Technical Report for UV-C-Based N95 Reuse Risk Management

Some of the available literature on decontamination of N95 FFRs reviewed in this document is a result of recent efforts to relieve the shortage of N95 FFRs during the SARS-CoV-2 outbreak. Thus, some recent research papers cited in this document are not yet peer reviewed. For clarity, wherever non-peer-reviewed research results are cited in this report, the citation is preceded by a “*”.

Summary of Updates in v2.1 Report:
Added UV-C source information to Data Summary Tables, as well as relevant recently published studies. Updated ‘Status of Federal Guidance’. Added discussion of peer-reviewed literature on UV-C inactivation of SARS-CoV-2 on N95 respirators as of 8/9/2020. Updated ‘Strategies’ section and added a new table of recently published studies informing implementation of UV-C decontamination of N95 respirators (Table 3). Minor updates throughout.

Executive Summary

Ultraviolet germicidal irradiation (UVGI) inactivates pathogens by damaging genomic material. UVGI has been widely applied for air, water, and surface decontamination. Recently, UVGI has been identified by the Centers for Disease Control (CDC) as one of the most promising methods for N95 filtering facepiece respirator (N95 FFR; also colloquially referred to as ‘N95 masks’) decontamination, and a workflow for UVGI-based decontamination was successfully implemented at the University of Nebraska Medical Center (UNMC), among other locations. Pathogen inactivation depends critically on ultraviolet (UV) wavelength (peak inactivation efficacy with ~260 nm UV-C light) and UV-C dose. It is essential to use sensors (radiometers or sensor strips with sensitivity at 254 nm and appropriate dynamic range) to validate that the marginally acceptable dose is reached within the treatment period. UV sources emitting at wavelengths much beyond 260 nm, such as sunlight and tanning bed lamps, have minimal or no germicidal efficacy.

We find in the literature that a UV-C irradiation dose of ≥1.0 J/cm² at the FFR surface yields inactivation of SARS-CoV-2 analogues (≥3-log reduction) on the majority of tested N95 facepieces. However, the literature also presents evidence that (i) inner FFR layers and/or certain FFR models may not receive a high enough dose as light transmittance varies among FFR models, (ii) FFR straps present a residual contamination risk and thus require a secondary decontamination method, (iii) it is challenging to ensure that all surfaces/layers are completely decontaminated due to shadowing effects, and (iv) higher doses may be necessary to inactivate other pathogens (especially bacterial spores). We conclude that UVGI protocols should be implemented only if there is a dire shortage of N95 FFRs and approval to do so. We also note that re-use of any N95 FFR may impact FFR fit, and we stress that a user seal check should be performed after every re-donning. We also stress that FFRs may be contaminated with pathogens other than SARS-CoV-2, and not all of these pathogens may have ≥3-log inactivation with the suggested workflows present in this report. Any decontamination approach should be accompanied by an industrial hygiene workflow involving user training and sterile processing as well as compliance with Food & Drug Administration (FDA) and Occupational Safety & Health Administration (OSHA) guidelines.
1. Overview

Our overarching goal is to expedite access to consolidated information on N95 filtering facepiece respirator (FFR) decontamination approaches for healthcare workers who are the frontline against the novel coronavirus (SARS-CoV-2) and essential to maintaining a robust response to the Coronavirus disease 2019 (COVID-19). In this document, we review ultraviolet germicidal irradiation (UVGI) N95 FFR treatment, as discussed in the literature. Effective decontamination requires inactivation of the SARS-CoV-2 virus and maintenance of both the fit and filtration efficiency of the N95 FFR while minimizing the risk of cross-contamination.

Upper-room and in-duct UVGI has been applied in hospitals to inactivate airborne pathogens, as a supplement to High Efficiency Particulate Air (HEPA) filtering (Sehulster et al., 2004). UVGI efficacy is critically dependent on UV wavelength (peak efficacy with UV-C light ~260 nm) and UV-C dose ($J/cm^2$). Dose ($J/cm^2$) is the product of irradiance ($W/cm^2$) and exposure time (s). Because UV-C irradiance is dependent on the distance and angle from a UV-C source, characterizing UV-C irradiance at each FFR location using UV-C sensors is needed (radiometers or sensor strips with sensitivity at 254 nm and appropriate dynamic range). Measured irradiance can then be used to calculate necessary exposure time to achieve a marginally acceptable dose of 1.0 $J/cm^2$. Due to limited UV-C transmission through N95 FFRs, both sides of the FFR should be illuminated, and the marginally-acceptable UV-C dose may not effectively decontaminate all FFR models.

We find in the literature that a UV-C irradiation dose of $\geq 1.0$ $J/cm^2$ at 254 nm peak wavelength inactivates SARS-CoV-2 analogues ($\geq 3$-log reduction) on the majority of tested N95 facepieces, although straps require a secondary decontamination method. At this UV-C dose, N95 FFR fit and filtration performance are not anticipated to be altered for at least 10 cycles (*B. Heimbuch & Harnish, 2019; Zhao et al., 2020). Repeated donning/doffing may have a larger detrimental effect on N95 integrity: for some N95 models, fit was found to fall below OSHA standards after 5 don/doff cycles, while others maintained fit for $>15$ don/doff cycles (Bergman et al., 2012).

