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Elastomeric Half Mask Respirators: An Alternative to Disposable Respirators and a Solution to Shortages during Public Health Emergencies

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Abstract

During public health emergencies such as an influenza pandemic, disposable filtering facepiece respirator (FFR) shortages have a significant impact on the national response, affecting many types of workplaces that rely on respiratory protection. During the COVID-19 pandemic, severe FFR shortages led the CDC to publish strategies for optimizing the supply of N95 FFRs. These strategies included the extended use and limited reuse of FFRs, wearing decontaminated FFRs, wearing respirators that meet an international respirator standard, or wearing FFRs that were past their manufacturer-designated shelf life. An additional strategy to mitigate supply shortages that was highlighted during the COVID-19 pandemic was to wear reusable respirators, such as elastomeric half mask respirators (EHMRs), or powered air-purifying respirators, which can be cleaned, disinfected, and reused. A decade of nationwide initiatives to increase the utility of EHMRs in healthcare settings were realized during the COVID-19 pandemic as EHMRs became more well-known and were used in healthcare settings for respiratory protection. This expanded use of EHMRs led to an increase in federal procurement, research, guidance, and private sector research and development of innovative EHMR designs by manufacturers to respond to workers' needs for both respiratory protection and source control. This paper describes the role of reusable EHMRs before and during the COVID-19 pandemic, and reviews past and current research, to inform successful EHMR implementation in healthcare and first responder settings.

Keywords

COVID-19; elastomeric half mask respirator; EHMR; N95 respirator shortage; pandemic

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INTRODUCTION AND BACKGROUND

Air-purifying respirators (APRs) include a variety of respiratory protective devices that remove gases, vapors, particulate or airborne aerosols, or a combination of these agents and protect the worker from inhaling harmful contaminants (Cichowicz, 2018). The National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) is the federal agency that houses the nation's Respirator Approval Program. Respirators are approved in accordance with federal regulations 42 CFR Part 84 and used by U.S. workers as outlined in the Occupational Safety and Health Administration's (OSHA's) Respiratory Protection Standard 1910.134 (Code of Federal Regulations, 2021; OSHA, 2011). Types of NIOSH-approved APRs include filtering facepiece respirators (FFRs), elastomeric half mask respirators (EHMRs), full facepiece elastomeric respirators, and powered air-purifying respirators (PAPRs). NIOSH's respirator approval process includes a thorough review of the manufacturer's quality assurance system and a thorough evaluation of the respirator, including general construction, product markings, and performance using NIOSH's Standard Testing Procedures (NIOSH, 2021d). Additionally, NIOSH NPPTL conducts a variety of post-approval activities, develops standards, and conducts research for respirators and other types of personal protective equipment (PPE).

FFRs, EHMRs, and PAPRs all are used in healthcare settings during routine and emergency scenarios. The purpose of this paper is to capture the specific role of EHMRs in the current public health emergency during which disposable respirator shortages occurred. Further, past and current research is briefly described to inform successful EHMR implementation in healthcare and first responder settings.

What are EHMRs?

EHMRs used in United States occupational settings under an OSHA-compliant respiratory protection program are NIOSH-approved tight-fitting, reusable APRs with a silicone, rubber, or other polymeric material facepiece. Covering the user's nose, mouth, and under the chin, EHMR facepieces often come in multiple sizes (e.g., small, medium, and large) and have adjustable straps (Bollinger & Schutz, 1987). EHMRs have the same OSHA assigned protection factor (APF) as FFRs (i.e., APF of 10) and offer at least the same level of protection as an N95 FFR. The NIOSH approval for EHMRs comprises the elastomeric facepiece configured with replaceable filters or cartridges[1] to provide gas, vapor, and/or particulate protection, as well as other components such as filter adaptors, retainers, and covers unique to the NIOSH approval holder (Cichowicz, 2018). The filters may be housed in a cartridge body or they may be disc or pancake-style filters, which are not housed in a cartridge body.

EHMR particulate filters can offer protection through N, R, or P series filters with 95, 99, or 100 filtration efficiency levels (i.e., a total of nine levels of protection). N-series filters are not resistant to oil, R-series filters are somewhat resistant to oil, and P-series filters are

[1]EHMRs can be equipped with cartridges or canisters. However, as of August 16, 2021, there are no NIOSH-approved EHMRs with canisters. Cartridges and canisters primarily differ by their sorbent bed volume.

strongly resistant to oil. OSHA's minimum requirement to change out particulate filters is when the filter is visibly soiled, wet, or damaged, or if the respirator becomes notably harder to breathe through (OSHA, 2011). Although not common in healthcare settings, EHMR chemical cartridges are typically comprised of activated carbon and can provide protection from various chemical classes or specific chemicals depending on the cartridge type. For chemical cartridges, there are different ways to determine change-out schedules, including the presence of an end-of-service-life indicator (ESLI) or online software tools that assist users in establishing change schedules (3M, 2021; MSA Safety, 2021).

NIOSH evaluates the EHMR filters/cartridges' inhalation resistance, exhalation resistance, exhalation valve leakage (if an exhalation valve is present), and filtration efficiency during the approval process. The first NIOSH approval for an EHMR with particulate protection was in 1995 and was issued to 3M (NIOSH, 2021a). As of December 14, 2021, NIOSH has close to 10,200 active approvals across all respirator types. Of these approvals, 2,604 (~26%) are for EHMRs, and specifically 2,158 (~21%) are for EHMRs with particulate protection (which may also include chemical cartridges/canisters combined with particulate filters) as illustrated in Figure 1.

Like all NIOSH-approved respirators, EHMRs must be used in the context of a complete respiratory protection program (RPP) in accordance with OSHA 1910.134. EHMRs must be fit tested annually which can either be done through a qualitative or quantitative fit test (NIOSH and OSHA, 2015). For qualitative fit testing, those EHMRs equipped with particulate filters can be evaluated for fit using saccharin (sweet-tasting) or Bitrex® (bitter-tasting) aerosols, whereas quantitative fit testing can be conducted using the ambient aerosol condensation nuclei counter test, which is applicable to APRs with particulate or chemical protection (NIOSH and OSHA, 2015).

EHMRs have maintenance requirements that include cleaning and disinfecting the facepiece, straps, valves, and valve covers immediately after removing (CDC, 2020c). Filters encased in a hard outer casing can be wiped down and reused; however, to date NIOSH has not approved an EHMR with filter material that can be cleaned or disinfected for reuse if not encased.

