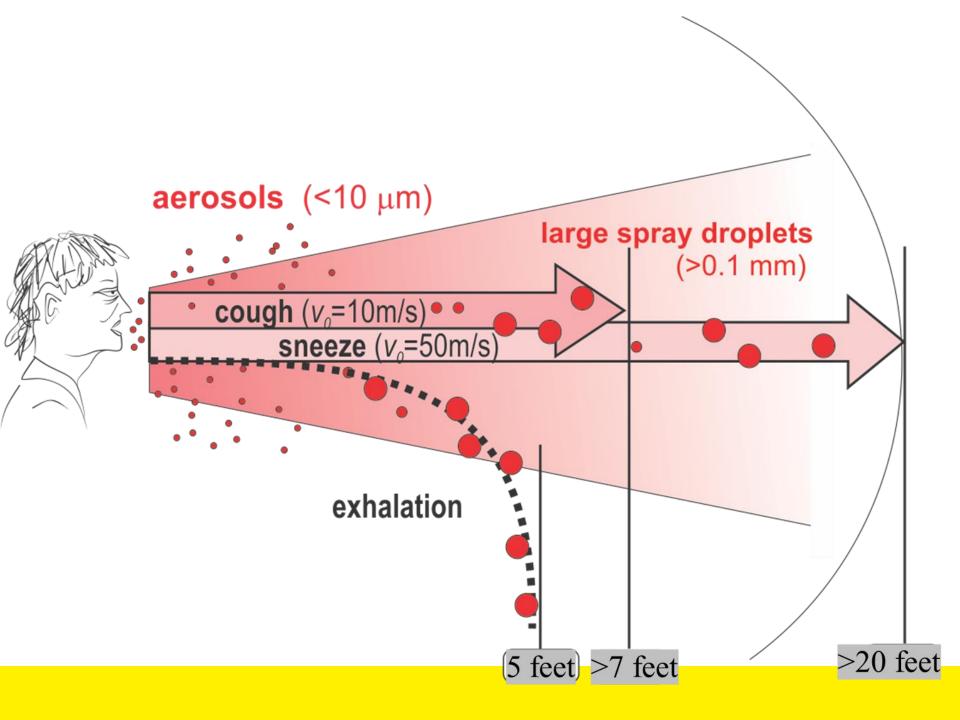
## **Particle Size Comparison**

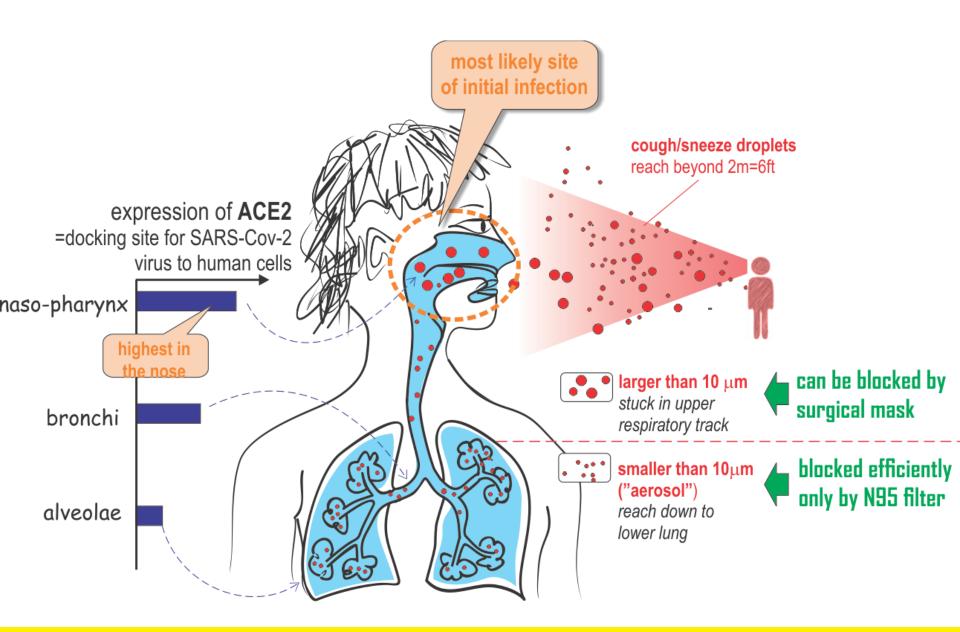


Size and scale are approximate.

