

Instructions for Healthcare Personnel: Requirements for Compatible N95 Respirators Decontaminated by TSS

This document outlines the healthcare facility's responsibilities for decontamination of compatible N95 respirators. The following must be adhered to specifically and consistently for the safety of Technical Safety Services (TSS) and healthcare facility personnel.

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the TSS 20-CS Decontamination System for the decontamination of NIOSH-approved, non-cellulose containing N95 respirators that do not have exhalation valves (hereafter referred to as the "compatible N95 respirators") for multiple-user reuse. Healthcare personnel should follow these instructions, as well as procedures defined by their facility, to prepare compatible N95 respirators for decontamination by TSS using the TSS 20-CS Decontamination System.

- The TSS 20-CS Decontamination System is not authorized for use with:
 - Respirators containing cellulose-based or paper materials;
 - Respirators containing exhalation valves; and
 - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators manufactured in China EUA and Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators.
- All compatible N95 respirators used in the TSS 20-CS Decontamination System must be free of visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).
- **Discard and do not collect compatible N95 respirators that are soiled or damaged.**
- **Decontaminated compatible N95 respirators are not sterile.**
- Discard compatible N95 respirators after 20 decontamination cycles.
- Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified must be discarded. All respirators will be labeled with the corresponding barcode ID number to ensure traceability, should a barcode tag be lost.
- **The TSS 20-CS Decontamination System has neither been cleared or approved for the decontamination of compatible N95 respirators for multiple-reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.**
- **The TSS 20-CS Decontamination System is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak unless the authorization is terminated or revoked sooner.**



Compatible N95 Respirator Marking and Collection

Prior to decontamination:

Collection containers are for compatible N95 respirators only; do not throw other personal protective equipment (such as gloves), paper towels, or waste into the designated containers for compatible N95 respirators. No other items will be decontaminated in the same decontamination cycle.

1. Ensure all used respirators are treated as biohazardous material. Biohazard protocols as defined by your healthcare facility must be followed.
2. Collect all used, compatible N95 respirators and inspect them. Compatible N95 respirators must meet the minimum requirements:
 - i. No visible blood or staining.
 - ii. No visible degradation, tears, or integrity issues.
 - iii. No more than (20) previous decontamination cycles, as indicated with a colored dot on respirator.
 - iv. Does not contain cellulose-based or paper materials.
 - v. Does not contain an exhalation valve

Following decontamination:

For each decontaminated, compatible N95 respirator, prior to donning, apply a unique barcode label that was provided by TSS to the rear part of the elastic strap, and write the barcode ID number on the respirator. Indelible ink (blue dot from permanent marker as seen in Figure 2), will be used to tag decontaminated, compatible N95 respirators after the 20th cycle. After use of the respirator after the 20th cycle, the respirator must be discarded.



Figure 1, Sample Barcode label





Figure 2, Sample respirator with indication (blue dot) of 20 decontamination cycles labeling

