Streamlining Regulatory Oversight of Respirators Used in Health Care Settings Will Improve Worker Protection

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Introduction

Respirators used in U.S. health care settings, including disposable filtering facepiece respirators (FFRs), full face respirators, reusable elastomeric half mask respirators (EHMRs), and powered air-purifying respirators (PAPRs), must be approved by the National Institute for Occupational Safety and Health (NIOSH) *(see Figure 1)*. The Occupational Safety and Health Administration (OSHA) requires that only NIOSH Approved® respirators be used in U.S. workplace settings to protect workers from inhalation hazards (NIOSH Approved® is a certification mark of the U.S. Department of Health and Human Services, registered in the United States and several international jurisdictions). When intended for use in health care, some FFRs are also subject to clearance from the U.S. Food and Drug Administration (FDA) (FDA, 2017). A continued lack of understanding, alignment, and communication regarding federal regulations and guidance on the use of air-purifying respirators (APRs) in health care settings is creating barriers to the use of certain NIOSH Approved respirators. The confusion resulting from multiple regulatory oversight processes impedes access to and raises the cost of effective respiratory protection, placing the health and safety of those working in the health care sector—including health care workers (HCWs) and support staff (e.g., facilities and environmental services)—and patients at risk.

Building on prior federal agency efforts to explain and simplify regulatory oversight processes for respirators used in health care, this paper aims to 1) clarify that a broad range of NIOSH Approved respirators—including FFRs, EHMRs, and PAPRs—are appropriate for use in health care to protect users from airborne infectious diseases and do not compromise patient or worker safety; and 2) highlight potential steps to address confusion about which respirators can be used in health care settings.

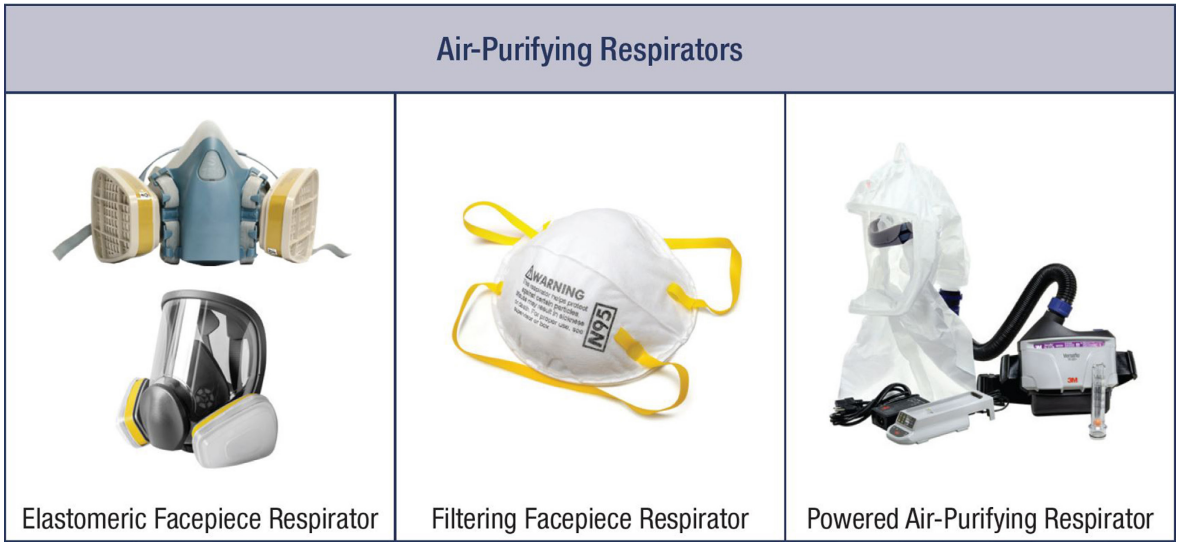

FIGURE 1 | Types of Air-Purifying Respirators
SOURCE: Adapted from NASEM, 2022b.

To achieve these aims, this paper will:

- Discuss the current state of the science on critical performance characteristics of respirators used in hospitals and other health care settings, including microbial particle filtration efficiency and the lack of evidence for fluid resistance, flame resistance, and biocompatibility requirements;
- Discuss experiences using NIOSH Approved respirators other than surgical N95® FFRs in hospitals and other health care settings (N95® is a certification mark of the U.S. Department of Health and Human Services and is registered in the United States and several international jurisdictions); and
- Identify and discuss necessary guidance and reg-ulatory actions to optimize respirator use in hos-pitals and other health care settings to promote and protect the health and safety of HCWs, support staff, and patients.