# Particle Size Comparison (cont.)









## **US Regulating Bodies**



- The National Institute of Occupational Safety and Health (NIOSH) tests and approves respirators in the US
- Testing/certification is based on the respirators physical and performance characteristics

Surgical masks and respirators are cleared for use as medical devices by the U.S. Food and Drug Administration (FDA), or equivalent agencies

٠

FDA

**NIOSH Certified** 

N95 Respirators

Surgical N95 Respirators

Surgical Masks

**FDA Cleared** 



### Masks often leave gaps Between the mask and the wearer

Masks help protect the patient



Certain masks help reduce wearer exposure to body fluids

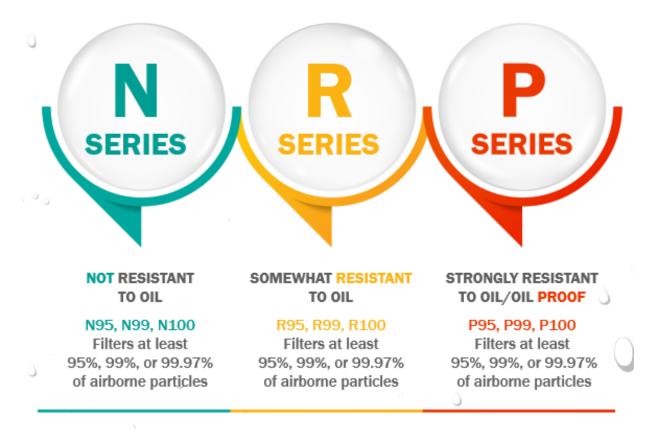


## Properly fitted particulate respirators fit tightly

Creating a seal between the face and the respirator

## **NIOSH RESPIRATOR FILTER CLASSES**

NIOSH classifies the filtering media in respirators based on its resistance to oil and its particle filtering efficiency. The resistance to oil is designated as "N", "R", or "P". Particle filtering efficiency is designated "95", "99", or "99.97".



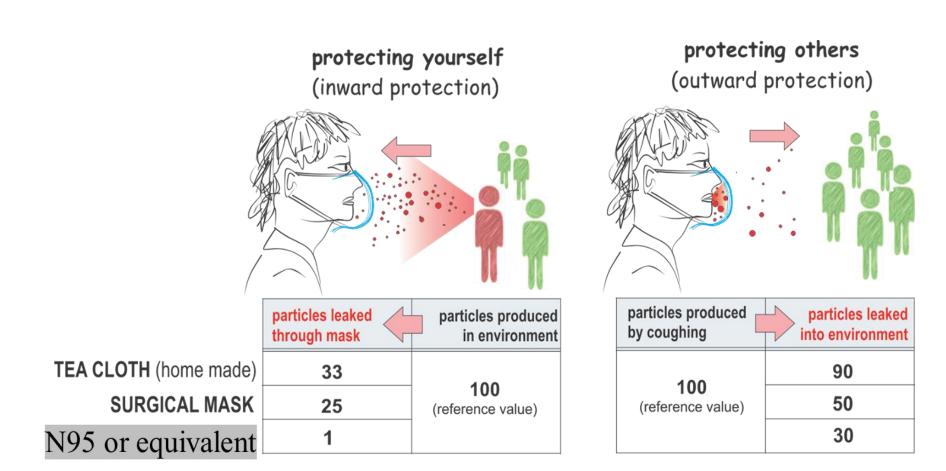
### Required Labeling of NIOSH-Approved N95 Filtering Facepiece Respirators

### Depiction of N95 Respirator and the Important Labeling

For more information about NIOSH-Approved respirators, go to: http://knowits.NIOSH.gov







### Three Key Factors Required for a Respirator to be Effective



Correct\*

Incorrect

- ① The respirator must be put on correctly and worn during the exposure.
- ② The respirator must fit snugly against the user's face to ensure that there are no gaps between the user's skin and respirator seal.

③ The respirator filter must capture more than 95% of the particles from the air that passes through it.



\*If your respirator has a metal bar or a molded nose cushion, it should rest over the nose and not the chin area.

# **Disposable Respirators Decon**



3M is collaborating with several sterilization companies and institutions that are investigating ways for hospitals to safely decontaminate 3M's N95 FFRs in line with the CDC guidance on Decontamination and Reuse of Filtering Facepiece Respirators.