Cleaning the reusable respirator components is typically done with soap and water with the intent to remove soiling agents such as cosmetics and facial oil. Disinfection includes the use of sanitizing agents to inactivate microbial agents. OSHA's respiratory protection standard provides general procedures for employers to use when cleaning/disinfecting respirators, which includes removing the filters, cartridges, or canisters; washing the components in warm water (110 °F max) with a mild detergent; immersing in bleach solution (1 mL bleach in 1 L water) for two minutes; rinsing in warm water (110 °F max); and hand drying or air drying (OSHA, 2011). Following cleaning/disinfection, the EHMR should be stored at room temperature in a dry area that is protected from exposure to hazards in accordance with the manufacturer's user instructions (NIOSH and OSHA, 2015). OSHA permits employers to use the cleaning recommendations provided by the respirator manufacturer as long as those procedures are as effective as those listed in Appendix B-2 (CDC, 2020c; OSHA, 2011). Although NIOSH does not currently require

manufacturers to establish cleaning and disinfection procedures, the respirator manufacturer may provide specific procedures for their EHMR in the user instructions as part of the NIOSH approval. These EHMR model-specific instructions may include the appropriate cleaning steps and specific cleaning/sanitizing solutions to be used. To address limitations associated with OSHA's or the manufacturer's cleaning/disinfection instructions, cleaning/disinfection processes have been developed, optimized, and evaluated through research studies that have been successfully implemented by many workplaces, like that of the protocol established by Bessesen et al. (Bessesen et al., 2015). In dusty workplace settings, the filter components are discarded when they become damaged, soiled, or clogged and when breathing resistance increases. However, healthcare setting users generally replace filter components annually since the environment is unlikely to have dust levels that result in increased breathing resistance (Hines, et al., 2021).

Key Benefits of EHMRs

EHMRs are the standard respiratory protective device used across many workplace settings such as automotive, chemical, manufacturing, and construction (National Academies of Sciences, 2019). However, as reported in one study prior to the COVID-19 pandemic, N95 FFRs have been the most common respiratory protection option among healthcare personnel, followed by PAPRs and, lastly, EHMRs (Wizner, 2016). Unlike FFRs, EHMRs are reusable, durable, and offer a variety of particulate and chemical protections through the various types of filters/cartridges available. They have been reported by healthcare personnel to have a better fit due to the facepiece material and adjustable straps, and personnel have reported an increased sense of protection while wearing EHMRs (Hines et al., 2017; Hines et al., 2019; NIOSH, 2020). The filters and cartridges are replaceable and easily changeable, which is valuable during times of high demand such as during a pandemic (Bach, 2017). EHMRs offer at least the same level of protection as an N95 FFR.

Additionally, EHMRs may potentially cost less over time and minimize hospital waste compared to disposable N95 FFRs. One hospital system reported that implementing EHMRs cost 10 times less per month than using disposable N95 FFRs (Chalikonda et al., 2020). Another hospital system reported that outfitting its 170 employees with N95 FFRs would cost $44,000 per year, whereas the total cost of using EHMRs would be approximately $2,000 per year (Elemental, 2020). A third hospital also reported estimates on cost, where annual costs for an EHMR program based on total cost/EHMR use, including a centralized decontamination program, was $123,560 less than a program based on single-use N95 FFRs (Hines et al., 2021). The EHMR manufacturer MSA Safety published a "cost of ownership" web calculator to compare the costs between N95 FFRs and EHMRs (MSA, 2021): Assuming 250 users at a facility, 1 N95 FFR used per day, 20 workdays per month, and a cost of the N95 FFR as $2.75; that of the EHMR as $18.75, and that of the replacement filter set as $7.50, annual savings for the first year of use would be $156,562.50 with one EHMR filter set change per year. It should be noted that additional costs are associated with EHMRs, including storage and cleaning/disinfection that may not be represented in these programs/tools.

Challenges of Implementing EHMRs

Challenges to implementing and using EHMRs include lack of familiarity/experience among healthcare personnel, discomfort while wearing the EHMR, possible difficulty communicating while wearing the EHMR, the facepiece shifting on sweaty or oily skin, the requirement to be carried during the workday and stored between shifts, the need to be tracked, cleaned and disinfected, and the need for a cartridge or filter change-out schedule (National Academies of Sciences, 2019; CDC, 2020b). Workers' perceptions of discomfort may be due to the EHMR's size and appearance, difficulty with breathing, interference with tasks (including interaction with patients) (Hines et al., 2019, 2017).

Prior to the COVID-19 pandemic, various studies were conducted to assess the user acceptability and logistical requirements of implementing EHMRs in healthcare settings. These studies reported as considerations: prevalence of use, stockpiling, user acceptance, communication, filter replacement, fit testing, cleaning, and disinfection. A brief review of this EHMR research initiated prior to the COVID-19 pandemic is given below, followed by research and other federal efforts related to EHMRs initiated in response to the pandemic.

EHMR Prevalence and Use in Healthcare Settings Prior to the COVID-19 Pandemic

In 2015, NIOSH and OSHA jointly published a Hospital Respiratory Protection Program Toolkit, which included resources for respirator program administrators to implement FFRs, EHMRs, or PAPRs in their RPPs (NIOSH and OSHA, 2015). In 2019, the National Academies of Sciences (NAS) published a report stating that EHMRs are a viable solution for respiratory protection during routine care and during an influenza pandemic (National Academies of Sciences, 2019). Despite these resources and report, the use of EHMRs in healthcare settings prior to the COVID-19 pandemic occurred but was generally infrequent and limited to a few hospitals in the United States (National Academies of Sciences, 2019; Wizner, 2016). As examples, the University of Maryland Medical Center and Faculty Physicians Inc. has been using EHMRs since 2009 as a result of N95 FFR shortages associated with the H1N1 influenza pandemic, and the Texas Center for Infectious Disease, a specialty hospital for treating tuberculosis, also used EHMRs prior to the COVID-19 pandemic (Elemental, 2020; The Joint Commission, 2020). In 2015, the Texas Center for Infectious Disease was reported to be the only known healthcare institution that used EHMRs as the primary respiratory protective device in its RPP, with reported justifications being the perceived reliability, better protection, comfort, cost effectiveness, and ease of fit testing and user seal checks experienced with EHMRs (National Academies of Sciences, 2019).

