

UPDATED GUIDANCE N95 RESPIRATORS



BULLETIN
AUGUST 18, 2021

FDA Revokes Emergency Use Authorization (EUA) of Non-NIOSH-Approved Respirators (6/30/2021)¹

Following the recent guidance from the CDC and FDA on May 27, 2021 (listed below), the FDA is now officially revoking the EUA for the following items, effective July 6, 2021:¹

- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (effective July 6, 2021)
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (effective July 6, 2021)
- Decontamination and Bioburden Reduction System EUAs for Personal Protective Equipment (effective June 30, 2021)

Based on the increased domestic supply of NIOSH-approved-respirators, “the FDA believes health care facilities should not use crisis capacity strategies any longer.”¹ This revocation and guidance is also aligned with the recent Emergency Temporary Standard (ETS) published by the Occupational Safety and Health Administration (OSHA) on 6-21-2021.

Healthcare facilities should “continue to increase inventory of their available NIOSH-approved respirators such as N95s and other filtering facepiece respirators (FFRs), Elastomeric respirators, and Powered air-purifying respirators (PAPRs)” according to the FDA as well as “transition from wearing disposable respirators for an extended time.”¹

For the official letter to healthcare professionals and facilities, please [click here](#).

CDC Updated Guidance and FDA Letter on Use of N95 Respirators in Healthcare (5/27/2021)

Recently, the CDC and FDA issued updated guidance calling on healthcare organizations to add more NIOSH-approved N95s now and end crisis capacity strategies for respirators.^{2,3,8,9} CDC recently updated its guidance for use of N95s. “Healthcare facilities should not be using crisis capacity strategies at this time and should promptly resume conventional practices,” reflecting the recent increase in available domestic supply of N95s. The CDC stated “Healthcare facilities should stop purchasing non-NIOSH-approved respirators for use as respiratory protection... (and) should return to using only NIOSH-approved respirators where needed.”⁹ It also said that for extended use of N95 respirators among cohorted patients, respirators should be discarded immediately after being removed and not re-used. Considerations should include the ability of the N95 respirator to retain its fit as well as contamination concerns.²

FDA Letter to Healthcare Providers (4/9/21)³

The FDA in a letter instructed healthcare facilities to: “Increase inventory of available NIOSH-approved respirators—including N95s and other FFRs” and to cease using non-NIOSH-approved imported respirators such as KN95s.^{2,7} “Even if you are unable to obtain the respirator model that you would prefer, the FDA recommends that you obtain and use a new respirator before decontaminating or bioburden reducing [and then re-using] a preferred disposable respirator.”³

Honeywell

N95s Recommended by CDC⁶

As variants of concern become more prevalent and COVID cases rise again in some areas,^{4,5} other recent CDC updates advised that the use of face masks to care for a patient with suspected or confirmed SARS-CoV-2 infection should be avoided.² The agency called for use of NIOSH-approved N95 respirators because N95s “offer the highest level of protection against inhalation of infectious particles.”⁶

Daily PPE Calculator Can Help Model Utilization

The Covid Staffing Project offers this open-source, simple calculator to estimate daily N95 usage for specific patient care settings under various PPE protocols, to help quickly determine a facility’s supply need for returning to conventional infection control practices.

<https://www.covidstaffing.org/modules/daily-ppe-calculator/>

NIOSH-approved N95 Respirators “offer the highest level of both source control and protection against inhalation of infectious particles.” – CDC⁶

	hospitalized	icu	ventilated
Expected PI Census	73	25	18

Provider Type	hospitalized	icu	ventilated
Registered Nurse	8	8	12
Care Partner	8	3	4
NALP/MA	8	3	4
Nurse Practitioner/PA/Resident	2	2	4
Intern	3	3	3
Respiratory Therapist	1	2	3
Pharm	2	2	2
Fellow/Non-CC Attending	2	2	2
ICU Attending	1	1	2
ICU attending assistant	1	1	2
Floor Attending/Non-Hosp Attending	1	1	2

Item	hospitalized	icu	ventilated	# of uses
N95 Mask	0	0	0	20
Surgical Mask	1	1	1	20
Glove	1	1	1	1
Glove (pair)	2	2	3	1
Cap	0	1	1	1
Face-shield	1	1	1	100
PAPR-Hood	0	1	1	500
Purple Wipes	1	2	4	1

Source: Vanderbilt University Medical Center and Michigan Medicine’s The Covid Staffing Project.⁷

Notes

1 FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators, U.S. Food and Drug Administration, June 30, 2021. <https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators>

2 Strategies for Optimizing the Supply of N95 Respirators, U.S. Centers for Disease Control and Prevention, April 9, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>

3 FDA Recommends Transition from Use of Decontaminated Disposable Respirators, U.S. Food and Drug Administration, April 9, 2021. <https://www.fda.gov/medical-devices/letters-health-care-providers/fda-recommends-transition-use-decontaminated-disposable-respirators-letter-health-care-personnel-and>

4 More Contagious Virus Variant Is Now Dominant in U.S., C.D.C. Chief Says, New York Times, April 7, 2021. <https://www.nytimes.com/2021/04/07/us/politics/covid-19-variant-delta.html>

5 COVID Press Briefing, U.S. CDC, HHS, NIH, April 16, 2021.

https://www.whitehouse.gov/wp-content/uploads/2021/04/COVID-Press-Briefing_16April2021_for-transcript.pdf

6 Centers for Disease Control and Prevention, Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic.

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

7 Daily PPE Calculator, The COVID Staffing Project, Vanderbilt University Medical Center, Michigan Medicine, et al. 2020. Created by Erkin Otles MSE, Alexandra Highet, Jordan Bohnen MD MBA, Brian C George MD MA, and Kyla Terhune MD MBA.

<https://www.covidstaffing.org/modules/daily-ppe-calculator/>

8 Update: FDA Recommends Transition from Use of Non-NIOSH-Approved and Decontaminated Disposable Respirators, Letter to Health Care Personnel and Facilities, U.S. FDA. May 27, 2021. <https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-recommends-transition-use-non-niosh-approved-and-decontaminated-disposable-respirators>

9 Strategies for Optimizing the Supply of N95 Respirators, Situational Update as of May 2021, U.S. CDC, May 27, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>

For more information

sps.honeywell.com

Honeywell | Safety and Productivity Solutions

9680 Old Bailes Rd

Fort Mill, SC 29707

1 (877) 841-2840

www.honeywell.com

© 2021 Honeywell International Inc.

**PROTECT
ONE.
PROTECT
ALL.**

Honeywell