### Four key aspects of successful decontamination reprocessing:

- inactivate the target organism, such as the virus that causes COVID-19;
- not damage the respirator's filtration;
- not affect the respirator's fit;
- and be safe for the person wearing the respirator.

## **COVID-19 EMERGENCY USE AUTHORIZATIONS**

### **Emergency Use Authorization (EUA)**

- Allow unapproved medical products or unapproved uses of approved medical products to help strengthen the nation's public health
- When no other adequate, approved, and available alternatives exist

### EUAs for Personal Protective Equipment with regard to COVID-19

- Decontamination/Sterilization systems
- Face Shields
- Non-NIOSH-Approved Disposable FFRs Manufactured in China
- NIOSH-Approved Air Purifying Respirators for use in Health Care Settings
- Imported, Non-NIOSH-Approved Disposable FFRs

"On April 3, 2020, in response to this evolving public health emergency and continued concerns about filtering facepiece respirator (FFR or respirator) availability, FDA concluded based on the totality of scientific evidence available that certain product classifications for imported disposable FFRs that are manufactured in China and not NIOSH-approved and for which data exists that supports the respirators' authenticity, are appropriate to protect the public health or safety..."

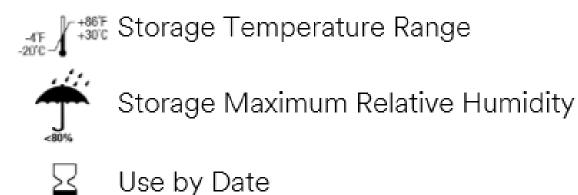
### Table 1. Respirators Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved N95 Filtering Facepiece Respirators

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13698:2011	PFF2	N95
		PFF3	N99 or lower
People's Republic of China	GB 2626-2006 GB 2626-2019	KN/KP95	N95
		KN/KP100	N95
Europe	EN 149-2001	P2	N95
		Р3	N99 or lower

### Table 1. Respirators Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved N95 Filtering Facepiece Respirators

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Japan	JMHLW-2000	DS/DL2	N95
		DS/DL3	N99 or lower
Korea	KMOEL-2017-64	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

# Shelf life – Disposable Respirators





LOT Manufacturer's Lot Number relevant to the device bearing the symbol

### Manufacturer

## **Reusable Respirators**

3M 6100 (Small) 3M 6200 (Medium) 3M 6300 (Large) 3M 6501 (Small) 3M 6502 (Medium) 3M 6503 (Large) 3M 7501 (Small) 3M 7502 (Medium) 3M 7503 (Large)







# **Filters**







# 3M 2071

3M 7093 3M 2091 P95 Particulate Filter P100 Particulate Filter P100 Particulate Filter

# Filters (cont.)

### 3M<sup>™</sup> Particulate Filters 2000 Series



	Part Number	Description
<ul> <li>Lightweight and easy to breathe through</li> </ul>	2071	Particulate Filter, P95
Assortment of filters available	2076HF	Particulate Filter, Hydrogen Fluoride/P95, with Nuisance Level Acid Gas Relief*
for a wide range of applications	2078	Particulate Filter, P95, with Nuisance Level Organic Vapor/Acid Gas Relief*
<ul> <li>Easier breathing through new 3-layer advanced Electret Filter</li> </ul>	2091	Particulate Filter, P100
Media in 2200 Series Filters	2096	Particulate Filter, P100, with Nuisance Level Acid Gas Relief*
	2097	Particulate Filter, P100, with Nuisance Level Organic Vapor Relief*
	2291	Advanced Particulate Filter, P100
	2296	Advanced Particulate Filter, P100, with Nuisance Level Acid Gas Relief*
	2297	Advanced Particulate Filter, P100, with Nuisance Level Organic Vapor Relief*

### 3M<sup>™</sup> Particulate Filter 7093, P100

- Unique, spring-loaded filter cover design simplifies negative pressure user seal checks
- Swept-back design provides enhanced field of view and greater comfort
- 7093C offers a lightweight, low profile design that combines P100 filtration with carbon-loaded features found in heavier combination cartridge products



7093	Particulate Filter, P100
7093B	Particulate Filter, P100, Bulk
7093C	Cartridge/Filter, Hydrogen Fluoride, P100 with Nuisance Level Organic Vapor and Acid Gas Relief*