Based on the results from other enveloped, ssRNA viruses, it is likely that this UV-C dose inactivates SARS-CoV-2; however, this has not yet been confirmed directly with SARS-CoV-2 in the peer-reviewed literature as of 4/22/2020. UV-C has been found to inactivate other pathogens (nonenveloped viruses, vegetative bacteria, and bacterial spores) on FFRs, although in many cases $\geq 3$-log reduction necessitated higher UV-C doses or was not achieved with the doses used in the study. While UVGI treatment is expected to significantly reduce the risk of contamination, healthcare personnel should continue to handle the respirator as if contaminated and reuse only their own FFR. Any decontamination approach should be accompanied by an industrial hygiene workflow involving user training and sterile processing to minimize risk of cross-contamination.

A workflow for UVGI-based decontamination was successfully implemented at the University of Nebraska Medical Center (UNMC), with a throughput of 90 FFRs/cycle (Lowe et al., 2020), and several other medical centers around the United States are developing similar UV-C N95 decontamination systems.
2. **Status of Federal Guidance**

In this unprecedented COVID-19 pandemic, due to a limited supply of N95 FFRs, the Centers for Disease Control and Prevention (CDC) have provided guidance that healthcare workers can practice extended use or limited reuse of N95 FFRs (CDC, 2020a). In addition, the CDC has provided guidance to hospitals on methods for decontaminating N95 FFRs during a crisis (CDC, 2020c).

The Occupational Safety and Health Administration (OSHA) states that cosmetics or other barriers should not be present during respirator use (OSHA, n.d.). Emergency use authorizations (EUAs) that the FDA has granted for N95 FFR decontamination during the COVID-19 pandemic also stipulate that cosmetics not be present on respirators sent for decontamination (Battelle, 2020).

After decontamination, the CDC recommends that a ‘user seal check’ is performed when the respirator is donned to ensure adequate seal (CDC, 2020c). A user seal check after every decontamination cycle is especially important because there is evidence that the fit factor of N95 respirators decreases with numerous don/doffs (Bergman et al., 2012).

Per FDA guidelines for N95 FFR decontamination EUAs, bioburden reduction requires ≥3-log reduction (corresponding to a 99.9% reduction) in non-enveloped viral activity while virucidal decontamination requires ≥6-log reduction (corresponding to a 99.9999% reduction) in viral activity (FDA, 2020). Based on this guideline, we describe a process as sufficiently “decontaminating” only when it leads to a ≥6-log reduction in viral activity, describe 3-log reduction in non-enveloped viral activity as “bioburden reducing”, and consider the level of enveloped viral inactivation to be sufficient if ≥3-log reduction is achieved. Here, viral reduction and decontamination only consider virucidal activity, unless otherwise specified. Considerations of mycobactericidal or sporicidal activity have separate FDA guidelines, and are not considered here. UV-C processes to inactivate SARS-CoV-2 on N95 FFRs are not expected to result in sterilization (killing of all microorganisms).

UVGI treatment was identified by the CDC as one of the most promising methods for treatment of N95 respirators under crisis conditions (CDC, 2020c); in this document we offer a summary of the evidence on UV-C decontamination of N95 FFRs. UV-C decontamination is also in broader use: per the recommendations of the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), UVGI using UV-C light (254 nm peak) is widely used in US healthcare facilities for pathogen reduction in air (Sehulster et al., 2004). In some settings, UVGI is also used for surface decontamination (Marra et al., 2018). The National Institute for Occupational Safety and Health (NIOSH) and the CDC offer guidelines for applying upper-room UVGI to kill or inactivate airborne tuberculosis bacteria in hospitals (CDC, 2014).

Any new methods for decontamination should be verified through organizations’ internal processes, which may include FDA clearance, prior to implementation. Please refer to current CDC guidelines that are updated regularly, as well as N95DECON’s Full Legal Disclaimer.

3. **UVGI Mode of Action & Appropriate Dosing in N95 FFRs**

UVGI inactivates pathogens primarily by damaging DNA and RNA (max UV absorption at 260 nm) (Anderson et al., 2000; Ito & Ito, 1986; Jay, 1995; Kowalski, 2009). Decontamination
is critically dependent on application of the appropriate UV wavelength (UV-C, with high efficacy near 260 nm (EPA, 2006) and dose (≥ 1.0 J/cm² for inactivation of SARS-CoV-2 analogues in N95 FFRs). UV-C light is attenuated as it passes through the N95 FFR layers, resulting in UV-C irradiance values at the internal filtering medium that are ~3-400x lower than the irradiance at the FFR surface, depending on FFR model (Fisher & Shaffer, 2011). A recent non-peer-reviewed preprint (Syphers, 2020) reports similar levels of UV-C transmission through N95 FFRs as was measured by Fisher & Shaffer. As a result, the required UV-C dose at the N95 surface for viral inactivation from N95 FFRs is several hundred-fold greater than the dose required for inactivation of these viruses on surfaces or in air (Table S1). An ASTM standard UVGI method for inactivating influenza virus on textile surfaces is being balloted.

Shadowing also reduces the dose that a target receives, and therefore shadows on the target N95 FFR(s) should be avoided by: (1) providing UV-C illumination from both sides of the FFR, and/or flipping the N95 FFRs mid-treatment to ensure all surfaces are exposed to the marginally-acceptable UV-C dose, (2) lining walls, ceiling, and other surfaces with UV-C-reflective materials to increase delivered UV-C dose (Rutala et al., 2014), and (3) ensuring there are no obstructions or materials between the N95 FFRs and the UV-C source that could block the line-of-sight or attenuate the UV-C before reaching the N95. It is important to note that glass blocks almost all UV-C light (International Ultraviolet Association, n.d.).

