

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, antimicrobial agents, or duck-billed designs (hereafter referred to as the "compatible N95 respirators") for multiple-user reuse by healthcare personnel (HCP) to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. HCP 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.

Respirators that are NIOSH-approved before decontamination (<https://wwwn.cdc.gov/niosh-cel/>) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.



- The TSS 20-CS Decontamination System is not authorized for use with:
 - Respirators containing cellulose-based or paper materials;
 - Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - Respirators with duck-billed designs; 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.
- HCP must perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standards prior to beginning a shift. If the user seal check does not pass, discard the respirator.
- 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 4 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 by FDA, but has been authorized for emergency use by FDA under an EUA 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 emergency use of 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, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is 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 (4) 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
 - vi. Does not contain antimicrobial agents.
 - vii. Does not have a duck-billed design.

Following decontamination:

HCP must receive the same model of decontaminated compatible N95 respirator for which they have been fit tested. If such model of respirator is unavailable, then healthcare facilities must provide HCP with fit testing prior to using an alternative model of decontaminated, compatible N95 respirator.

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 4th cycle. After use of the respirator after the 4th cycle, the respirator must be discarded.



Figure 1, Sample Barcode label



Figure 2, Sample respirator with indication (blue dot) of 4 decontamination cycles labeling