# Cartridges

### 3M<sup>™</sup> Combination Cartridges/P100 Particulate Filters 6000 Series



- Particulate filter is permanently attached to cartridge for easy, one-step assembly
- Unique design for enhanced comfort and visibility

60921 📉	Cartridge/Filter, Organic Vapor/P100
60922 🤜	Cartridge/Filter, Acid Gas/P100**
60923 📉	Cartridge/Filter, Organic Vapor/Acid Gas/P100**
60924 📉	Cartridge/Filter, Ammonia/Methylamine/P100
60925 📉	Cartridge/Filter, Formaldehyde/Organic Vapor/P100
60926 📉	Cartridge/Filter, Multi-Gas/Vapor/P100**
60928 📉	Cartridge/Filter, Organic Vapor/Acid Gas/P100***
60929 📉	Cartridge/Filter, Mercury Vapor/Chlorine Gas/P100

## Cleaning & Disinfecting – Reusable Face Pieces

### Possible disinfection methods:

- Sodium hypochlorite solution (at a free chlorine concentration of 5,000 ppm) with 1-minute contact time
- 70% Isopropanol solution with 5-minute contact time

**Note:** Soaking in IPA solution resulted in degradation of inhalation valves after ~ 20 cycles, for some 3M facepieces. Pay close attention to this area during inspection, for all facepieces.

### If an EPA-registered disinfectant is required please consider the following:

• 3M<sup>™</sup> Neutral Quat Disinfectant Cleaner Concentrate 23A (EPA Reg. No. 47371-129-10350)

## **Cleaning & Disinfecting – Filters & Cartridges**

Image				
Name	Disc Filters	Pre-Filter Pads	7093/7093C/603X	6092X/609X Cartridges
Wipe outside surface as indicated in disinfecting product user instructions with damp cloth and disinfecting solution				

Image		0	THE REAL PROPERTY AND A DECIMAL OF A DECIMAL	0	
Name	603	501	Pre-Filter Pad	603/501/Pre-fil ter Assembly	501/Pre-filter pad/cartridge Assembly
Cleaning Method	Wipe, spray or soak	Wipe, spray or soak		Wipe outside surfaces as indicated in disinfecting product user instructions with damp cloth and disinfecting solution. Do not allow disinfecting solution to reach the pre-filter.	

## **OSHA GUIDANCE**

### Worker Exposure Risk to COVID-19

### **Classifying Worker Exposure to SARS-CoV-2**

Worker risk of occupational exposure to SARS-CoV-2, the virus that causes COVID-19, during an outbreak may depend in part on the industry type and need for contact within 6 feet of people known to have, or suspected of having, COVID-19.

OSHA has divided job tasks into four risk exposure levels, as shown below. Most American workers will likely fall in the lower exposure risk (caution) or medium exposure risk levels.

#### **Occupational Risk Pyramid for COVID-19**

#### VERY HIGH EXPOSURE RISK

Jobs with a high potential for exposure to known or suspected sources of COVID-19 during specific medical, postmortem, or laboratory procedures. Workers include:

 Healthcare and morgue workers performing aerosol-generating procedures on or collecting/handling specimens from potentially infectious patients or bodies of people known to have, or suspected of having, COVID-19 at the time of death.

#### HIGH EXPOSURE RISK

Jobs with a high potential for exposure to known or suspected sources of COVID-19. Workers in this category include:

· Healthcare delivery, healthcare support, medical transport, and mortuary workers exposed to known or suspected COVID-19 patients or bodies of people known to have, or suspected of having, COVID-19 at the time of death.

#### MEDIUM EXPOSURE RISK

Jobs that require frequent/close contact with people who may be infected, but who are not known or suspected patients. Workers in this category include:

. Those who may have contact with the general public (e.g., schools, high-population-density work environments, some high-volume retail settings), including individuals returning from locations with widespread COVID-19 transmission.

#### LOWER EXPOSURE RISK (CAUTION)

Jobs that do not require contact with people known to be, or suspected of being, infected.

Workers in this category have minimal occupational contact with the public and other coworkers.

For more information, see the Guidance on Preparing Workplaces for COVID-19.



OSHA sharp we have 🔹 osha.gov/covid-19 • 1-800-321-OSHA (6742) • @OSHA\_DOL 🎔

Medium

Lower Risk (Caution)

The four exposure risk levels represent

probable distribution of risk.