In addition to shadowing, materials deposited on the respirator from the skin of the user, like cosmetics and sunscreen, may also block UV-C light, hindering UV-C decontamination. Thus, such skin products should not be worn by users. OSHA also states that cosmetics or other barriers not be present during regular respirator use (OSHA, n.d.). As is advisable with N95 FFR treatment for reuse, UV-C is viewed as risk mitigation for extraordinary circumstances rather than complete decontamination. Healthcare personnel are advised to approach reuse of N95 FFRs as if the treated N95 FFR is contaminated but with mitigated risk.

4. **Potential for SARS-CoV-2 Inactivation**

Several studies have demonstrated UV-C inactivation of influenza and coronaviruses in N95 FFRs. Influenza and coronaviruses are hypothesized to be suitable SARS-CoV-2 analogues because they are also enveloped, single-stranded RNA viruses. A non-peer-reviewed report to the FDA by the contracting research laboratory ARA (*B. Heimbuch & Harnish, 2019*) found that UV-C treatment of 1.0 J/cm² at the surface of N95 FFR coupons from one FFR model yielded no detectable virus (≥3.95-log reduction) for six influenza and coronavirus strains considered, including MERS-CoV and SARS-CoV. When viral inoculations were covered with artificial soiling agents (skin oil or saliva), N95 coupons also yielded no detectable virus after UV-C treatment. Similar UVGI doses were effective for H5N1 and H1N1 in separate, peer-reviewed studies ([B. K. Heimbuch et al., 2011; Lore et al., 2012](#)) (Table 1). At a UV-C dose of 0.5 J/cm² the viable virus remaining on N95 FFR coupons was 2–3 log lower than on coupons not exposed to UV-C, but detectable, indicating a UV-C dose of 0.5 J/cm² may be insufficient for decontamination (*B. Heimbuch & Harnish, 2019*).

In considering different models of N95 FFRs, Heimbuch & Harnish studied the efficacy of UV-C viral inactivation across 15 different models. In 11 out of the 15 models tested, a UV-C dose of 1.0 J/cm² at the N95 surface was effective in inactivating H1N1 influenza by ≥ 3-log.
The same study found that UVGI treatment was effective for the elastic straps of only 4 of 15 models; thus, straps may require a secondary decontamination method. N95 FFR models with a hydrophilic facepiece were less effectively decontaminated with UV-C than hydrophobic models (*B. Heimbuch & Harnish, 2019). Similarly, related peer-reviewed literature measured ≥ 3 log reduction in H1N1 viability on the facepieces of 12 of 15 tested models and on the elastic straps of 7 of 15 tested models (Mills et al., 2018).

In addition to the N95 FFR model, other factors may influence UV-C inactivation efficacy. High humidity decreases UV-C efficacy on generic surfaces (Tseng & Li, 2007) and on the surfaces of N95 FFRs (Woo et al., 2012), suggesting that a drying step prior to N95 FFR treatment could be beneficial. In contrast to Heimbuch & Harnish, soiling agents have been found to reduce UV-C inactivation efficacy of both MS2 bacteriophage from N95 FFRs (Woo et al., 2012) and C. difficile spores from glass and plastic surfaces (Wallace et al., 2019). The effect of soiling agents on UV-C decontamination may depend on the exact concentration and composition of the soiling agent, and/or how the soiling agent is applied (e.g., mixed in with pathogens or applied on top of pathogen inoculation). Pathogen transmission mode may also impact UV-C decontamination efficacy: N95 FFRs inoculated with larger MS2 droplets (9-10 μm) generally had lower UV-C bioburden reduction efficiencies as compared to FFRs inoculated with smaller MS2 aerosols (1-2 μm) (Woo et al., 2012). Given that studies use a variety of methods to apply pathogens on an N95 FFR (aerosols, droplets, and/or pipetted solution), the question of whether pathogen application method impacts UV-C decontamination efficacy merits further study.

While a UV-C dose of 1.0 J/cm$^2$ at the N95 FFR surface inactivates coronavirus analogues for many models, higher doses may be required to inactivate other classes of pathogens, such as nonenveloped viruses, bacteria and bacterial spores, and fungi. A meta-analysis investigating the impact of UVGI on prevention of healthcare-associated infections demonstrated mixed results depending on the pathogen type (Marra et al., 2018). See Appendix A and Table S1 for a summary of UV-C inactivation studies performed on other pathogens.

As of August 9th, 2020, research on UV-C inactivation of SARS-CoV-2 is ongoing. Smith et al. observed that 0.63 J/cm$^2$ of 254 nm UV-C light led to a significant reduction of SARS-CoV-2 RNA infectivity in cell culture for only one out of three N95 models tested (*Smith et al., 2020). It should be noted that this RNA-based assessment of viral infectivity differs from the plaque or fifty percent tissue culture infectious dose (TCID$_{50}$) assays more commonly employed for viral inactivity measurements. It remains unclear whether UV-C would more fully decontaminate SARS-CoV-2 from multiple N95 models if a dose above the minimally-acceptable 1 J/cm$^2$ were applied, or if respirators were inoculated with a lower SARS-CoV-2 titer that more closely represents a realistic exposure expected for a healthcare worker. Other recent studies have investigated the impact of LED and pulsed UV sources on SARS-CoV-2 inactivation on N95 respirators. One recent manuscript reports SARS-CoV-2 inactivation in some N95 FFR models after UV-C treatment using an LED source. However, caution should be exercised in interpretation or adoption of the reported approach, as the applied UV-C doses were not reported and perhaps not measured (Fischer et al., 2020). As a result, even though the results suggest that UV-C LED sources could be promising, the study
is difficult — perhaps even impossible — to accurately reproduce. Similarly, another recent manuscript reporting SARS-CoV-2 inactivation after UV treatment with a pulsed xenon source also shows significant viral inactivation (>4.79-log); however, the dose associated with this level of inactivation is not reported (Simmons et al., 2020). These data underscore the importance of accurate measurement and reporting of wavelength and UV-C dose for reproducible viral inactivation protocols.

