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Regulatory Considerations for Hospitals Decontaminating N95 Filtering Facepiece Respirators

Intended Audience: Hospital administrators, Decision makers

1. Introduction

This document provides an overview of the current U.S. federal regulations and guidance regarding N95 Filtering Facepiece Respirator (FFR) decontamination. The Centers for Disease Control and Prevention (CDC), the National Institute for Occupational Safety and Health (NIOSH), which is part of the CDC, the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA) have separate responsibilities on rulemaking, regulation enforcement and developing science-based guidance.

In the context of N95 FFR use during the COVID-19 crisis, the CDC and NIOSH perform research and publish health and safety guidance but do not publish regulations. NIOSH provides a testing, approval, and certification program ensuring all respirators in the workplace meet expected respiratory protection standards (42 CFR Part 84). Because N95 FFRs marketed and intended for use in hospitals are considered class-II medical devices (e.g. surgical N95 FFRs), the FDA has the rule-making authority on the design and clearance of these N95 FFRs (section 201(h), FD&C Act). OSHA is tasked with protecting employee health and safety, and has both rule-making authority and authority to enforce respiratory protection standards, including standards related to the use of FFRs to protect worker health in hospitals and clinics (29 CFR Part 1910.134). Both the FDA and OSHA work with CDC/NIOSH to develop these regulations and standards. Twenty-five states have their own state-level Occupational Safety and Health Administration, which can write state worker protection standards that protect workers at the same level or a higher level than federal OSHA. Every state has a health department that has authority to regulate hospitals for the protection of patients.

Regulations have changed in response to the COVID-19 pandemic and will continue to change. Always refer to publications from the agencies themselves for the most up-to-date information. This document does not constitute legal advice.

2. Federal regulations and recommendations addressing N95 FFR shortages without decontamination

To address the shortage of N95 FFRs during the current COVID-19 pandemic[1], OSHA requires[2] hospitals to first implement several strategies proposed by the CDC[3] to limit the need for N95

FFRs prior to implementing a decontamination process. These include engineering controls (e.g., airborne infection isolation rooms), administrative controls (e.g. designated healthcare personnel (HCP), cohorting patients), work practices (e.g., handwashing, disinfecting surfaces), and appropriate use of personal protective equipment (PPE), such as gloves, face shields, masks, and gowns. The CDC recommends these strategies as part of an overall plan to address the crisis.

In case of an expected or realized shortage of N95 FFRs, the FDA's Emergency Use Authorizations (EUAs)[4] allow hospitals to use approved alternative FFRs in addition to the N95 FFR during the COVID-19 crisis. These include the following:

- NIOSH-approved FFRs[5-7]
- NIOSH-approved FFRs that are past their manufacturer's shelf-life[5,8]
- Powered air purifying respirators (PAPRs) approved by NIOSH[5,9]
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China[10,11]
- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators[12]

The CDC also lists counterfeit and falsely advertised N95 FFRs as well as ways to identify NIOSH-approved and counterfeit respirators.[13] OSHA has suspended enforcement of annual fit testing as required in respiratory protection standard 29 CFR 1910.134, provided hospitals make a good-faith effort to comply with the standard in addition to other conditions outlined in their March 14, 2020 memo.[14] However, when suitable N95 FFRs cannot be acquired to meet the shortage, OSHA's April 3, 2020 memo permits[15] hospitals to follow CDC-recommended extended use and limited reuse guidance.[16] In addition to the above stated measures, OSHA instructs hospitals to monitor and prioritize their N95 FFR supply according to CDC standards and provide surgical masks and eye protection as interim measures.[15]

3. Federal regulations and recommendations regarding FDA-authorized decontamination strategies in a shortage crisis

When extended N95 FFR use alone cannot safely address the shortage, decontamination and reuse may need to be considered. At present, the FDA has expressed authority over hospitals to regulate the reprocessing of single-use medical devices, including those N95 FFRs marketed and intended for use in hospitals (e.g. surgical N95 FFRs).[17-19] Due to the COVID-19 pandemic, FDA has issued a guidance document[19] for all reprocessors, including hospitals, regarding how to apply for Emergency Use Authorization (EUA) of an N95 FFR decontamination system. At the time of publishing this document, seven decontamination systems have received FDA EUAs. These EUAs are expected to be active during the COVID-19 public health emergency only and do not imply the decontamination systems are cleared or approved devices for standard decontamination or bioburden reduction of FFRs.[19] Up-to-date

information is available on the FDA PPE EUA website[4]. For each authorized decontamination system, the FDA publishes an authorizing letter and three other documents: a fact sheet, instructions for healthcare personnel, and instructions for healthcare facilities. The CDC[20] provides information on decontamination methods not currently covered in the FDA EUAs.

