

Instructions for Healthcare Facilities: 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 your personnel. TSS will require all personnel who release respirators to provide a signed copy of this document.

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 "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 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://www.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.
- All compatible N95 respirators used in the TSS 20-CS Decontamination System must be free of visible damage and visual soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).
- Report to your healthcare facility and discard compatible N95 respirators with visible soiling (e.g., blood, dried sputum, makeup, soil) or damage – do not use and do not send for decontamination.
- **Discard 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.
- **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:

1. The healthcare facility should create a collection station at the point of generation (i.e. floor/unit).

NOTE: Only compatible N95 respirators should be placed at this collection station for decontamination; 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.
2. Healthcare personnel must ensure all used respirators are treated as biohazardous material. Biohazard protocols as defined by your healthcare facility must be followed.
3. Healthcare personnel will collect all used, compatible N95 respirators and inspect them.
 - a. 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.
4. Healthcare personnel will follow instructions provided by TSS in Instructions for Healthcare Personnel: Requirements for Compatible N95 Respirators Decontaminated by TSS.

Compatible N95 Respirator Transportation

1. The healthcare facility personnel who are assigned to decontamination (i.e., those with training for collection/transport of such materials) should collect the containers containing the compatible N95 respirators at the collection stations, and place them into the appropriate container for transportation, such as a closed case cart, to minimize risk of environmental contamination. The case cart should have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.
2. The case cart should be transported to facility's decontamination area.

Following decontamination:



Healthcare facilities must ensure that HCP 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, healthcare personnel will 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 the 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.

Complete the chain of custody provided and confirm the quantity and type of all decontaminated, compatible N95 respirators collected.

In signing this document, I testify the following to be accurate:

I acknowledge that in signing any TSS chain of custody to release respirators, I am indicating that I have read & understood this document, and that I have complied with the requirements of this document.

Signature:	
Printed Name:	
Title:	



Organization:	
Date:	

Reporting:

Healthcare facilities will report any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator to TSS, and the healthcare facility must discard the respirator.

Healthcare facilities will report adverse events of which they become aware. This includes monitoring healthcare personnel using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections

Report Adverse events to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088.