5. **Integrity of N95 Filtering Facepiece Respirators**

Overall, the UV-C doses necessary for SARS-CoV-2 analogue inactivation on N95 FFRs have been found to have minimal detrimental effects on N95 fit and filtration performance over 10-20 treatment cycles. However, it is possible that the process of donning/doffing may cause FFR fit to reach unacceptable levels within a shorter number of cycles. One study found N95 FFR fit to decline with each donning and doffing without additional decontamination processes. For some N95 models, fit was found to fall below OSHA standards after 5 don/doff cycles, while others maintained fit for >15 don/doff cycles (Bergman et al., 2012).

Controlled laboratory studies have subjected 15 respirator models to 10–20 donning/doffing cycles and UVGI treatment (1.0–1.2 J/cm² per cycle), then assessed: strap elasticity (with Imada force tester), particle penetration and breathing resistance (TSI 8130 automated filter tester to evaluate respirator function according to the (CDC, 1997), and fit factor (Static Advanced Headform STAH connected to TSI Portacount 8038 automated breathing machine, subjected to a 240-s respiration test, testing for a fit factor >100) (*B. Heimbuch & Harnish, 2019). Although donning and doffing yielded a statistically significant difference in fit factor for some models, minimal detrimental effects due to UV-C exposure specifically were observed for respirator fit, air flow resistance, or particle penetration from this dose (10 cycles, 1.0–1.2 J/cm² per cycle) of UV-C (*B. Heimbuch & Harnish, 2019). Other evaluation of low doses corroborated good FFR performance after UVGI treatment (Viscusi et al., 2009). At 10²–10³ higher UVGI doses (120–950 J/cm²), a substantial effect (>90% in some cases, but highly variable across N95 FFR models) on respirator material breaking strength was observed (Lindsley et al., 2015). As variation in response to UVGI is to be expected from different N95 FFR models, the respirator must pass the ‘user seal check’ as recommended by the CDC after decontamination to ensure respirator fit integrity is maintained (CDC, 2018).

6. **Data Summary Tables**

**Table 1. Impact of UV-C on enveloped viruses**

<table>
<thead>
<tr>
<th>Author</th>
<th>Organism, soiling agent, &amp; method of application</th>
<th>Material</th>
<th>UV-C dose</th>
<th>Efficacy</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>SARS-CoV-2; 50 μL pipetted on</td>
<td>N95 FFR (AOSafety N9504C)</td>
<td>Approx. 1.98 J/cm² (estimated from manufacturer-specified)</td>
<td>Approx. 3-log reduction</td>
<td>LED high power UV germicidal lamp (260-285 nm; LEDi2)</td>
</tr>
</tbody>
</table>

Influenza & coronavirus strains: ssRNA enveloped virus
## Table 2. Impact of UV-C on N95 FFRs

<table>
<thead>
<tr>
<th>Author</th>
<th>FFR Model</th>
<th>UVGI UV-C dose (J/cm(^2))</th>
<th>Particle Penetration</th>
<th>Breathing Resistance (mmH(_2)O) (max = 25)</th>
<th>Respirator Material Damage (out of 13 layers)</th>
<th>Strap Damage</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>N95 FFRs</td>
<td>1.0-1.2</td>
<td>0.18-3.29% (10 cycles) 0.12-2.74%</td>
<td>4.53-14.93</td>
<td>No obvious effect from UV-C. Some fit degradation</td>
<td>No significant difference from UV-C alone.</td>
<td>254-nm UV-C (Fresh-Aire)</td>
</tr>
</tbody>
</table>
7. Strategies

The University of Nebraska Medical Center (UNMC) published one of the first protocols demonstrating implementation of UV-C N95 decontamination (including N95 FFR handling logistics and treatment), which has been the basis of additional research and discussion for UV-C treatment of N95 FFRs during the 2020 SARS-CoV-2 pandemic. The UNMC protocol exposes each side of N95 FFRs to 0.9–1.2 J/cm\(^2\), depending on FFR position within the treatment field (Lowe et al., 2020). This UNMC Process Flow is a 51-step process defined by role (healthcare worker, courier, UV-C associate) and covers the safe handling (intake, transport, processing, return), labeling (UV-C-decontaminated N95 FFRs should be returned to their specific original user as the process is not expected to be sterilizing), and ancillary PPE and hygiene required for the protocol. As with any decontamination strategy, an appropriate industrial hygiene workflow involving user training (Beam BL, 2020), sterile processing, and other critical considerations must be implemented to avoid cross-contamination or damage to the N95. The Association for Professionals in Infection Control and Epidemiology (APIC) has recently disseminated guidance for infection prevention workflows for UV-C decontamination of N95 FFRs during the COVID-19 crisis, in collaboration with N95DECON (APIC, 2020).