Regulatory Landscape for Respirators Used in Health Care

Relevant Federal Authorities

Three federal agencies have oversight responsibilities related to the use of respirators in health care. OSHA has regulated health and safety standards in U.S. workplaces since 1970—including the use of respiratory protection—and since 1979 has required employers in general industry, including health care, to select NIOSH Approved respirators when necessary to protect workers from inhalation hazards (OSHA, 1971; 1979). In 1972, NIOSH was authorized to certify respirators used in U.S. workplaces (Spelce et al., 2019). It was not until decades later that the FDA extended its regulatory authority regarding the sale of medical devices to include NIOSH Approved N95® respirators for HCWs (FDA, 2004). The FDA designated these respirators as Class II medical devices and required that they undergo a premarket clearance process—or 510(k) clearance—that requires manufacturers to demonstrate that their respirators meet certain standards for fluid resistance, flame resistance, and biocompatibility to be considered surgical respirators (FDA, 2004). The 510(k) clearance process—one of the regulatory pathways the FDA uses to evaluate the safety and effectiveness of a medical device before it can be legally marketed for sale—differs from the NIOSH approval process (FDA, 2023c). To ensure NIOSH Approved respirators will provide wearers with an expected level of respiratory protection, NIOSH conducts a series of tests on respirators submitted by the manufacturer for approval to certify that the respirators meet minimum construction, performance, and respiratory protection standards—per 42 CFR Part 84 (NIOSH, 2021). Once a respirator has been evaluated by NIOSH and shown to have met the standards, it receives NIOSH approval and the manufacturer is granted authorization to market the device as "NIOSH certified" (NIOSH, 2021). The FDA does not conduct its own device testing as part of the 510(k) clearance process but rather reviews data manufacturers are required to submit that demonstrate that the device's safety and effectiveness are substantially equivalent to an existing legally marketed device (FDA, 2023c).

Lack of Regulatory Alignment and Confusion Created by Differing Federal Regulatory Processes

In contrast to other industries, where only OSHA and NIOSH have regulatory authority for respiratory protection programs and devices, the additional regulatory authorities and processes required for respirators in health care have resulted in uncertainty among respirator manufacturers, purchasers, and users (NASEM, 2017). Before a 2017 memorandum of understanding (MOU) between NIOSH and FDA (MOU 225-18-006), N95 FFRs were required to undergo NIOSH approval and FDA clearance through separate regulatory processes before they could be labeled and marketed for use in health care as "surgical N95 respirators" (also known as SN95 FFRs) (FDA, 2017). Currently, manufacturers seeking to market a FFR as an SN95 FFR must submit an application to NIOSH, which conducts an evaluation of the device against threshold criteria—elements used by the FDA to determine if a device must undergo the 510(k) clearance process for medical devices—as specified in the MOU. If the respirator submitted to NIOSH for approval exceeds the FDA's threshold evaluation criteria for N95 FFRs, the device undergoes both the FDA's 510(k) clearance process and NIOSH's respirator approval process (FDA, 2022). An N95 FFR exceeds the FDA threshold evaluation criteria and would be subject to the 510(k) clearance process if 1) the N95 FFR is labeled or intended for use/protection against any of the following: specific disease and/or infection prevention, viral or bacterial filtration performance, antimicrobial function, hypoallergenicity, and filtration of surgical smoke or plumes; or 2) the N95 FFR contains technologies including, but not limited to antimicrobial coatings, coatings intended to modify the performance of the product that are not related to the product's respiratory protection characteristics, drug delivery systems, products that contain nanoscale technologies, or the combination of an N95 FFR with another FDA-regulated product (FDA, 2017). If the device does not exceed the threshold criteria, it will be exempt from the 510(k) process and will only undergo review by NIOSH, which must evaluate its perfor-

mance against both NIOSH and FDA requirements. Current NIOSH Approval Holders looking to market a previously NIOSH Approved N95 FFR to the health care industry as an SN95 FFR are required to submit a new application to NIOSH, including their testing data on flame resistance, fluid resistance, and biocompatibility (FDA, 2017).

