Prehospital Use of the Critical Care Decontamination System (CCDS) for N95 Respirators

Product (EMS38) Purpose
Use of personal protective equipment (PPE) during the COVID-19 pandemic response is at unprecedented levels. In order to slow usage rates and maintain supply chain stability, the U.S. Food and Drug Administration (FDA) has authorized an Emergency Use Authorization (EUA) for the emergency use of an N95 respirator decontamination system. This is one of several EUAs for decontamination technologies granted by the FDA. This document is intended to provide basic information on the Critical Care Decontamination System (CCDS) for pre-hospital use.

Developed By
The Federal Healthcare Resilience Task Force (HRTF) is leading the development of a comprehensive strategy for the U.S. healthcare system to facilitate resiliency and responsiveness to the threats posed by COVID-19. The Task Force’s EMS/Pre-Hospital Team is comprised of public and private-sector EMS and 911 experts from a wide variety of agencies and focuses on responding to the needs of the pre-hospital community. This Team is composed of subject matter experts from the National Highway Traffic Safety Administration (NHTSA) Office of Emergency Medical Services (OEMS), National 911 Program, Center for Disease Control (CDC), Federal Emergency Management Agency (FEMA), U.S. Fire Administration (USFA), U.S. Army, U.S. Coast Guard (USCG), Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency (CISA) and non-federal partners representing stakeholder groups. Through collaboration with experts in related fields, the team develops practical resources for field providers, supervisors, administrators, medical directors and associations to better respond to the COVID-19 pandemic.

Intended Audience
Federal, as well as State, Local, Tribal, and Territorial Government’s (SLTTs) Fire Rescue and EMS agencies

Expected Distribution Mechanism
EMS.gov, Stakeholder Calls, EMS stakeholder organization’s membership distribution, Email mechanisms, USFA webpage, USFA GOVdelivery and USFA and other social media. We would like EA to assist us with distributing to FEMA and HHS RECs.

USG Agency/ Program Consulted During Drafting
Members of the team were from USFA and CDC

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MANUFACTURER SYSTEM REQUIREMENTS

- **Method**: vapor phase hydrogen-peroxide (VPHP)
- For use in decontaminating N95 or N95-equivalent respirators
- Respirators can undergo up to 20 decontamination cycles with the CCDS.
- Due to incompatibility, the CCDS is not authorized for use with respirators containing cellulose-based materials.
- All compatible N95 respirators provided to CCDS must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup).
- If N95 respirators are soiled or damaged, they will be disposed of and not returned after decontamination.
- Healthcare personnel should follow the instructions provided by the CCDS program in Instructions for Healthcare Personnel
- **There is not a cost for use of the system**
- First responders will have access to the system(s) in their region
- Healthcare facilities and first responder agencies need to request a Site Location Code from the CCDS program.
- The Site Location Code must be placed by the healthcare facility or first responder agency on each of their N-95 respirators.
- This is not a one-for-one exchange program – if the N95 cannot be disinfected, it will not be replaced. Decontaminated N95s will be returned to the healthcare facility with the designated facility code and chain-of-custody forms.

LOCATIONS

The CCDS location for your area can be found by contacting your state or local EMS agency / public health agency / Emergency Operations Center (EOC).

NOTE: If there is not one in your area, a request can be submitted through your local EOC to utilize others.

- **Further information can be found on the CCDS Site**

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This guidance applies to all EMS delivery models including but not limited to: free standing, municipal third-service; fire-based, hospital-based, private, independent, volunteer, and related emergency medical service providers.