Additional implementation strategies are summarized in Table 3.

Table 3. Published implementation strategies for UV-C N95 decontamination

<table>
<thead>
<tr>
<th>Authoring group</th>
<th>Implementation type</th>
<th>UV-C source type</th>
</tr>
</thead>
<tbody>
<tr>
<td>E: (‘B. Heimbuch &amp; Harnish, 2019), F: (Lindsley et al., 2015), G: (Zhao et al., 2020)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(20 cycles)</td>
<td>Some fit degradation from donning/doffing.</td>
</tr>
<tr>
<td>F</td>
<td>3M 1860</td>
<td>120-950</td>
</tr>
<tr>
<td></td>
<td>3M 9210</td>
<td>120-950</td>
</tr>
<tr>
<td></td>
<td>GE 1730</td>
<td>120-950</td>
</tr>
<tr>
<td></td>
<td>KC 46727</td>
<td>120-950</td>
</tr>
<tr>
<td>G</td>
<td>3M 1860, Moldex 1500</td>
<td>1-10</td>
</tr>
<tr>
<td></td>
<td>254-nm and 265 nm UV-C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospital protocol for room-scale N95 decontamination with full processing workflow (with personnel roles)</td>
<td>254 nm UV-C (ClorDiSys Torch)</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>I</td>
<td>Hospital protocol for room-scale N95 decontamination with full processing workflow</td>
<td>254 nm UV-C (Surfacide Helios)</td>
</tr>
<tr>
<td>J</td>
<td>Implementation guidance for infection prevention workflows for N95 decontamination</td>
<td>N/A</td>
</tr>
<tr>
<td>K</td>
<td>Peer-reviewed study on characterization of a room-scale hospital decontamination system for N95 processing</td>
<td>254 nm UV-C (Diversey MoonBeam3)</td>
</tr>
<tr>
<td>L</td>
<td>Peer-reviewed study on design and characterization of cabinet-based N95 decontamination system targeted at lower-resource settings</td>
<td>254 nm UV-C</td>
</tr>
<tr>
<td>M</td>
<td>Peer-reviewed ray-trace modeling workflow for UV-C N95 treatment chamber design</td>
<td>254 nm UV-C</td>
</tr>
<tr>
<td>N</td>
<td>Peer-reviewed design of a room-scale UV-C treatment system (not designed for N95 decontamination specifically)</td>
<td>254 nm UV-C</td>
</tr>
</tbody>
</table>

H: (Lowe et al., 2020); I: (Brickman et al., 2020); J: (APIC, 2020); K: (Ontiveros et al., 2020); L: (Purschke et al., 2020); M: (Baer et al., 2020); N: (Bentancor & Vidal, 2018)

All but one surveyed minimum-dose data demonstrating active viral reduction on N95 FFRs (Table 1) used low-pressure mercury UV-C sources with peak emission at 254 nm. Because both pathogen inactivation and light transmittance (through materials like N95 layers) are wavelength-dependent (Kowalski, 2009), sources with different emission spectra (e.g., LED sources, medium-pressure mercury sources, or pulsed xenon sources) could also be effective for viral inactivation but will have different minimum doses for bioburden reduction or enveloped viral inactivation. Implementation of these sources must specifically assess the minimum dose through viral inactivation studies with accurate dose measurements. Both research and validation dose measurements for any sources must use appropriate, wavelength-matched detectors.

Validation of (1) UV-C viral inactivation and (2) subsequent N95 FFR reuse suitability (e.g., filtration efficiency, fit factor) is widely considered in the peer-reviewed literature and should be considered for all new processes (Bergman et al., 2012; *B. Heimbuch & Harnish, 2019; Lore et al., 2012; Mills et al., 2018). Both of these critical features are dependent on UV-C dose, as summarized in Tables 1 and 2. **UV-C treatment design must exceed a value of 1.0 J/cm² for all surfaces of each N95 FFR and the delivered dose should ideally be verified with every UV-C cycle, but periodically at a minimum** (e.g., daily, after a set number
Dose measurements should be performed with an accurately calibrated (e.g. traceable to standards such as those from the National Institute of Standards and Technology) UV-C-specific sensor to measure the UV-C irradiance or dose at each FFR position. Variation in irradiance is anticipated across the exposure area; the total exposure time should be chosen such that all N95 FFR surfaces are exposed to at least the marginally acceptable dose of 1.0 J/cm$^2$.

It is imperative to use caution and validate each source, as not all UV sources provide the required UV-C wavelength range, irradiance, or irradiance uniformity: in particular, sunlight and some consumer products (e.g., tanning bed lamps, nail polish curing lamps, and home-use “sterilization” lamps) do not generate sufficient UV-C irradiance to decontaminate N95 FFRs in a reasonable exposure duration (CDC, 2020b; O’Sullivan & Tait, 2014). Even more worrisome, there have been reports of UV sources falsely claiming to be germicidal, with emitted wavelength ranges not consistent with germicidal efficacy. In addition, UV-C sources emitting wavelengths below 210 nm can produce ozone (Kowalski, 2009), which is hazardous to human health. As a result, it is critical to measure the wavelength and irradiance of UV-C sources with sensors specific to UV-C to ensure sources emit radiation within the UV-C germicidal range (200-280 nm with peak efficacy at ~260 nm). Viral inactivation efficacy has been reported to be ~10X lower at 300 nm (beyond UV-C range) compared to 254 nm (EPA, 2006; Lytle & Sagripanti, 2005), highlighting the importance of using appropriate sources emitting in the UV-C range. The measured UV-C-specific irradiance values should then be used to calculate the time required to reach a minimum UV-C dose in excess of 1.0 J/cm$^2$ across all N95 FFR surfaces.

