

**COVID-19 Webinar for Disease-Specific Care Certification**

# **Q&A With The Joint Commission**

September 24, 2020



# Panel

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# Food and Drug Administration (FDA)



## Emergency Use Authorization

Emergency Use Authorization (EUA) information, and list of all current EUAs



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Under section 564 of the Federal Food, Drug, and Cosmetic Act ([FD&C Act](#)), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

# Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices



On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined, pursuant to section 564 of the [Federal Food, Drug and Cosmetic \(FD&C\) Act](#), that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the disease COVID-19.

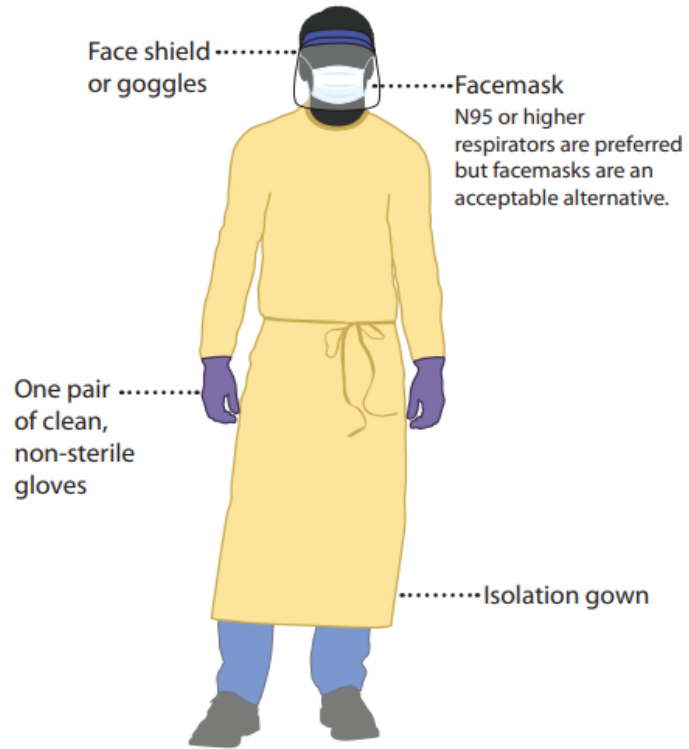
On the basis of this determination, the Secretary of HHS has subsequently declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID-19 (February 4, 2020), personal respiratory protective devices (March 2, 2020), and other medical devices, including alternative products used as medical devices (March 24, 2020), for use during the COVID-19 outbreak pursuant to section 564 of the Act and subject to the terms of any authorization under that section.

# FDA EUAs (9/17/20)

- Blood Purification
- CRRT and HD Devices
- In Vitro Diagnostics
- Decontamination Systems for PPE
- Infusion Pump
- PPE
- Remote or Wearable Patient Monitoring Devices EUAs
- Respiratory Assist Devices EUAs
- Ventilators and Ventilator Accessories EUAs
- Other Medical Device EUAs