A 2015 survey reported that out of 289 clinicians, only 10% of respondents reported that EHMRs were available to them (compared to 94% for N95 FFRs); 6% of respondents reported that EHMRs were stockpiled in their facilities as compared to 67% for N95 FFRs (Pillai, 2015). In a 2016 survey developed by NIOSH and the American Association of Occupational Health Nurses, EHMRs were the least reported type of respirator used in the respondents' healthcare setting: 25.8% respondents reported use of EHMRs in the past year (n=57/220) as compared to 95.3% for N95 FFRs (n=221/232) and 76.9% for PAPRs

(n=173/225). The exclusive use of EHMRs (i.e., solely using EHMRs and not FFRs or PAPRs) was not reported in either year the survey was distributed (Wizner, 2016).

EHMR Stockpiling Prevalence and Considerations Prior to the COVID-19 Pandemic

In 2009, a preparedness study was conducted to determine what PPE would be needed during an influenza pandemic. Veterans Affairs (VA) medical centers reported that N95 FFRs would be cost-prohibitive for staff with prolonged periods of exposure, and instead, EHMRs with three sets of filters could be issued to those staff (e.g., physicians, nurses, respiratory technicians). An estimated 1,000 EHMR facepieces and reusable goggles would be needed per 50,000 patients. N95 FFRs would be limited to workers with infrequent exposure (Radonovich, 2009).

Also in 2009, the InterAgency Board for Equipment Standardization and Interoperability (IAB) published a report describing the gaps in respiratory PPE for infectious disease responses and recommendations for federally funded caches (The InterAgency Board, 2009). The IAB reported that the available number of N95 FFRs were not sufficient to meet the potential demands during an infectious disease response and provided recommendations regarding the appropriate logistics for training on the selection, use, care, fit testing, donning, doffing, and re-use of respirators and other types of PPE. The IAB also recommended that agent and circumstance-specific hierarchies be developed for first responders regarding the type of respirator (e.g., FFR, EHMR), filtrating series (N, R, P), or filtration level (95, 99, 100).

In 2015, the VA reported that the projected number of N95 FFRs needed for a 1918-like influenza pandemic would be 1.7–7.3 billion, with an estimated purchase cost of $1–5 billion and an annual storage cost of $100 million (Baracco, 2015). The VA reported that although EHMRs are infrequently used in healthcare settings, they could fill an important supply gap should supply shortages occur for N95 FFRs. For a population of 1 million, 10,612 EHMRs ($74,000–$127,000) would be needed per 6,112,500 N95 FFRs ($512,000–$1,001,000). The VA also reported that stockpiling a combination of disposable N95 FFRs and EHMRs would be the best approach for most health care organizations (Baracco, 2015).

In 2017, the NAS provided considerations regarding stockpiling EHMRs and noted both storage advantages and disadvantages. While EHMRs are bulkier and take up more space per unit in storage than FFRs, fewer EHMRs are required to meet pandemic needs (National Academies of Sciences, 2019). Regarding deployment of EHMRs to end users, healthcare facilities may not have the specific EHMR models and sizes to adequately transition from FFRs during surge situations, where fit testing and training would be needed.

In 2019, the inventory of 29 U.S. stockpiles showed that 31 APR models were available but less than 1% of them were EHMRs (69,072 out of approximately 53 million total stockpiled respirators). The EHMRs stockpiled at that time were the 3M 6000 series facepieces (3M 6100/6200/6300) and were stockpiled at two facilities. The corresponding 3M 2071 P95 cartridge filters for these EHMRs were also stockpiled across two facilities (n=377k) (L. A. Greenawald, Moore, Wizner, & Yorio, 2021).

At the onset of the COVID-19 pandemic, the Assistant Secretary for Preparedness and Response (ASPR) Strategic National Stockpile (SNS) did not stockpile EHMRs. This may have been due to funding limitations and because the priority was to address surge production capacity for FFRs (DHHS, 2017; Luce, 2020; Slack & Pulver, 2020). In June 2020, one EHMR manufacturer encouraged its stakeholders to voice their concerns to the federal government regarding the need to purchase and stockpile EHMRs at the federal stockpile level (MSA, 2020).

User Acceptance Studies Initiated Prior to the COVID-19 Pandemic

User acceptance of EHMRs has been reported as one potential barrier to implementing EHMRs as part of an RPP in healthcare settings. In 2008, Project BREATHE was initiated by the VA to understand performance parameters to design an ideal new healthcare respirator (National Academies of Sciences, 2019). This included prioritizing considerations for protection, durability, comfort, and compliance with federal standards.

In one study workers who were already assigned and wearing N95 FFRs, EHMRs, or PAPRs as part of their RPP completed a questionnaire regarding their attitudes, beliefs, and respirator preferences under different risk scenarios. N95 FFR users rated their respirators more favorably than those who wore EHMRs or PAPRs regarding comfort and communication; however, EHMR users rated their respirators higher regarding sense of protection (Hines et al., 2019). Reusable respirators were statistically significantly more likely to be preferred over N95 FFRs in higher-risk inpatient scenarios compared to “usual circumstance” scenarios (Hines et al., 2019). The results of this study suggested that reusable respirators are an acceptable alternative to N95 FFRs in healthcare settings of higher risk and offer a viable solution to prevent pandemic-generated respirator shortages. In another study, 289 infectious disease clinicians were queried as to any concerns regarding the use of N95 respirators, PAPRs, and EHMRs (Pillai, 2015). Limited data was collected for EHMRs as the majority of respondents reported that they were unsure or did not respond to prompts regarding the comfort, communication, cleaning, and cost of the potential expanded use of EHMRs. Interestingly, the respirator conservation strategies from most to least endorsed by these infectious disease clinicians included extended use of N95 FFRs, reuse of N95 FFRs, use of PAPRs, use of surgical masks, and lastly, use of EHMRs (Pillai, 2015). Free text queries of this survey led to a theme surrounding the lack of knowledge about EHMRs. In 2017, there was still a lack of awareness among healthcare settings and a reported need for education about EHMRs being a viable option for respiratory protection (Bach, 2017).

Communication and Speech Intelligibility Studies Initiated Prior to the COVID-19 Pandemic

Effective communication with patients and coworkers in healthcare settings is critical for patient care (Palmiero, 2016). In 2010, Radonovich et al. evaluated the speech intelligibility when comparing surgical masks, N95 FFRs, PAPRs, and EHMRs in the healthcare setting (Radonovich L, 2010). The worst-performing respirator evaluated was the EHMR, associated with a speech intelligibility rating of 72% compared to 85%, on average, among the surgical masks, FFRs, and PAPRs (collectively) and 89% without a respirator. EHMRs

with voice augmentation equipment was associated with higher speech intelligibility than models without this equipment (Radonovich L, 2010).