8. **Primary Risks and Unknowns**

We anticipate the following to be the primary risks and unknowns from UVGI decontamination of N95 FFRs:

1. **Direct exposure to UV-C light is harmful to humans.** Proper engineering controls must be established prior to using UV-C systems to ensure that all users are protected from the UV-C light source before the light is turned on.

2. **UV wavelengths of 175–210 nm can generate ozone, which is hazardous to human health.** Some low pressure UV lamps and most medium pressure UV lamps emit some 185 nm UV and thus will generate ozone (Kowalski, 2009). UV-C sources with minimal or no ozone generation should be selected, and/or adequate ventilation should be confirmed to minimize ozone risk.

3. **UV-C only inactivates viruses subjected to the necessary UV-C dose.** There remain open questions about UV-C penetration into N95 FFR materials, and the amount of penetration likely varies widely across N95 FFR models (Fisher & Shaffer, 2011). Although the ARA report (B. Heimbuch & Harnish, 2019) and related peer-reviewed literature (Mills et al., 2018) demonstrate >3-log viral reduction (measured from fluid extraction from the N95 FFR materials), live virus could persist inside the N95 FFR. As such, UV-C and other deactivation approaches should be viewed as risk mitigation for extraordinary circumstances rather than complete decontamination.
4. UV-C light sources may generate shadows (as any light source would), and the configuration of N95 FFRs should be designed to avoid or mitigate shadow generation on the FFR surface. For instance, UV-reflective materials may be used and/or N95 FFRs may be rotated and/or flipped to ensure that the adequate dose is applied across the entire surface area of the FFR (and this dose should be validated with a UV-C-specific sensor).

5. Reports have demonstrated residual virus on N95 FFR straps post UV-C exposure (likely due to the ability of N95 FFR attachment straps to twist and be shielded from the UV-C light), suggesting a need for supplementary decontamination of the straps (*B. Heimbuch & Harnish, 2019; Mills et al., 2018). Mills et al. suggest wiping N95 FFR straps with a compatible disinfectant (Mills et al., 2018). If this additional step is employed, extra caution should be used to avoid touching the N95 FFR facepiece as common disinfectant chemicals can degrade N95 FFR function (Price & Chu, 2020).

6. Although ≥ 1.0 J/cm$^2$ dose of UV-C resulted in ≥ 3-log reduction in viral activity of SARS-CoV-2 analogues, such an observation does not imply full decontamination of the N95 FFR, as the N95 may still be contaminated with other pathogens that might not be similarly susceptible to UV-C irradiation.

9. Conclusions

UVGI protocols should be implemented only if there is a dire shortage of N95 FFRs and approved to do so. If implemented properly, with validation of the delivered UV-C dose to the FFR, it is likely that UVGI inactivates SARS-CoV-2 on the outer layers of non-shadowed regions of the N95, based on results from similar viruses, but the dose for 3-log inactivation has not been confirmed directly for SARS-CoV-2 by peer-reviewed studies as of 8/05/2020. UVGI has shown promise as an effective method for inactivation of viruses and bacterial spores on N95 respirator material; however, UVGI cannot inactivate pathogens that it does not illuminate. For that reason, UVGI may not effectively decontaminate inner layers of the FFR and an auxiliary method of decontamination may be necessary for FFR straps. Furthermore, to avoid user-to-user cross contamination, N95 FFRs should be returned to their original user as not all pathogens may be effectively inactivated by UVGI treatment. N95 FFR model-dependent decontamination efficacy has been reported. We once again stress that (i) after each round of decontamination, a user seal check should be performed, (ii) extended cycles of doffing and re-donning may affect FFR fit, and (iii) that the FFR should not be considered fully decontaminated, as there may be other pathogens contaminating the FFR whose activity may not be fully reduced by UVGI. Thus, UVGI treatment should be viewed as risk management rather than complete decontamination. Healthcare personnel should continue to handle the respirator as if it is contaminated and reuse only their own N95 FFR.

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Appendix A: Effect of UV-C on other pathogens

**UV-C susceptibility of different pathogens in air, water, and on surfaces**

The UV-C dose required to inactivate pathogens in air, water, and on surfaces is organism-dependent, due to organism-to-organism differences in nucleic acid structure and nucleotide content, as well as varying amounts of UV-absorbing proteins and other photoprotective components. Higher UV-C doses are generally required to inactivate bacterial and fungal spores, as compared to viruses and vegetative bacteria (Kowalski, 2009). Among viruses, ~3x higher UV-C doses are required to inactivate viruses with double-stranded RNA or DNA on surfaces, as compared to single-stranded viruses; higher dosage requirements are attributable to damage of one strand being able to be repaired using the second strand as a template (Tseng & Li, 2007). While enveloped viruses are generally more susceptible to inactivation by mechanical and chemical agents (World Health Organization, 2004), it is unclear whether the UV-C susceptibility of enveloped and non-enveloped viruses differ. Blazquez et al. found that in water, enveloped viruses were inactivated with lower UV-C doses than non-enveloped viruses (Blázquez et al., 2019); however, it is unclear what the mechanism of the observed difference is, as well as whether similar trends exist for viruses in air or on other materials.