For one applying for an EUA for decontamination of N95 FFRs, there are steps that may be taken to help facilitate a more complete EUA submission and expedite FDA evaluation:

- Engaging early with the FDA before EUA submission[21]
- Including a well-organized summary of the available scientific evidence regarding the decontamination system's safety and effectiveness[19,21]
- Demonstrating that the known and potential benefits outweigh the known and potential risks[20] and demonstrating the extent to which this is known and unknown[19]
- Listing any available or approved alternatives[19,21] and justifying why these solutions are inadequate or unavailable[21]
- Conveying information on the scope of potential impact and responsiveness to meet the potential demand[21]
- Identifying FFRs compatible with the decontamination or bioburden reduction system[19]
- Limiting the use of the decontamination or bioburden reduction system to FDA-cleared or authorized FFRs[19]
- Outlining the collection, sorting, discarding, decontamination or bioburden reduction, and cycle tracking of compatible surgical masks and/or respirators[19]
- Conveying the extent of user safety with respect to exposure from process residuals[19]
- Creating a monitoring and reporting procedure for adverse effects to the users of the processed FFRs and/or operators of the decontamination or bioburden reduction system[19]

These steps in no way guarantee success of an EUA submission.

The FDA recommends EUA applicants specify their intended use and level of decontamination or bioburden reduction based on three tiers:[19]

1. **Tier 1: Decontamination of Surgical Masks and/or Respirators for Single- or Multiple-Users**

   ≥6-log spore reduction of the most resistant spore for the proposed process

   OR

   ≥6-log reduction of a Mycobacterium species (e.g., M. terrae or M. abscessus)

2. **Tier 2: Decontamination of Surgical Masks and/or Respirators for Single-Users Only**

   ≥6-log reduction of 3 non-enveloped viruses

   OR

≥6-log reduction of two gram-positive and two gram-negative vegetative bacteria

3. **Tier 3: Bioburden Reduction of N95 Respirators for Single-Users Only to Supplement Existing CDC Reuse Recommendations**

   ≥3-log reduction of a non-enveloped virus

   OR

   ≥3-log reduction of two gram-positive and two gram-negative vegetative bacteria

   OR

   Other evidence demonstrating that the bioburden reduction system will reliably achieve >3-log reduction in non-enveloped virus or vegetative bacteria, which could include, where appropriate, published scientific literature, and scientific and engineering studies

The FDA also requests additional information on the description of the chain of custody and safeguards to prevent inadvertent exposure (e.g. residual chemicals), material compatibility, filtration performance, fit test data, and a copy of the labeling scheme for the decontaminated FFRs among other requested information. FDA requirements are detailed in Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

4. Federal regulations and guidance relevant to N95 FFR last-resort decontamination and reuse

In the situation where FDA-authorized decontamination systems are unavailable during an N95 FFR shortage crisis and the CDC's recommended N95 FFR supply optimization strategies have already been implemented, some hospitals[22,23] have pursued an in-house decontamination strategy. Antimicrobial effectiveness, N95 FFR performance (filtration and fit), safety (e.g., to healthcare workers, decontamination staff, etc), and practical application of any decontamination methods employed can all be considered in choosing a decontamination method. To provide guidance on decontamination, the CDC[20] has published a series of documents that identify decontamination methods aimed at inactivating SARS-CoV-2. Below is a list of federal regulations and guidance from federal agencies related to decontamination of N95 FFRs for the consideration of hospitals pursuing this last-resort option. This list is not exhaustive.

The regulations referenced with each statement will provide more complete information for the given item.

1. An entity may guarantee the level of decontamination or bioburden reduction achieved by a device intended for a medical application; however, such statements typically

require authorization by the FDA if publicized or promoted (S. Clark, personal communication, April, 2020).