In 2016, speech intelligibility using the Speech Transmission Index (STI) was leveraged from a National Fire Protection Association standard and evaluated across surgical masks, N95 FFRs, and EHMRs. The EHMR models had the most significant impact on speech intelligibility, differing from baseline by 42% for the two models tested and falling in the “Poor” and “Fair” STI quality category. (Palmiero, 2016). Full facepiece APRs with chemical, biological, radiological, and nuclear (CBRN) protections are evaluated by NIOSH for speech conveyance/intelligibility using a modified rhyme test (MRT) where a score of ≥70% is required (NIOSH, 2007). No speech conveyance/speech intelligibility is currently required for NIOSH-approved EHMRs. One study leveraged this CBRN MRT and pass/fail threshold of ≥70% to assess the speech intelligibility between N95 FFRs and EHMRs, where a significant difference between these two types of respirators was found with the N95 FFR having a higher MRT score, though both types of respirators exceeded this minimum threshold (Ciconte, R and Danyluk Q., 2013).

Training and Fit Testing Studies Initiated Prior to the COVID-19 Pandemic

NIOSH NPPTL has an ongoing study to evaluate the successful and rapid fit testing and training of EHMRs across three acute care hospitals; this study is titled “Just-in-time Elastomeric Training and Fit Testing” (JET FIT) (NIOSH, 2020). At one of these hospitals, an outbreak simulation was conducted among healthcare personnel where 80% of participants wore an EHMR and 20% wore an N95 FFR. Both user groups were rapidly fit tested and trained using a video. Inspection, donning, positive-pressure user seal check, negative-pressure user seal check, doffing, and disinfection were evaluated among the two user groups (Pompeii et al., 2020). In the EHMR group, 92.2% passed fit testing during the first attempt compared with 88.5% in the N95 FFR group. The mean time to complete fit testing for the EHMR group, including total number of attempts, was not statistically significantly different compared to the N95 FFR group, suggesting that healthcare personnel can be rapidly fit tested and trained to use EHMRs during public health emergencies (Pompeii et al., 2020). The data collection at these acute care hospitals was completed between 2017 and 2020 and early results from two of these three hospitals were published; complete methods and results are under development and publications will be forthcoming.

Cleaning and Disinfection Studies Initiated Prior to the COVID-19 Pandemic

The protocol described by Bessesen et al. is a simple approach to cleaning and disinfecting EHMRs in healthcare settings (Bessesen et al., 2015; CDC, 2020c). Through this research, it was found that healthcare workers following the manufacturer’s instructions made multiple errors but those that followed the protocol developed by Bessesen made no errors when disinfecting the facepieces (Bessesen et al., 2015). In a separate study, cleaning and disinfection perceptions were evaluated among healthcare EHMR users where 52% of those surveyed reported always disinfecting their respirators in accordance with the hospital’s standard practice, and 9% of those surveyed reported regularly cleaning the EHMR with soap and water in accordance with the manufacturer’s recommendations (Hines SE et al., 2020a).

In a study of decontamination of elastomeric face masks, wiping only (without submersion in water/detergent) with a disinfectant wipe did not consistently remove all viral contaminants; however, submersion in detergent and water along with disinfection did. The most consistent viral removal occurred with use of bleach (Hines et al., 2020b).

In one study, the durability of five new EHMR models was evaluated after being cleaned 0, 75, and 150 times with 0.5% Neutrawash and disinfected with 0.1% bleach (ARA, 2019). EHMR cartridges (where the filters were enclosed) were cleaned by wiping with a 0.5% Neutrawash solution and then with a PDI SaniCloth wipe. Fit testing was conducted, and the EHMRs were evaluated against NIOSH's minimum performance requirements for filtration efficiency, exhalation valve leakage, and inhalation/exhalation resistance. Out of these tests, only one inhalation resistance failed, but it was potentially attributed to the use of a wrong size mannequin. The study concluded that the EHMR models evaluated maintained their integrity and would continue to provide the same level of respiratory protection to healthcare workers whether new or cleaned 150 times using the developed cleaning protocol (ARA, 2019).

The efficacy of EHMR cleaning and disinfection agents and cleaning/disinfection frequency has not been well characterized. In one study, EHMRs were contaminated with influenza virus and soiling agents (e.g., artificial skin oil, artificial saliva) (Lawrence et al., 2017). Upon treatment of the EHMRs with cleaning or cleaning plus disinfectant, cleaning alone was reported to be sufficient for removing/killing influenza. However, respirator material type and design, and the specific hazard(s) being disinfected (e.g., SARS-CoV-2, hepatitis C, bacterial spores), should be considered when implementing cleaning/disinfection protocols. NIOSH has funded two acute care hospitals to evaluate the effectiveness of various disinfectants at removing microorganisms from the surface of EHMRs (NIOSH, 2020).

THE ROLE OF EHMRs IN CURRENT AND FUTURE PANDEMICS

In the spring of 2020 and with the onset of wider EHMR use in healthcare settings, numerous media reports raised awareness and publicized advantages of EHMRs for use during the COVID-19 pandemic amidst the reported FFR shortages (Elemental, 2020; Fitzgerald, 2020; Forgany, 2020; Luce, 2020; Soucheray, 2020). These reports highlighted the advantages of EHMRs, including their cost savings, comfort, protection, and acceptability by healthcare personnel.

The expanded use of EHMRs during the COVID-pandemic prompted the development and introduction of numerous EHMR guidance documents, procurement actions, and research activities which are briefly described below.

FFR Shortages and CDC Optimization Strategies for "N95 Respirators"

During the COVID-19 pandemic, disposable FFR shortages had a substantial impact on the national response, affecting many workplaces that rely on respiratory protection. Severe FFR shortages resulted in workers relying on alternative approaches to respiratory protection. CDC/NIOSH published strategies to optimize the supply of N95 FFRs (referred to as "N95 respirators" in the CDC guidance to align with common terminology used in

healthcare) (CDC, 2021b; de Perio et al., 2020). These strategies included conventional, contingency, and crisis capacity strategies. Crisis capacity strategies are not commensurate with contemporary U.S. standards of care and should only be considered during periods of known N95 respirator shortages (CDC, 2021b). These crisis capacity strategies for N95 FFRs included the extended use and limited reuse of N95 FFRs, use of decontaminated N95 FFRs, wearing FFRs that meet an international respirator standard (e.g., KN95) that are similar to NIOSH-approved N95 FFRs, and wearing N95 FFRs that are past their manufacturer-designated shelf life (CDC, 2021b).