**UV-C susceptibility of different pathogens on N95 FFRs and textiles**

UV-C irradiation has been shown to yield ≥ 3-log reduction of several pathogens from N95 FFRs. A higher UV-C dose is required for decontamination of N95 FFRs, due to reduced UV-C transmittance through the layers of the FFR material (Fisher & Shaffer, 2011). The required UV-C dose to inactivate both enveloped and nonenveloped viruses from N95 FFRs is several hundred-fold greater than the dose required for inactivation of these viruses on surfaces (Table S1). MS2, a nonenveloped virus, has generally been reported to require higher UV-C doses to achieve 3-log reduction from N95 FFRs (Fisher & Shaffer, 2011; Vo et al., 2009) as compared to enveloped influenza and coronaviruses (B. Heimbuch & Harnish, 2019; Mills et al., 2018); however, it is unclear whether other differences in study design (e.g., FFR model and method of virus application to the FFR) also contribute to the difference in required UV-C dose.

While UV-C has been demonstrated to inactivate several species of vegetative bacteria and bacterial spores on N95 FFRs and other textiles (Bentley et al., 2016; Fu et al., 2020; Kenar et al., 2007; Lin et al., 2018; Smolle et al., 2018; Tomas et al., 2015), 3-log reduction was not always demonstrated and it is unclear how many bacterial pathogens would be inactivated by the 1.0 J/cm^2 UV-C dose required for coronavirus inactivation on N95 FFRs. For example, UV-C inactivation of C. difficile on N95 FFRs has not been studied. However, much higher UV-C doses are required to inactivate C. difficile spores on surfaces (~0.17-0.63 J/cm^2; Wallace et al., 2019) as compared to MS2 on surfaces (~0.006-0.010 J/cm^2; Tseng & Li, 2007). It is unclear whether the same trend (higher UV-C doses required to inactivate C. difficile spores as compared to MS2 on surfaces) would hold true in the case where these organisms are on N95 FFRs. Additionally, E. faecium in polycotton swatches was inactivated to a lower degree (<1.97-log reduction) by UV-C (Smolle et al., 2018) as compared to laundering (3- to 4-log reduction) (Tano & Melhus, 2014).
Table S1. Impact of UV-C on microorganisms

<table>
<thead>
<tr>
<th>Author</th>
<th>Organism, soiling agent, &amp; method of application</th>
<th>Material</th>
<th>UV-C dose</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Influenza &amp; coronavirus strains: ssRNA enveloped virus</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Lore et al., 2012)</td>
<td>H5N1 droplets</td>
<td>N95 FFR (3M 1860, 3M 1870)</td>
<td>1.8 J/cm²</td>
<td>&gt; 4-log reduction</td>
</tr>
<tr>
<td>(Mills et al., 2018)</td>
<td>H1N1. 1 µL drops of suspension pipetted on. Artificial saliva or artificial skin oil were placed on top of dried virus solution to study the effects of soiling.</td>
<td>N95 FFR (15 models)</td>
<td>1.0 J/cm²</td>
<td>≥ 3-log reduction for 12/15 FFR models and 7/15 FFR straps for all soiling conditions</td>
</tr>
<tr>
<td>(*B. Heimbuch &amp; Harnish, 2019) - Option Task B</td>
<td>Influenza strains (H1N1, H5N1, H7N9), MERS-CoV, SARS-CoV, all pipetted as 1 µL drops and dried. Artificial saliva or artificial skin oil were placed on top of dried virus solution to study the effects of soiling.</td>
<td>N95 FFR (3M 1870)</td>
<td>1.0 J/cm²</td>
<td>No detectable virus (≥ 3.95-log reduction) for all organisms for all soiling conditions</td>
</tr>
<tr>
<td>(*B. Heimbuch &amp; Harnish, 2019) - Base Task 4</td>
<td>H1N1, pipetted as 1 µL drops and dried. Artificial saliva or artificial skin oil were placed on top of dried virus solution to study the effects of soiling.</td>
<td>N95 FFR (15 models)</td>
<td>1.0 J/cm²</td>
<td>≥ 3-log reduction for 11/15 FFR models and 4/15 FFR straps for all soiling conditions</td>
</tr>
<tr>
<td>(Walker &amp; Ko, 2007)</td>
<td>Murine hepatitis virus (coronavirus)</td>
<td>Air</td>
<td>1.83 x 10⁻³ J/cm²</td>
<td>3-log reduction*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*estimated based measured viral susceptibility to UV-C in air</td>
</tr>
<tr>
<td><strong>MS2: ssRNA nonenveloped virus</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Vo et al., 2009)</td>
<td>MS2 droplets</td>
<td>N95 FFR (Willson N1105)</td>
<td>4.32 J/cm²</td>
<td>3-log reduction</td>
</tr>
<tr>
<td>(Fisher &amp; Shaffer, 2011)</td>
<td>MS2 aerosol</td>
<td>N95 FFR (6 models)</td>
<td>0.32-40 J/cm² (equates to 0.1 J/cm² at the internal filtering medium)</td>
<td>≥ 2.9-log reduction</td>
</tr>
</tbody>
</table>
| (Woo et al., 2012) | MS2 droplets (9-10 µm) and aerosol (1-2 µm), in water, beef extract (BE), or artificial saliva (AS) | N95 FFR (3M 1870) | 3.6 J/cm² | Droplets: 4.8-, 2.7-, 2.5-log reduction in water, BE, AS
Aerosols: 5.2-, 3.0-, 2.7-log reduction in water, BE, AS |
### Table: Decontamination of N95 FFRs

