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FDA Reissues Respirators EUAs with New Decontamination-for-Reuse Instructions

Updated policy clarifies that agency is only authorizing decontamination systems’ emergency use for non-cellulose-compatible N95 respirators

The Food and Drug Administration June 7 reissued emergency use authorizations that revise policy on the types of respirators that can be decontaminated for reuse.

Citing a response to public health concerns, FDA determined that certain respirators should not be decontaminated for reuse by health care professionals during the COVID-19 public health emergency. The agency says it no longer finds it safe to recommend the decontamination and reuse of Chinese-manufactured respirators due to the possibility of varying design-and-performance results. Additionally, respirators that have exhalation valves are no longer recommended for decontamination and reuse.

Moving forward, FDA is only authorizing decontamination systems’ use on non-cellulose-compatible N95 respirators. Health care personnel should not reuse respirators that are incompatible with authorized decontamination systems but have nonetheless been decontaminated.

In all instances, health care personnel should continue to utilize the decontamination process only when new, FDA-cleared N95 respirators, NIOSH-approved N95 respirators, or other FDA-authorized respirators are not available.

FDA tomorrow at noon ET will host a webinar on respirators for health care personnel use during the COVID-19 pandemic. Learn more.

If you have questions about this policy change, contact AHA’s Mark Howell at mhowell@aha.org.