Research in this area finds that commonly used non-surgical NIOSH Approved N95 FFRs meet and/or exceed the performance of SN95 FFRs when subjected to testing standards used by the FDA for fluid resistance and flammability (Portnoff et al., 2021; Rengasamy and Niezgoda, 2019; Rengasamy et al., 2021; 2018; 2015). The same is likely true for other NIOSH Approved respirators, including reusable EHMRs, as the silicone and other polymeric and elastomeric materials commonly used in the manufacturing process (NASEM, 2019) have been demonstrated to be flame- and fluid-resistant (Alarifi, 2023; Schwark and Müller, 1996; Zare et al., 2021). Furthermore, NIOSH Approved respirators must be biocompatible, as the NIOSH respirator approval process requires testing for toxicity to human cells, skin sensitization, and skin irritation, all of which encompass FDA's biocompatibility evaluation endpoints for devices in contact with intact skin (FDA, 2023e; NIOSH, 2020; NASEM, 2017). Thus, this oversight process redundancy has created confusion and needless additional regulatory requirements, resulting in increased costs for respirator manufacturers seeking to market their N95 FFRs to healthcare as SN95 FFRs. Manufacturers of SN95 FFRs are required to submit and pay for each NIOSH approval, as well as the registration and listing fees required by the FDA for medical devices. Furthermore, should the submitted FFR exceed the FDA's threshold criteria, as mentioned above, manufacturers are then required to pay fees associated with the FDA's 510(k) clearance process (FDA, 2023a; 2023d; NIOSH, 2015b). These costs are subsequently passed on to those who purchase these devices, including those in the health care industry.

The fact that FDA testing requirements do not always reflect the hazards or occupational safety protocols found in most health care settings adds to the confusion, as was noted by a representative from OSHA at the December 2022 public meeting of the Standing Committee on Personal Protective Equipment for Workplace Safety and Health (NASEM, 2022a). This confusion could lead to respirator manufacturers spending additional resources to overengineer their products for situations that are unlikely to occur. For instance, testing the flame resistance, fluid resistance, and biocompatibility of FFRs, EHMRs, or PAPR hoods requires that respirator manufacturers spend additional time and resources on situations like perioperative fires that are unlikely to impact protective devices (NASEM, 2017). Furthermore, if fluid exposures are of concern for HCWs, the common protection procedure and OSHA recommendation is to don a face shield along with an N95 FFR, as the face shield will provide greater protection than a fluid-resistant N95 FFR would. Importantly, the face shield will protect the wearer's eyes in addition to the nose and mouth (NASEM, 2017; OSHA, n.d.).

The current lack of regulatory alignment may lead respirator manufacturers to submit their devices to extensive, expensive, and in some respects, redundant testing processes. This is a particular challenge for smaller companies with fewer resources. Some respirator manufacturers trying to enter the health care market for the first time during the COVID-19 pandemic found the combination of NIOSH and FDA requirements overly cumbersome and a financial impediment (NASEM, 2023). For some new manufacturers, the complexity of the respirator approval process was too daunting and caused them to switch to manufacturing non-regulated face coverings (NASEM, 2023).

The additional FDA testing requirements have led to respirator overregulation and contributed to supply chains that are increasingly more expensive, complicated, and vulnerable to shortages during surges (Shirley et al., 2017). The additional testing burden is also likely to discourage manufacturers from marketing their devices to health care organizations, which has implications for respirator supply and respiratory protection options for HCWs. Health care organizations need to have access to a wide range of makes, models, and sizes of respirators to ensure that all personnel can achieve adequate fit (NASEM, 2017).

Beyond the impacts to manufacturers, the additional FDA testing requirements may also lead HCWs, purchasers, and others to mistakenly believe that only SN95 FFRs can be used in health care settings. In addition, there is a current misconception that SN95 FFRs provide an increased level of respiratory protection over standard NIOSH Approved N95 FFRs. These current and potential misconceptions could contribute to respirator supply and access issues in periods of surge as HCWs and their hospital systems believe they can only use SN95 FFRs, placing HCWs at increased respiratory hazard exposure risk. Such misconceptions may also impede the adoption of reusable and properly fit-tested EHMRs, which are at least as effective as SN95 FFRs at protecting HCWs from inhalation hazards and have been preferred by HCWs over SN95 FFRs in certain high-risk scenarios (Hines et al., 2019b; 2020b). Furthermore, some inhalation hazards present in health care are gases and/or vapors—such as anesthetic waste gas or chemotherapy drug vapors—and would require EHMRs or PAPRs equipped with gas/vapor cartridges since SN95 FFRs are only effective for protection against particulates (NIOSH, 2015a).