Consistent with these crisis capacity strategies, in March 2020, the Food and Drug Administration (FDA) published emergency use authorizations (EUA) for healthcare settings, which separately authorized the temporary use of 1) all particulate APRs that were either NIOSH-approved or previously NIOSH-approved but had since met their manufacturer-designated shelf life; 2) specific decontamination methods for specific NIOSH-approved respirator models; and 3) respirators that met an international standard (i.e., non-NIOSH-approved respirators) (FDA, 2021b, 2021c). NIOSH conducted assessments on many different international respirator models and found several instances where these respirators had filtration efficiencies below 95% and substantial inconsistencies in filtration performance (Andrews et al., 2021; NIOSH, 2021b, 2021c). The results directly contributed to FDA continuously updating the EUAs to add and remove RPDs authorized for use in healthcare settings. Specifically, in part due to these findings, on May 7, 2020, the FDA revised the EUA for RPDs manufactured in China by removing many of the manufacturers and models initially included in Appendix A of the EUA (Andrews et al. 2021). NIOSH also evaluated decontaminated N95 FFRs and found that 8 of the 19 decontamination techniques evaluated negatively impacted the fit and/or filtration efficiency of the N95 FFR on which the technique was tested (Quinn, 2021). There are also implications related to extended use/reuse of FFRs, including self-inoculation and potential loss in effectiveness after multiple donnings (Fisher & Shaffer, 2014). As the supply of NIOSH-approved N95 FFRs increased, on June 30th, 2021, the FDA revoked the EUAs related to imported, non-NIOSH-approved FFRs, and the decontamination of FFRs. On July 12th, the FDA reissued the EUA related to NIOSH-approved respirators to continue authorizing the use of NIOSH-approved particulate APRs but no longer authorize the use of FFRs past their manufacturer-designated shelf life (FDA, 2021b).

Federal Government Efforts Related to Expanded Use of EHMRs

As an alternative to N95 FFRs, a strategy commensurate with U.S. standards of care includes wearing a NIOSH-approved reusable respirator, such as an EHMR or PAPR. By having the same APF, EHMRs offer equivalent protection to N95 FFRs. Also, the filtration mechanism for particulates—whether biological or non-biological in nature—is based on particle size, shape, and density (Brosseau LM & Shaffer R, 2014). Therefore, biological particles (including those containing SARS-CoV-2, the virus that causes COVID-19) and non-biological particles would be adequately filtered by EHMRs with a minimum of a N95-series filter.

As mentioned above, in March 2020 the FDA issued the EUA authorizing the use of all NIOSH-approved particulate APRs in healthcare settings, to include NIOSH-approved FFRs, EHMRs, full facepiece elastomeric APRs, and PAPRs (de Perio et al., 2020; FDA, 2020). Concurrently, the CDC and NIOSH provided recommendations and strategies to optimize the supply of EHMRs and PAPRs in healthcare settings during conventional and surge demand (CDC, 2020a, 2020c). The CDC's optimization strategies for EHMRs included recommendations for use, inspections, cleaning and disinfection, extended use of filter cartridges, filter replacement, storage, sharing EHMRs, and OSHA's temporary waiving of fit testing requirements during the COVID-19 public health emergency (CDC, 2020c; OSHA, 2020). Details of the optimization strategies will not be provided here, but of note was the extended use of filter cartridges as a crisis capacity strategy. The CDC recommended the use of particulate filter cartridges housed in a hard, cartridge body (as opposed to open, pancake-style/flexi filters) due to their ability to be wiped down (CDC, 2020c). As a contingency capacity strategy during surge demand, the CDC recommended that unless the particulate filter cartridges were visibly soiled, wet, or damaged, or if the respirator becomes notably harder to breathe through, the filters could be used for at least one year (CDC, 2020c). This practice was used successfully by the University of Maryland School of Medicine and TCID (American College of Medical Toxicology, 2020; National Academies of Sciences, 2019). The CDC also held a webinar titled "Elastomeric Respirators for U.S. Healthcare Delivery, Key Considerations" early in the pandemic to communicate the utility of EHMRs in healthcare settings (CDC, 2020b). This webinar provided background about respiratory protection and the hierarchy of infection protection measures, an overview of the CDC optimization strategies for EHMRs, results from an EHMR study in healthcare settings, and lessons about EHMR use in healthcare settings.

In addition to the CDC's EHMR optimization strategies and webinar, the continued shortage of N95 FFRs resulted in additional EHMR-related response activities from the federal government. On March 19, 2020, the Federal Emergency Management Administration (FEMA) activated the National Response Coordination Center (NRCC) to lead and coordinate the federal response for the COVID-19 pandemic (DHS, 2020). NRCC housed several task forces, including the Healthcare Resilience Task Force. In June 2020, this Task Force was transitioned to the Department of Health and Human Service's Assistant Secretary for Preparedness and Response (HHS ASPR) and referred to as the Healthcare Resilience Working Group (HRWG). Within the HRWG, the Supply and Preservation Team—comprised of representatives from the CDC (including NIOSH and other entities within CDC), FDA, ASPR, Department of Homeland Security (DHS), and FEMA—assisted in the development, education, and promotion of federal PPE guidance. These activities included educating and promoting the CDC's optimization strategies, including the use of NIOSH-approved EHMRs as a viable alternative to N95 FFRs. The HRWG's Supply and Preservation Team activities related to the promotion of EHMRs included conducting several webinars with state, territorial, local, and tribal entities, publication of a fact sheet related to EHMRs and PAPRs, and initiation of a webinar hosted by the American College of Medical Toxicology (American College of Medical Toxicology, 2020; HHS ASPR Healthcare Resilience Working Group, 2020). This webinar included panelists representing hospital systems sharing their experiences using EHMRs in healthcare settings prior to

COVID-19, as well as a hospital system that fully implemented EHMRs as a result of N95 FFR shortages (FEMA and HHS, 2020) (American College of Medical Toxicology, 2020). DHS also held various trainings related to reusable respirators and how to implement them as part of an RPP (DHS, 2021).