<table>
<thead>
<tr>
<th>Source</th>
<th>Pathogen/Species</th>
<th>Surface Type</th>
<th>Energy Density (J/cm²)</th>
<th>Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Tseng &amp; Li, 2007)</td>
<td>MS2</td>
<td>Surfaces</td>
<td>-0.006-0.010</td>
<td>&gt;3-log reduction</td>
</tr>
<tr>
<td>(Lin et al., 2018)</td>
<td>Bacillus subtilis spores, aerosolized</td>
<td>N95 FFR (3M 8210)</td>
<td>2.27 J/cm², 5.7 J/cm²</td>
<td>2.27 J/cm² → ~2.7-log reduction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5.7 J/cm²</td>
<td>No detectable spores</td>
</tr>
<tr>
<td>(Bentley et al., 2016)</td>
<td>E. coli, P. aeruginosa, S. aureus (drug-sensitive and drug-resistant), S. pseudointermedius (drug-sensitive and drug-resistant) 1-2 mL suspension pipetted on.</td>
<td>Microfiber, polyester, and cotton fabric swatches</td>
<td>0.27 J/cm²</td>
<td>&gt;2.5-log reduction for all bacteria on all fabrics. No detectable bacteria in 20/24 conditions.</td>
</tr>
<tr>
<td>(Wallace et al., 2019)</td>
<td>C. difficile spores (with and without tri-part soiling agent) MRSA and MS2 (with and without 5% FBS)</td>
<td>Glass &amp; plastic</td>
<td>0.17-0.63 J/cm²</td>
<td>C. diff: mean 2.1-log reduction with soiling agent across all UV-C doses; mean 3.2-log reduction without soiling agent across upper 3 doses. MRSA: mean 2.9-log reduction with FBS, mean 3.4-log reduction without FBS MS2: mean 3.7-log reduction with FBS, mean 2.9-log reduction without FBS</td>
</tr>
<tr>
<td>(Fu et al., 2020)</td>
<td>5 Candida strains</td>
<td>Bed sheets</td>
<td>0.075 J/cm²</td>
<td>&gt;3-log reduction in all strains</td>
</tr>
</tbody>
</table>

### Appendix B: Sunlight is not an effective decontamination approach for N95 FFRs

As of 4/22/2020, the CDC does not list sunlight as an appropriate method of N95 FFR decontamination (CDC, 2020c). UV-C radiation with a peak wavelength of 254 nm, at a dose of ≥1.0 J/cm², has been found to inactivate viral particles from N95 FFRs (B. Heimbuch & Harnish, 2019). However, UV-C radiation from sunlight is absorbed by the top layer of the atmosphere, so negligible UV-C radiation reaches the surface of the earth (CDC, 2020b). Sunlight at the earth’s surface consists of UV-A (320-400 nm) and UV-B (280-320 nm) radiation. UV-A radiation is considered non-germicidal, while UV-B radiation has germicidal effects which are much weaker than UV-C (Kowalski, 2009). Theoretical calculations for the necessary sunlight exposure time needed to achieve UV-B germicidal effects in US cities (equivalent to a 1.0 J/cm² UV-C dose) suggest timescales of 57 - 5000 days, depending on season and geographic location (Sagripanti & Lytle, 2007). Furthermore, studies with simulated
sunlight showed minimal to no effect in inactivating MS2 and human adenovirus on the surface of fresh produce (Carratalà et al., 2013).

UV-B radiation has some germicidal effects; studies of UV-B irradiation on MS2 bacteriophage and murine noroviruses (MNV) in suspension (not on surfaces) demonstrated a 4-log reduction with UV-B doses of 0.909 J/cm² and 0.367 J/cm², respectively (Lee & Ko, 2013). To reach these doses, 0.34-4.2 hours of sunlight exposure would be required, assuming UV-B irradiance from sunlight of ~60-300 μW/cm² (though UV irradiance from sunlight varies significantly depending on geographic location, season, and time of day) (Heisler et al., 2007). For comparison, 4-log reduction of MS2 in phosphate buffered saline solution (Beck et al., 2016) required ~0.07 J/cm² of UV-C – over an order of magnitude lower. However, the UV-C dose required for viral inactivation in N95 FFRs is ~1000x higher than for viral inactivation in water, air, or on hard nonporous surfaces (Table S1) (Kowalski, 2009). Thus, many days of sunlight exposure would be required to achieve a sufficient virucidal dose on N95 FFRs, in agreement with theoretical estimates (Lytle & Sagripanti, 2005).

As of 4/22/2020, to our knowledge, in the peer reviewed literature, there is no evidence of viral inactivation of SARS-CoV-2 on N95 FFRs by sunlight. As of 4/22/2020, we have not found any studies in the peer-reviewed literature assessing N95 respirator integrity after exposure to sunlight. As a result, we conclude that there is no evidence in the peer-reviewed literature that supports sunlight-assisted disinfection and decontamination of N95 FFRs, specifically. Extensive experimental verification and validation must be performed before considering sunlight as a disinfection method for N95 FFRs, and evidence from the peer-reviewed literature on viral inactivation by the wavelengths present in sunlight (UV-A and UV-B, not UV-C) suggest that sunlight-assisted N95 decontamination will not be effective.

References


FDA. (2020, April). *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease*