Experiences During the COVID-19 Pandemic

Emergency Use Authorizations

During the COVID-19 public health emergency, the FDA issued a series of emergency use authorizations (EUAs) for respirators used in health care (FDA, n.d.). The first EUA, issued on March 2, 2020, was intended to address the global shortage of FFRs by stating that all NIOSH Approved APRs (powered and non-powered, reusable, and single-use—see Figure 1) other than SN95 FFRs may be used in health care settings (Hinton, 2021). Since non-SN95 FFRs were already permitted for use in health care settings under OSHA regulations (OSHA, 1971), this EUA further complicated an already confusing regulatory landscape and perpetuated misperceptions about the types of respirators that can be used in health care outside of the context of an EUA. While the FDA has clarified that the EUA is not tied to the public health emergency declaration (FDA, 2023b), the potential for the EUA being revoked risks even further confusion regarding the selection and use of non-surgical respirators in health care settings, including reusable respirators that may have been purchased and stockpiled by health systems during the pandemic.

Despite these challenges, the March 2020 EUA prompted more widespread use of NIOSH Approved APRs other than SN95 FFRs in health care settings (Greenawald et al., 2021), allowed HCWs to better recognize the effectiveness of these devices (Chang et al., 2020), and presented the opportunity for performance evaluation related to source control—a respirator's ability to filter respiratory secretions exhaled by its wearer to prevent disease transmission to others—when using respirators with exhalation valves.

Reusable Respirators

During the COVID-19 pandemic, there was an increased desire to implement reusable NIOSH Approved APRs (EHMRs, PAPRs) as health care facilities had limited supplies of single-use FFRs, which have little adjustability compared to reusable respirators (Greenawald et al., 2021). As supply chain challenges limited the availability of N95 FFR makes and models previously used for fit testing at health care facilities, reusable APRs helped to provide HCWs with access to adequately fitting respirators (Chalikonda et al., 2020). Health care organizations with access to reusable APRs were less affected by the shortages of disposable N95 FFRs (Greenawald et al., 2021). Additionally, a recent study demonstrated the potential for significant cost savings—conservatively, a tenfold reduction per month—by implementing an EHMR program that reduced reliance on FFRs by 95% (Chalikonda et al., 2020). Multiple studies have documented HCWs' preference for reusable NIOSH Approved APRs over FFRs, including perceptions of increased protection, and the increased adoption of EHMRs and PAPRs in health care settings during COVID-19 has not resulted in evidence suggesting increased risks to HCWs or patients (Bray and Vanberkel, 2023; Bryant et al., 2024; Haas et al., 2023; Maleczek et al., 2022; McMahon et al., 2021; Munro et al., 2021; Varangu et al., 2023). Additionally, in limited circumstances when HCWs cannot be fit to an FFR, cannot shave facial hair for religious reasons, or have hypersensitive skin issues, a loose-fitting PAPR must be used for protection. While cleaning and disinfection requirements do not limit the utility of reusable APRs, having consistent guidance on the storage and disinfection of reusable respirators could encourage more widespread use of non-disposable respirators (Hines et al., 2019a; 2020a). These user experiences during COVID-19 and previous research on respirator performance indicate the appropriateness of NIOSH Approved respirators other than SN95 FFRs for protecting HCWs and patients from COVID-19 and other respiratory hazards found in health care settings.

Past Progress and Further Opportunities to Streamline the Respirator Approval Process

Over the last 10 years, NIOSH and FDA have engaged in multiple activities to simplify regulatory oversight of SN95 FFRs in health care settings (NIOSH, 2014). In 2016, NIOSH sponsored a National Academies of Sciences, Engineering, and Medicine (the National Academies) workshop on opportunities for integrating FDA and NIOSH processes used to evaluate respirators used by HCWs (NASEM, 2017). The 2017 MOU between NIOSH and FDA mentioned above—MOU 225-18-006—was a direct result of that workshop and provides a model for coordination and collaboration between the two agencies regarding the regulation of SN95 and N95 FFRs used in health care (FDA, 2017). In restructuring the process by which SN95 FFRs are approved for use in health care and allowing NIOSH to first evaluate if the submitted FFR exceeds the FDA's threshold evaluation criteria, the 2017 MOU was seen as a way to expedite SN95s to market, particularly during times of increased demand (FDA, 2017).

