RN ALERT »

FDA Says N95 Decontamination Cannot be Described as "Safe or Effective"

The U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for systems to decontaminate N95 filtering facepiece respirators, including systems manufactured by Battelle, STERIS, Advanced Sterilization Products, and others.

What does this mean?

These EUAs state »

> "No descriptive printed matter... may represent or suggest that such products are safe or effective for the decontamination of compatible N95 respirators for... reuse by HCP to prevent exposure to pathogenic biological airborne particles."

Nurses must be informed of the risks posed by these decontamination systems »

- » Employers must provide nurses notice of the instructions and procedures used by the health care facility — "Instructions for Healthcare Personnel".
- » Employers must notify nurses of the significant known and potential risks and benefits of the emergency use of decontaminated N95 respirators — "Fact Sheet for Healthcare Personnel".

Nurses have the right to report any adverse health effects from wearing decontaminated N95 respirators and these should be reported to your employer immediately. This includes »

- » Signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection.
- » Signs and symptoms associated with the decontamination system such as upper airway irritation, shortness of breath, skin irritation, hypersensitivity to odors, nausea, fatigue, and headache.
- » Discoloration or other signs of degradation such as strap breakage, improper fit, face-seal leakage, and delaminated nose-foam (discard and report to your employer).

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Nurses should also report issues directly to the FDA »

Decontamination systems that have been given EUAs are required to provide weekly reports to the FDA of any problems or adverse events that they are aware of. Issues that these companies do not report will be overlooked by the FDA. Report adverse events, including problems with test performance or results, to MedWatch online or over the phone .

- » Submit a FDA MedWatch online reporting form 3500 » www.bit.ly/FDA-MedWatch.
- » Contact the FDA Hotline » 1-800-FDA-1088.

FAQs

What is an emergency use authorization?

The U.S. Food and Drug Administration may grant an emergency use authorization to allow unapproved medical products to be used when a public health emergency is declared and remains in effect until the precipitating emergency has ended. An EUA does not constitute FDA approval.

Does an EUA mean the product or process is safe and effective?

No. Because EUAs are not the same as traditional FDA approvals or clearance, they have a much lower burden of evidence. The process used by the FDA to issue an EUA lacks scientific rigor because the safety and effectiveness of the product do not need to be proven.

What are the conditions of EUA authorization?

The FDA establishes safeguards or conditions for each EUA that must be followed, including information on emergency use, fact sheets, and reporting and monitoring of adverse events. Nurses must be adequately informed if a health care facility plans to or is currently decontaminating N95 respirators. This applies whether your employer is conducting decontamination onsite or has outsourced to another company.

For more information »

Nurses can view the FDA's requirements at » www.bit.ly/FDA-Covid19-EUA.