Beginning with discussions originating in the HRWG and other federal government COVID-19 task forces, a strategy was established between NIOSH and ASPR's SNS to supplement the supply of FFRs with EHMRs across the nation. In collaboration with the SNS, NIOSH published a Federal Register Notice (FRN) to receive input on the nationwide distribution strategy and participation in EHMR demonstration projects to better understand user acceptance and implementation barriers for EHMRs (Federal Register, 2020). Further, in February of 2021, ASPR's SNS published a solicitation to procure EHMRs. With NIOSH NPPTL's technical support, the solicitation included the procurement of 375,000 NIOSH-approved EHMRs with particulate filters and 375,000 replacement sets of particulate filters (DHHS ASPR, 2021). Specifically, these EHMRs were to have no or filtered exhalation valves, where P100 particulate filters were preferred but N95 particulate filters were also acceptable. The particulate filters were specifically requested to be housed in a cartridge body (as opposed to open, pancake-style filters). This solicitation closed in March 2021.

Although not a federal agency, the IAB is a voluntary panel of emergency preparedness and response practitioners with participation from local, state, and federal government organizations. In collaboration with International Personnel Protection Inc. and Emergency Response Tips, the IAB published guidance for first responders regarding respiratory protection strategies during a pandemic, including for both disposable and reusable respirators. The recommendations were for three phases of supply levels: when respirator supplies are available, low, or are depleted (Baxter CM & Stull JO, 2020). When EHMR with particulate filters are available, P100 filters are recommended. NIOSH-approved EHMRs with particulate filters or chemical cartridges are not interchangeable between manufacturers, unlike NIOSH-approved APR CBRN canisters which can be interchanged during an emergency (NIOSH, 2018) (the IAB guidance states that when APR CBRN respirator supplies are low, the emergency rule may be utilized if authorized by the incident commander to leverage APR CBRN canister interoperability).

Throughout the COVID-19 pandemic, NIOSH NPPTL led the U.S. efforts related to the regulatory approval, development of guidance, initiation of new research, and increasing awareness of EHMRs as a viable alternative to N95 FFRs (e.g., through numerous webinars, blogs, webpages). One specific EHMR effort stemmed from the increasing concerns from organizational settings whose employees needed not only respiratory protection but also source control to avoid the unfiltered air potentially infecting a worker or patient. The FDA acknowledged that a major obstacle limiting the wider use of reusable respirators in healthcare settings has been the inclusion of exhalation valves as a design feature, suggesting the respirator cannot provide adequate source control (FDA, 2021a). Specifically, the exhaled air through the exhalation valve might be contaminated and could potentially compromise the sterile field. During the COVID-19 pandemic, the CDC initially did not recommend the use of respirators (FFRs or EHMRs) with exhalation valves in certain healthcare settings, including operating rooms, due to the wearer's unfiltered breath exiting

the valve (CDC, 2021a) (NIOSH, 2021e). The CDC's original guidance for users that did not have an alternative to wearing a respirator with an exhalation valve was to cover the exhalation valve with a cloth face covering, surgical mask, or procedure mask (HHS ASPR Healthcare Resilience Working Group, 2020). NIOSH NPPTL began conducting research on N95 FFRs with exhalation valves and found that even without covering the valve, N95 FFRs with exhalation valves provide the same or better source control than surgical masks, procedure masks, cloth masks, or fabric coverings (Portnoff L, 2020). The CDC's guidance for N95 FFRs was updated to reflect these findings, but continued to state that EHMRs with an exhalation valve should not be worn where source control is needed such as in surgical and other healthcare settings due to concerns that air coming out of the exhalation valve may contaminate the sterile field (CDC, 2021a). Healthcare facilities continue to recommend covering their EHMR exhalation valves with surgical masks (Hines et al., 2021). NIOSH NPPTL is also currently funding and conducting EHMR exhalation valve research (NIOSH, 2021e), which will be briefly expanded upon in a later section.

In response to industry demand for respirators with exhalation valves to have source control capabilities, some EHMR manufacturers re-designed products to meet the needs of protecting the wearer and providing adequate source control to protect others. NIOSH NPPTL evaluated and approved these EHMRs that either did not have exhalation valves (Table I) or were designed with filtered exhalation valves (Table II) and met NIOSH's minimum performance requirements. The NIOSH Approval Holders MSA Safety, Dentec Safety Specialists, GVS Filter Technology, and AirBoss Defense have NIOSH-approved EHMRs with no exhalation valve, where the absence of an exhalation valve forces both the inhaled and exhaled air to go through the particulate filters. These approvals are only for EHMRs with particulate protection. The NIOSH Approval Holder 3M™ has the NIOSH-approved EHMR 6000 series configured with an accessory filter to be installed over the exhalation valve as part of six specific NIOSH approvals. This filter allows the exhaled air to be filtered through the accessory filter. In addition to these specific approvals with particulate protection, the 3M 6000 series has separate NIOSH approvals for the use with chemical cartridges, so the accessory filter has the potential to be applicable across many industries. These innovative advancements in EHMR technology alleviate the concern for source control, especially in healthcare settings where a sterile field may be necessary. All current NIOSH-approved respirators can be found on NIOSH's Certified Equipment List (NIOSH, 2021a). As it is not currently required for approval, NIOSH did not assess speech intelligibility for these respirators.

Data Gaps Identified During the COVID-19 Pandemic

Exhalation Valves and Source Control—During the COVID-19 pandemic, healthcare agencies and personnel expressed concerns that SARS-CoV-2 may spread from unfiltered exhaled air passing through the respirator's exhalation valve. As noted above, while preliminary data suggests that the exhaust of particles through FFRs with exhalation valves is less than or comparable to that of masks without valves (e.g., cloth masks, procedure masks), research gaps remain related to droplet source generation, source control, and droplet airborne mechanisms (NIOSH, 2021e; Portnoff et al., 2020). There is currently not published data regarding exhaled air for EHMRs with exhalation valves.

Prior to manufacturers redesigning their EHMRs to have no exhalation valves or to have filtered exhalation valves, NIOSH NPPTL initiated several research studies to better understand the effects of covering the exhalation valve. These studies include 1) covering or modifying the EHMR to redirect exhaled breath through the filters and evaluating the exhalation resistance and concentration of carbon dioxide inside the facepiece; and 2) evaluating exhalation valve adaptors and assessing their effects on filtration efficiency and pressure buildup inside the facepiece (NIOSH, 2021e). These studies are ongoing, and publication is forthcoming.

Filter Changeout in Hospital and First Responder Settings—Another area of interest has centered around particulate filter changeout in both hospital and non-hospital settings during extended use. The CDC's contingency capacity strategy for particulate filter replacement of up to one year was based on experienced healthcare providers in healthcare settings, where the air is generally free from dust, oily aerosols, or other contaminants that may be not be representative of first responder environments. The authors are aware of one EHMR manufacturer who has evaluated the filtration efficiency and breathing resistance of P100 particulate filters in a hospital system after 0, 3, 6, 9, and 12 months of use; this study is ongoing. The authors are not aware of similar studies for first responder settings.