To build on the regulatory streamlining achieved by the 2017 MOU, the National Academies hosted NIOSH and FDA at the Fall 2022 meeting of the Standing Committee on Personal Protective Equipment for Workplace Safety and Health to discuss the current state of the science on critical characteristics of APRs used in hospitals and other health care delivery settings (NASEM, 2022a). The meeting included presentations on experiences with these APRs in health care

settings, particularly during the COVID-19 pandemic, and guidance and regulatory actions that might achieve better alignment among federal agencies with oversight authority and support improved health care access to NIOSH Approved respirators. Several experts from regulatory agencies, health care, and the respirator industry participating in this event reiterated key messages from the 2016 National Academies workshop, including that the science indicates: 1) there are no meaningful filtration performance differences between N95 FFRs and SN95 FFRs; 2) flammability is a low-likelihood hazard; 3) N95 FFRs offer the same level of protection for HCWs with no increased risk of patient infection compared to SN95 FFRs, and 4) that OSHA standards only require use of NIOSH Approved respirators in health care (NASEM, 2017). These key messages are consistent with the literature, which shows that NIOSH Approved N95 FFRs either meet or exceed the FDA's requirements of filtration performance, fluid resistance, and flame resistance for SN95 FFRs and are in alignment with current OSHA standards (Rengasamy et al., 2021; 2018; 2017; 2015). The authors believe that this collective evidence indicates that the FDA-required performance tests do not add meaningful additional protection for either patients or HCWs.

Streamlining regulatory communication and guidance on respirator selection and use will help clarify which respirators can be used in health care while simultaneously improving user confidence in their respiratory protective equipment. Since many HCWs and employers may believe that non-SN95 FFRs do not provide adequate protection, retiring the SN95 designation will reduce confusion about the type of respirators that are acceptable and effective in health care settings. Retiring this designation would also increase the variety of NIOSH Approved respirators available for use in health care settings, providing HCWs with access to a greater number of respiratory protective devices. Removing barriers to respiratory protection access in the health care sector will enhance worker safety and has indirect benefits for patients, as a Joint Commission survey demonstrated that when HCWs are protected from workplace hazards, they are less prone to errors, contributing to safer patient care (Braun et al., 2019; WHO, 2020). Together, alignment of performance requirements and guidance on respirator use can ensure the maintenance of an adequate respirator supply and multiple options for protective devices for health care organizations and HCWs.

Suggestions for a Path Forward

Research in laboratory and health care settings has demonstrated the effectiveness and feasibility of non-SN95 NIOSH Approved respirators in protecting HCWs from airborne transmissible disease exposure (Bray and Vanberkel, 2023; Bryant et al., 2024; Haas et al., 2023; Hines et al., 2019a; 2020a; Maleczek et al., 2022; McMahon et al., 2021; Munro et al., 2021; Portnoff et al., 2021; Rengasamy and Niezgoda, 2019; Rengasamy et al., 2021; 2018; 2015; Varangu et al., 2023). While the 2017 MOU helped to streamline regulatory oversight processes for FFRs, this policy change did not eliminate confusion in health care settings about the differences between N95 and SN95 FFRs nor the other kinds of NIOSH Approved respirators that may be used in health care. Opportunities remain for agencies with oversight authority to commit to further collaborative streamlining of the regulatory approval process while ensuring greater worker protection and lowering costs for respirator manufacturers and health care purchasers.

With this paper, the authors seek to put forward a path that will:

- Streamline and clarify the respirator approval process and simplify the selection process for end users in health care settings;
- Improve the variety of and access to NIOSH Approved respirators in health care;
- Reduce confusion regarding the effective and appropriate use of NIOSH Approved reusable respirators (EHMRs, PAPRs) in health care settings and inform HCWs of their benefits during both routine and surge use;
- Reduce the economic and environmental burden associated with health care's use of disposable respirators;
- Reduce the risk of supply chain vulnerability to respirator shortages; and
- Keep both HCWs and their patients safe and healthy.

Possible first steps for an improved path forward include:

- Retiring the SN95 FFR designation, given that NIOSH Approved APRs, which are widely used across diverse industries, have been shown to adequately protect HCWs and patients;
- Federal authorities, including FDA, NIOSH, and OSHA, should collaborate to develop a unified statement (i.e., a joint advisory) clarifying the permitted use of all NIOSH Approved APRs in health care; and
- Federal authorities, including FDA, NIOSH, and OSHA, should collaborate to develop a comprehensive educational initiative that provides guidance on the selection and use of appropriate

NIOSH Approved APRs in specific health care applications, with particular emphasis on the use and benefits of reusable APRs like EHMRs and PAPRs.

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