### **Guidance on Preparing Workplaces for COVID-19**



## **OSHA Enforcement Guidance**

Interim Enforcement Response Plan for Coronavirus Disease 2019 (COVID-19) Enforcement Guidance for Recording Cases of Coronavirus Disease 2019 (COVID-19) Expanded Temporary Enforcement Guidance on Respiratory Protection Fit-Testing for N95 Filtering Facepieces in All Industries During the Coronavirus Disease 2019 (COVID-19) Pandemic

Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak

Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic

Enforcement Guidance on Decontamination of Filtering Facepiece Respirators in Healthcare During the Coronavirus Disease 2019 (COVID-19) Pandemic

Discretion in Enforcement when Considering an Employer's Good Faith Efforts During the Coronavirus Disease 2019 (COVID-19) Pandemic

### https://www.osha.gov/SLTC/covid-19/

Expanded Temporary Enforcement Guidance on Respiratory Protection Fit-Testing for N95 Filtering Facepieces in All Industries During the Coronavirus Disease 2019 (COVID-19) Pandemic

# **OSHA enforcement memo:**

If a user's respirator model (e.g., model x) is out of stock, employers should consult the manufacturer to see if it recommends a different model (e.g., model y or z) that fits similarly to the model (x) used previously by employees."

A good faith effort to comply with 29 CFR 1910.134 includes stressing the importance of visual inspection, user seal checks and proper training as part of an overall respiratory protection program.

Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic

# **OSHA enforcement memo:**

If respiratory protection must be used, and either acceptable NIOSH-certified alternatives or alternatives that were NIOSH-certified except for having exceeded their manufacturer's shelf life are not available for use in accordance with OSHA's April 3, 2020 memorandum, employers may consider using respirators and filters certified under standards of other countries or jurisdictions, as described in Tables 1 and 2 of Appendix A. Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic

# **OSHA enforcement memo:**

If respiratory protection must be used, employers may consider use of alternative classes of respirators that provide equal or greater protection compared to an N95 FFR, such as NIOSH-approved, non-disposable, elastomeric respirators or powered, air-purifying respirators (PAPRs). Other filtering facepiece respirators, such as N99, N100, R95, R99, R100, P95, P99, and P100, are also permissible alternatives for those who are unable to obtain N95 FFRs. However, per 29 CFR § 1910.134(d)(1)(ii), when considering N95 alternatives, check to ensure that they are NIOSH-approved, at www.cdc.gov/niosh/npptl/topics/respirators/disp\_part/default.html. When these alternatives are not available, or where their use creates additional safety or health hazards, employers may consider the extended use or reuse of N95 FFRs or use of N95 FFRs that were NIOSH-approved but have since passed the manufacturer's recommended shelf life.

### HTTPS://WWW.3M.COM/3M/EN\_US/WORKER-HEALTH-SAFETY-US/COVID19/



**General Respiratory Protection** 



**Respirator Selection and Use** 

Considerations



Respirator Shelf Life Conditions



Cleaning and Disinfecting Respirators



Other PPE

Information



Respirator Demonstration and Training Videos



Fit Testing Resources

Emergency Use Authorization for Products Imported from Other Countries Information

Respiratory Protection in Healthcare

# Quiz

- 1. N95 is the minimum filter class and efficiency recommended for bioaerosols.
  - a. TRUE
- 2. Masks can be classified as surgical or procedure masks.
  - a. TRUE
- 3. The official name for the disease that is causing the 2019 novel coronavirus outbreak is named SARS-CoV-2.
  - a. FALSE
- 4. In the absence of N95 filters any filter class and efficiency can be used for bioaerosols.
  - a. TRUE
- 5. Under CDC guidelines, respirators similar to NIOSH N95 approved in other countries can be use as part of crisis measures.
  - a. TRUE

# Quiz (cont.)

- Disposable respirators can be disinfected with 70% Isopropanol or Sodium hypochlorite solution.
  - a. FALSE
- 7. Disposable respirators correct use includes straps placement and nose clip adjustment.

a. TRUE

- 8. OSHA guidance 3990 established the occupational risk pyramid for COVID-19.
  - a. TRUE
- 9. Reusable respirators can be disinfected with Isopropanol 70% or Sodium hypochlorite solution.
  - a. TRUE
- 10. Surgical masks are designed to protect the wearer.
  - a. FALSE

# Q&A Session THANK YOU!