Communication—Over the past decade, both healthcare and first responder user groups have cited communication as a barrier for implementation of EHMRs. Although more common with full facepiece elastomeric APRs, recent NIOSH-approved EHMRs have speech diaphragms to assist in communication by enhancing speech transmission (as shown in Table I). Additionally, NIOSH NPPTL continues a research effort to design and produce prototypes of EHMRs specifically for healthcare settings, with considerations for speech diaphragms, field of vision, head harness comfort, and overall low-profile (Fernando, 2021).

EHMR Stockpiling Considerations—In the 2018 NAS report, the durability and reusability of elastomeric respirators are reported to make them desirable for stockpiling for emergencies, where the need for large volumes of respirators can be anticipated (National Academies of Sciences, 2019). NIOSH does not require approval holders (respirator manufacturers) to establish a shelf life for EHMR facepieces or particulate filters, but many choose to do so. If designated by the manufacturer, EHMR particulate filters typically have a manufacturer-designated shelf life of two or five years. In 2020, NIOSH published results from collecting and testing stockpiled 3M 2071 P95 filters (n=172) to determine if they still met NIOSH's minimum performance requirements for filtration efficiency and inhalation/exhalation resistance (Greenawald et al., 2020). Four manufacturing lots of these particulate filters were collected from two U.S. stockpile facilities. All filters were manufactured in 2006, and testing took place approximately eight years past their 5-year manufacturer-designated shelf life. When evaluated, all filters met NIOSH's minimum performance requirements; however, this evaluation was limited to only a single-filter model as this was the only EHMR filter model available among the ten partnering stockpile facilities. More data are needed regarding performance across different models and filter efficiency levels if filters are stored longer than their manufacturer-designated shelf life (this is not recommended but may be a reality). In general, product rotation and replenishment

should occur for all types of stockpiled PPE prior to exceeding the manufacturer-designated shelf life.

Regarding the costs of stockpiled EHMRs, the NAS report states that EHMRs have the lowest costs when considering acquisition and warehousing. However, implementation costs, including maintenance, cleaning/disinfection, or staff training have not been factored into those analyses, and additional total comparative costs analyses are needed between different types of respirators (National Academies of Sciences, 2019).

There are logistical challenges to stockpiling EHMRs that must be considered. First, components of the NIOSH-approved EHMR configuration may have differing designated shelf life dates, such as between the facepiece (e.g., 10 years) and the filter cartridges (e.g., 5 years), which may cause issues if all components are packaged together as one kit. Additionally, replacement components may also be stockpiled, including the appropriate number of replacement straps, inhalation valves, and exhalation valves. Some manufacturers may have specific fit testing adaptors for their EHMR models and it may be beneficial for these to be stockpiled as well. Finally, stockpile managers should consider the appropriate size distribution of facepieces based on intended end users (e.g., nearby hospitals). Through NIOSH's personal communication with EHMR manufacturers, an average facepiece size distribution for healthcare settings is approximately 25% small, 60% medium, and 15% large, which was incorporated into the SNS EHMR solicitation (DHHS ASPR, 2021).

User Acceptance and Implementation Barriers—NIOSH is working with two hospital systems to develop EHMR implementation guidance for hospital settings (NIOSH, 2020, 2021e). In February 2021, the University of Maryland School of Medicine published this implementation guidance (Hines et al., 2021). The Allegheny Health Network completed its guidance, which is available upon request. These guidance documents will help U.S. healthcare settings transition from disposable respirators to EHMRs while implementing EHMRs as part of their RPPs (NIOSH, 2021e).

NIOSH and partners are continuing to explore perceptions and concerns of healthcare personnel when wearing EHMRs. Most recently, the University of Maryland published their NIOSH-funded research on the physiological impact of wearing a surgical mask over an EHMR. This research showed physiological parameters (e.g., carbon dioxide, oxygen saturation, heart rate) remained within normal ranges when wearing an EHMR with a surgical mask covering the exhalation valve (Zhuang et al, 2021). NIOSH is collaborating with two acute care hospital systems to survey nearly 1,000 EHMR wearers to understand their perspectives and concerns regarding EHMRs in healthcare settings. (NIOSH, 2020). Concurrently, NIOSH continues to explore strategies to increase the supply of EHMRs (Greenawald et al., 2020). As previously mentioned, NIOSH is assisting the SNS with the nationwide distribution strategy of those 375,000 EHMRs procured by the SNS. The FRN seeking input and participation in the distribution was open to all healthcare settings, including hospital, intensive care units, outpatient, first responders, correctional facilities, long-term care, and dental clinics. During the development of this FRN, multiple unions and associations—such as the New York State Nurses Association, American Federation of Teachers, and American Federation of Government Employees—formally endorsed the

use of EHMRs in healthcare settings. The input regarding the nationwide deployment of EHMRs provided by stakeholders—as well as a discussion on the development of the demonstration projects—is discussed in Paper 2 of this series (Haas et al., 2021), and the results of these nationwide demonstration projects will be in forthcoming publications.

CONCLUSIONS AND ADDITIONAL RESOURCES

Reusable respirators such as EHMRs are a potential solution to disposable respirator shortages during a public health emergency. The COVID-19 pandemic and associated N95 FFR shortages led to the increased awareness of the existence and utilization of EHMRs in healthcare settings and promulgated the advancement of EHMR technology and research related to user acceptance, cleaning/disinfection, source control capabilities, communication, and filter changeout.

Stockpiling practices for EHMRs should be further explored, including the storage and potentially differing shelf lives of the EHMR components if stored together (e.g., facepiece and filter). Additionally, stockpile purchasers should take the end users into consideration when purchasing the EHMR facepiece size distribution and filter/cartridge type. Coordination between stockpiles and healthcare settings should occur so the end users are aware of and familiar with the EHMR model and sizes prior to a public health emergency.

If EHMRs are part of an RPP during conventional operations, users will have the opportunity to become more familiar with these devices, be trained, and fit tested prior to an emergency. However, additional research in organizational and user acceptance, implementation guidance, and training may still be needed for wider adoption. Importantly, guidance is generally limited to hospital settings, while guidance is lacking for other healthcare settings such as long-term care facilities, outpatient settings, first responders (e.g., emergency medical services, police), and other occupations with high risk of exposure to infectious diseases. Current EHMR implementation guidance may need to be updated, or new guidance may need to be developed for these unique worker settings. The results of the current and future projects will inform this guidance for workers across various healthcare settings and will be described in future publications.