2. The FDA does not intend to object to the distribution and use of sterilizers, disinfectant devices, and air purifiers that are intended to be effective at killing the SARS-CoV-2 virus but do not already have FDA marketing authorization, without prior submission of a premarket notification, submission of PMA Supplement, Registration and Listing requirements, and Unique Device Identification requirements where such devices do not create an undue risk in light of the public health emergency.[24] More complete information is in Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.
3. OSHA standards 1910.132(a,b)[25], 1910.134(c)(1)(v)[26], and 1910.134(h)(1)[26] require hospitals to maintain FFRs in a sanitary and reliable condition. OSHA states these issues should be addressed in the hospital's respiratory protection program (RPP)[27].
4. OSHA's temporary enforcement guidelines during the COVID-19 outbreak indicate compliance safety and health officers (CSHOs) may exercise enforcement discretion as long as hospitals, among other actions:
    a. Implement the hierarchy of controls in an effort first to eliminate or substitute out workplace hazards, then use engineering controls, administrative controls, and safe work practices to prevent worker exposures to respiratory hazards[28];
    b. Prioritize efforts to acquire and use equipment in the following order[28,]:
        i. NIOSH-certified equipment[6,7]; then
        ii. Non-NIOSH-approved, imported FFRs certified in accordance with standards of other countries or jurisdictions except the People's Republic of China, then
        iii. Non-NIOSH-approved imported FFRs manufactured in China[28] that meet at least one of the following criteria[10,11]; then
            1. Manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA; or
            2. Has a regulatory authorization under a jurisdiction, including the Chinese National Medical Products Administration (NMPA) registration certification by an appropriate provincial or municipal regulatory authority, that can be authenticated and verified by FDA; or
            3. Was previously listed in Appendix A under the April 3, 2020 letter of authorization as an authorized respirator because it demonstrated acceptable performance to applicable standards as documented by test reports, has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH's Standard Test Procedure (STP) TEBAPR-STP-0059 within 45 calendar days of the date of issuance of this EUA, and

has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent.

iv. Facemasks (e.g., surgical masks, procedure masks)[28]

c. Prioritize efforts to acquire and use approved respirators that are not beyond their manufacturer's recommended shelf life before using expired, approved respirators[28];
d. Prioritize efforts to use approved respirators still within the manufacturer's recommended service life before attempting extended use and reuse.[28] Extended use or reuse of equipment should follow the CDC's Strategies for Optimizing the Supply of N95 Respirators[3], OSHA's April 3, 2020 memo[28], and OSHA's April 24, 2020 memo[27];
e. Use homemade masks or improvised mouth and nose covers only as a last resort (i.e., when no respirators or facemasks are available).[28] Improvised masks are not personal protective equipment and, ideally, should be used with a face shield to cover the front and sides of the face. When this measure is the only resort, hospitals are referred to the CDC guidance[29];
f. Make a good-faith effort to comply with OSHA PPE[25] and respirator[26] standards and to obtain other alternative filtering facepiece respirators, reusable elastomeric respirators, or PAPRs appropriate to protect workers[14,15,27,28,30];
g. Switch to an equivalent-fitting make/model/size/style N95 or other FFR when supplies of the N95 FFR for which the HCP was fit are depleted[31];
h. Implement plans for the safe reuse of respirators that maintain structural and functional integrity and the filter material is not physically damaged, soiled, or visibly contaminated (e.g., with blood, oil, paint)[15];
i. Hospitals should identify and evaluate respiratory hazards on an ongoing basis to update their RPPs when changes in workplace conditions affect respirator use[15];
j. Follow a decontamination method or procedure listed by the respirator manufacturer or, in the absence of manufacturer's recommendation, a third party[20,27]. CDC does not recommend decontamination as a standard method but acknowledges it may need to be considered during an FFR shortage crisis to conserve supplies.[20]
k. Demonstrate effectiveness of any decontamination method(s) used against the likely contaminant(s) (i.e., pathogens) of concern[27].
l. Ensure that any decontamination method(s) used does not produce additional safety hazards (e.g., electrical arcs resulting from placing FFRs with metal parts into microwaves or presence of residual chemicals following decontamination), and that workers are adequately protected from those hazards through appropriate engineering and administrative controls, safe work practices, and personal protective equipment.[27]
m. Train HCPs to[27]
    i. perform a user seal check[32] prior to reusing a decontaminated FFR;

   ii. follow appropriate precautionary measures prior to using a decontaminated filtering facepiece respirator;
   iii. understand that if the structural and functional integrity of any part of the respirator is compromised, it should not be used by that individual as respiratory protection;
   iv. visually inspect the FFRs to determine if the structural and functional integrity of the respirator has been compromised or is visibly soiled and, if so, to dispose;
   v. don/doff[33] to prevent self-contamination
n. Provide surgical masks and eye protection (e.g., face shields, goggles) as an interim measure to protect against splashes and large droplets (note: surgical masks are **not** respirators and do not provide as much protection during aerosol-generating procedures)[15,27]

While N95DECON is unaware of the FDA enforcing reprocessing regulations during the COVID-19 pandemic, N95DECON's information is not exhaustive and is not a replacement for guidance from the CDC/NIOSH, FDA, and OSHA. The information in this document is subject to change with the COVID-19 situation, and this document may be considered invalid at any time. Please see the CDC's Situation Summary[1], the FDA's EUA listing[4], OSHA's COVID-19 Summary[2,34], and other updated documents from federal agencies for information.

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