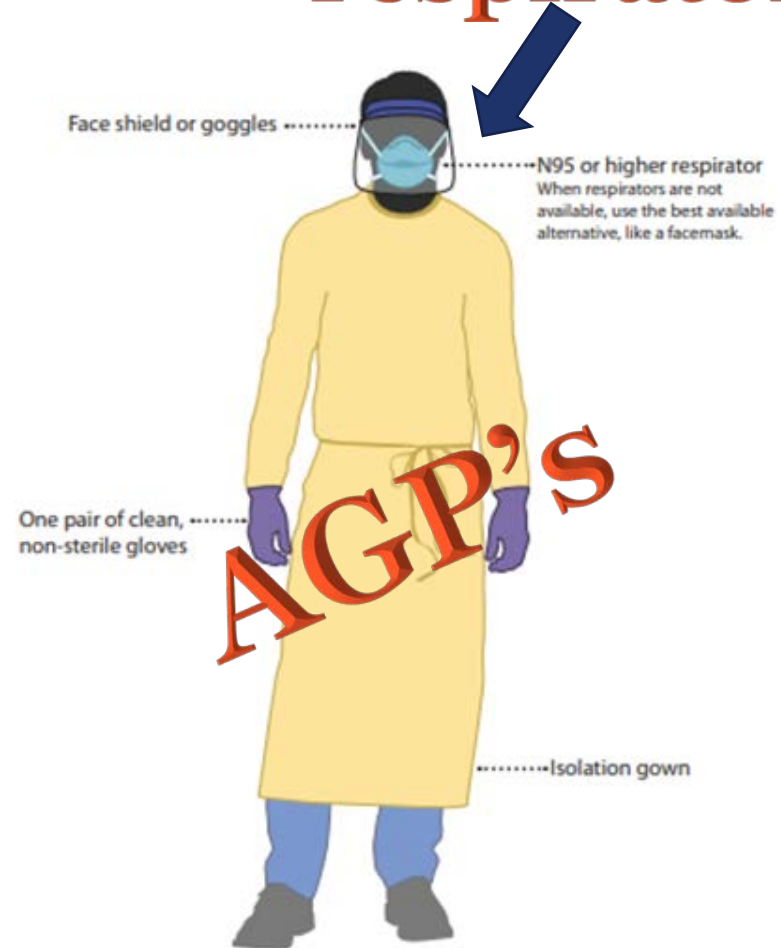
# PPE Selection

## Acceptable Alternative PPE – Use Facemask

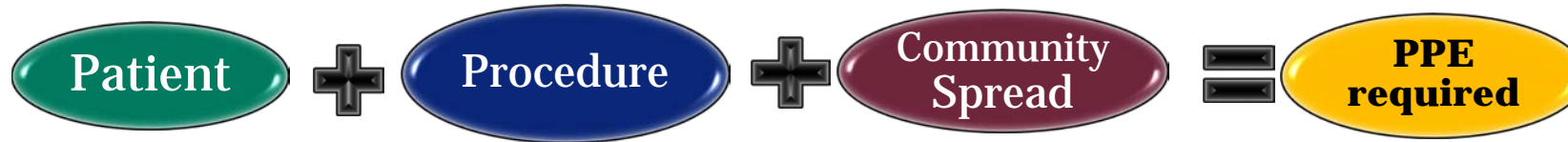


[cdc.gov/COVID19](https://cdc.gov/COVID19)

# N95 or higher respirator



# PPE Selection: Risk= Resources Needed



COVID-19 Patient?	Aerosol Generating Procedure?	Spread of COVID in community?	Type of PPE
Yes	Yes	Any level	FFR, face/eye protection, gloves, gown
Yes	No	N/A	FFR or mask, face/eye protection, gown, gloves
No/ Unknown	Yes	Moderate or substantial	FFR and face/eye protection, gloves, gown
No/Unknown	Yes	Minimal or limited	FFR or mask *
No/Unknown	No	Moderate or Substantial	Mask and eye protection *
No/ Unknown	No	Minimal or Limited	Mask or cloth covering (source control) *

FFR: Filtering Facepiece Respirator

\* Additional PPE as required by Standard and Transmission based Precautions

# Room Turnover Time

- Considerations
  - Size of room?
  - Number of air exchanges/hour?
  - Length of time patient was in room?
  - Patient coughing/sneezing?
  - Patient wearing face covering?
  - PPE worn?
  - Aerosol generating procedure?