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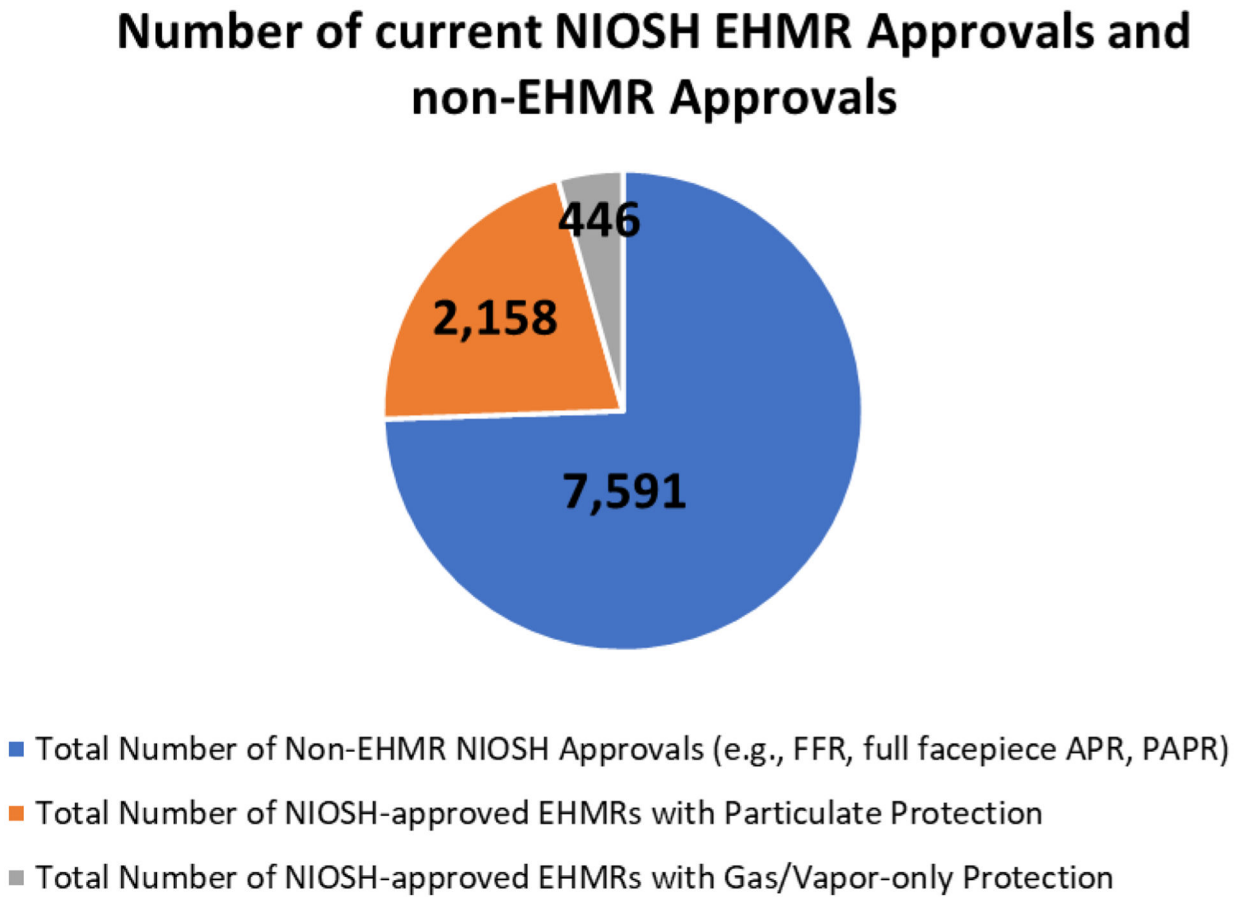
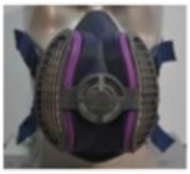


Figure 1.
Total number of active NIOSH non-EHMR approvals (blue), those EHMRs offering particulate protection (orange; Schedule 84A) and those EHMRs offering only gas/vapor protection (grey; Schedule 23C) spanning approvals from 1995 – 2021. Data current as of December 14th, 2021.

Table I.

Current NIOSH Approvals for EHMRs with No Exhalation Valve (as of 12/27/2021)

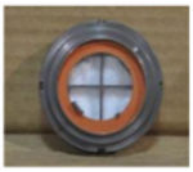
NIOSH Approval Holder	NIOSH Approval Number	Description	Notes	Picture
MSA Safety Innovation	TC-84A-9256* (P100) TC-84A-9257 (P100) TC-84A-9260 (P95) TC-84A-9261 (P95)	Advantage 290 with P100 or P95 filters	No exhalation valve; no speech diaphragm	
MSA Safety Innovation	TC-84A-9309 (P100) TC-84A-9310 (P100) TC-84A-9311 (P95) TC-84A-9312 (P95)	Advantage 900 with speech diaphragm and with P100 filters	No exhalation valve; with speech diaphragm	
Dentec Safety Specialists Corp.	TC-84A-9355 (N95) TC-84A-9356* (P100)	Comfort-Air 400 NX series with 158DN5 (N95) or 158TLP0 (P100) filters	No exhalation valve	
AirBoss Defense Group	TC-84A-9371 (N100)	41A00 (small/medium) and 41A07 (large/x- large) with S-70062 filter (N100 filter)	No exhalation valve; with visor accessory	
GVS Filter Technology UK Ltd	TC-84A-9320 (P100)	Elipse with P100 filters	No exhalation valve	

* = purchased by the SNS in 2021. Some models approved after the SNS solicitation.

Photos courtesy MSA, Dentec, AirBoss Defense Group, and GVS

Table II.

Current NIOSH Approvals for EHMRs with a Filtered Exhalation Valve (as of 12/16/2021)

NIOSH Approval Holder	NIOSH Approval Number	Description	Notes	Picture
3M™	TC-84A-0376* (N95) TC-84A-0022 (P100) TC-84A-0071 (P100) TC-84A-5536 (N95) TC-84A-5544 (P100) TC-84A-5894 (P100)	6000-series with N95 or P100 filter and exhalation valve filter	Exhalation valve accessory	

* = purchased by the SNS in 2021.

Photo courtesy 3M™