**The number of air changes per hour (ACH) and time and efficiency.**

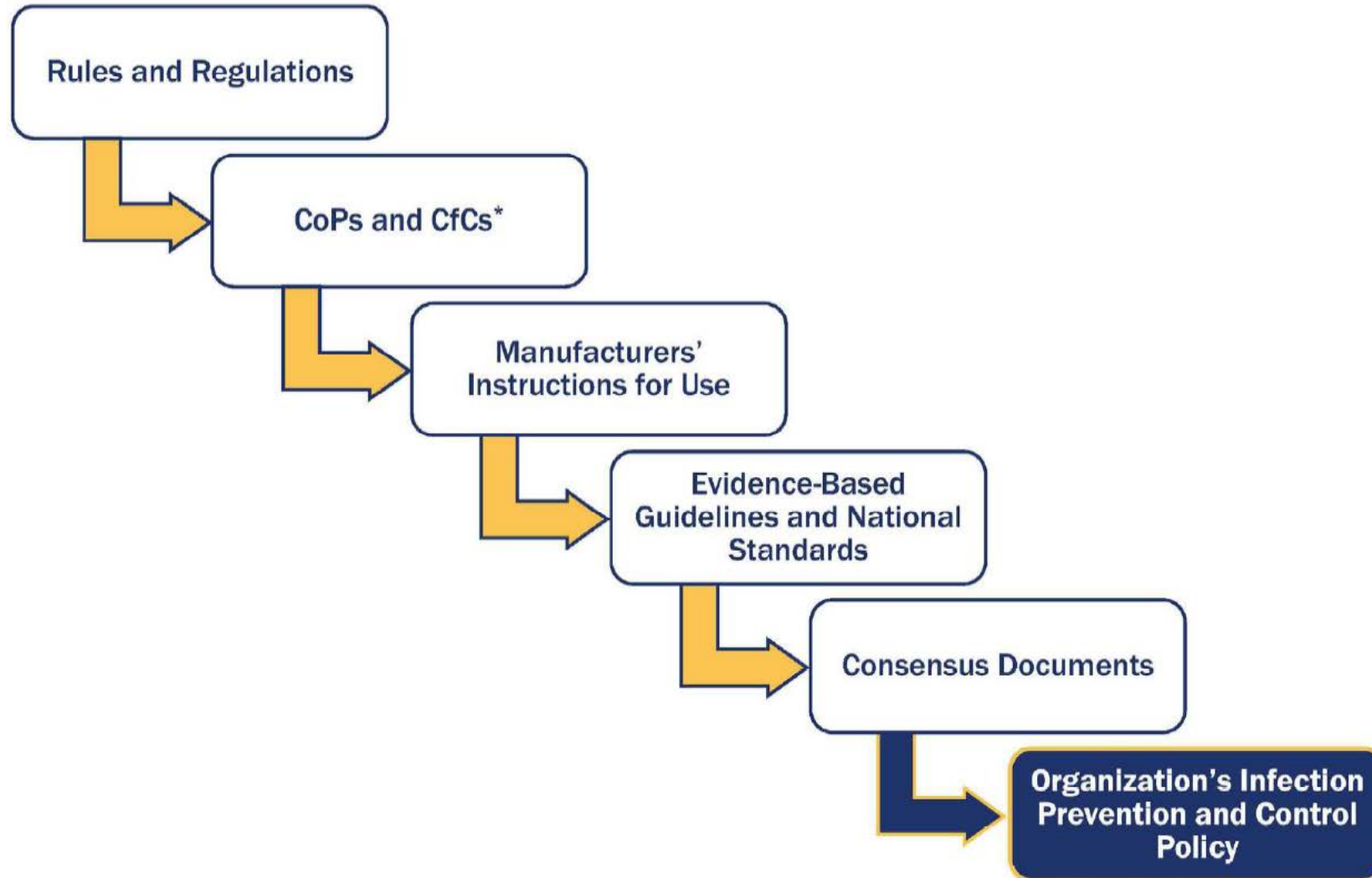
<b>ACH</b>	<b>Time (mins.) required for removal 99% efficiency</b>	<b>Time (mins.) required for removal 99.9% efficiency</b>
<b>2</b>	138	207
<b>4</b>	69	104
<b>6+</b>	46	69
<b>8</b>	35	52
<b>10+</b>	28	41
<b>12+</b>	23	35
<b>15+</b>	18	28
<b>20</b>	14	21
<b>50</b>	6	8

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html>

<https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1>



# Follow the Hierarchy



# Searching Health Departments

## Coronavirus Disease 2019 (COVID-19)



Your Health ▾

Community, Work & School ▾

Healthcare Workers & Labs ▾

Health Depts ▾

Cases & Data ▾

More ▾

 Health Departments

Key Resources

Contact Tracing +

Infection Control

Testing

Surveillance & Data Analytics +

Laboratory Capacity

Community Mitigation +

Staffing Resources

Financial Resources

Communication Resources for +

### HEALTH DEPARTMENTS

## State, Territorial, Local and Tribal Health Department Search

Updated Aug. 28, 2020

[Print](#)

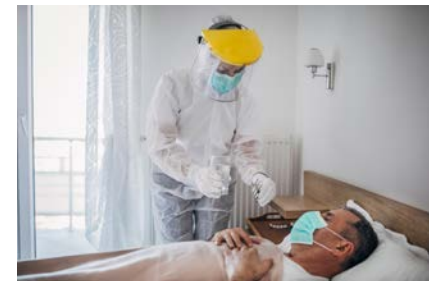


### Search for Resources Created by Health Departments

Search term	State/Territory	Health Department
<input type="text" value="Search"/>	<div><p>All States/Territories</p><p>Alabama</p><p>Alaska</p><p>Arizona</p></div> <p><small>(Ctrl + click to select multiple)</small></p>	<div><p>All Health Departments</p><p>Alabama Public Health Department</p><p>Alaska Division of Public Health</p><p>Arizona Department of Health Services</p></div> <p><small>(Ctrl + click to select multiple)</small></p>
		<p><a href="#">Advanced Search</a> <input type="button" value="Search"/></p>

# Thank You

We support your efforts in response to the COVID-19 pandemic and hope to provide helpful resources



# COVID-19 resources

Accreditation & Certification ▾

Standards ▾

Measurement ▾

Performance Improvement ▾

Resources ▾

About Us ▾

## What Your Organization Needs to Know About the Coronavirus

Trusted Guidance. Trusted Resources.

 [View resources](#)

# Resources

- COVID Resources

- <https://www.jointcommission.org/covid-19/>

- Standards Interpretation

- <https://www.jointcommission.org/standards/standard-faqs/>