

**DRAFT NIOSH HEALTHCARE PERSONAL PROTECTIVE  
TECHNOLOGY (PPT) TARGETS  
FOR 2020 TO 2030**

**NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)  
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

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## INTRODUCTION

The health and welfare of 18 million U.S. healthcare personnel (HCP) remains an important priority for the Centers for Disease Control and Prevention (CDC) and the CDC's National Institute for Occupational Safety and Health (NIOSH). NIOSH accomplishes its mission to protect the U.S. workforce from injury and illness through scientific research, practice interventions, and collaborative partnerships. Industrial hygienists, infection control practitioners and other HCP, social scientists, engineers, and others work closely with professional societies and government agencies to develop and promote ways to reduce harmful workplace exposures to physical and chemical agents and infectious diseases. Reports issued by the Healthcare and Social Assistance Sector Council of the National Occupational Research Agenda (NORA) and the NIOSH Strategic Plan [1] demonstrate the success of these efforts.

While infection prevention and control efforts [favor engineering and administrative measures](#) over personal protective technology (PPT), PPT nevertheless plays an important role in preventing transmission of infectious diseases. **In this document, we distinguish between PPT and personal protective equipment (PPE). PPT includes PPE worn by individuals (e.g., respirators) and the technical methods (e.g., fit testing methods), processes, techniques, tools, and materials that support the development and use of PPE worn by individuals. This document intentionally and prominently incorporates this distinction throughout.**

PPE frequently worn by HCP include gowns, gloves, goggles, face shields, head covers, respirators, shoe covers, and surgical masks. While some PPE, such as surgical masks and gloves, have been worn in healthcare settings for over 100 years, the emergence of new pathogens (e.g., human immunodeficiency virus) and increased medical knowledge (e.g., mode of transmission of *Mycobacterium tuberculosis*) have further evolved PPE use. In addition to infectious hazards, non-infectious hazards such as [chemicals](#) and [exposure to drugs](#) continue to pose a threat to HCP.

In 2006, the NIOSH Personal Protective Technology Laboratory (NPPTL) began an initiative to develop and execute a comprehensive strategic approach to HCP protection. The resulting NIOSH Healthcare PPT Action Plan focused resources on and raised awareness about the PPT needs of HCP during a potential influenza pandemic. NIOSH undertook a research agenda to advance clinical practices, drive performance standards development, and inform regulation. NIOSH also implemented an information dissemination program to apprise healthcare organizations and HCP about the roles and importance of PPE in protecting themselves. After several updates since the Action Plan's inception, the most recent plan ([2013-18](#)) focused on PPE used to reduce exposures to viral respiratory pathogens, including the influenza virus.

Reflecting on the nation's past decade of experiences with infectious diseases (e.g., influenza, Ebola, and coronavirus) and non-infectious hazards (e.g., antineoplastic and other hazardous drugs), NIOSH recognizes a need for additional types of PPT and an opportunity to address existing gaps by leveraging NIOSH's unique capabilities related to PPT research, development, performance standards and test methods, and conformity assessment. To respond to this growing need, NIOSH developed the DRAFT NIOSH Healthcare PPT Targets for 2020 to 2030 (Draft PPT Targets), which inform NIOSH's PPT efforts during this decade. The public health response

to the COVID-19 pandemic has delayed NIOSH’s efforts to obtain public input on the Draft PPT Targets; NIOSH will finalize the Draft PPT Targets after receipt of the requested public input.

NIOSH’s Draft PPT Targets define six broad objectives:

1. Conduct workplace exposure assessments and subsequent hazard evaluations to inform PPT policy, standards, and conformity assessment needs.
2. Develop, evaluate, and continually innovate PPE performance requirements and test methods through the integration of advanced PPT and design guidance.
3. Develop and disseminate strategies and tactics to extend PPT supplies during emergencies, disasters, or PPT shortages.
4. Develop and disseminate guidance and best practices to inform PPT implementation and enhance user adherence.
5. Provide national leadership to inform the design and execution of NIOSH’s Respirator Approval Program (RAP) and other PPT conformity assessment schemes.
6. Expand U.S. capacity for PPT research and innovation.

NIOSH engages in the following process to meet these objectives, further discussed in detail in this document:

- Analyzing knowledge gaps by summarizing input from stakeholders, selective literature review, and assessment of current relevant trends and legislation where applicable.
- Identifying priorities and detailing supporting targets that will help to close critical gaps in the protection of HCP, acknowledging that the achievement of the stated targets depends upon the resources available.

NIOSH’s overarching goal (to reduce worker illness and injury and to advance worker well-being) informs or directs the design, evaluation, standards development, conformity assessment (i.e., the demonstration that a product meets specified requirements), selection, care, maintenance, and use of PPT to ensure HCPs are protected from known and emerging hazards in all healthcare settings.

## **THE BURDEN OF HCP MORBIDITY AND MORTALITY**

Currently, the healthcare industry in the United States employs almost 17 million people [2]. Bureau of Labor Statistics data show that employment growth in the healthcare industry will account for nearly one-third of the projected job growth for all industries from 2016 to 2026, adding 4.0 million jobs during this period. Several factors continue to increase healthcare demands, such as the aging “baby boomer” population, longer life expectancies, and growing rates of chronic conditions [3]. Healthcare settings include ambulatory healthcare services, hospitals, nursing and residential care facilities, dental offices, clinics, and private home care—all of which provide services that involve complex care once only considered appropriate for hospital facilities. The Bureau of Labor Statistics projects that one of the fastest-growing occupational groups, home healthcare aides, will grow 33.7% by 2029 [4].

In 2020, the Healthcare and Social Assistance Sector reported 5.5 injury and illness cases per 100 full-time workers (about 806,200 total cases), a number higher than any other private industry sector, including industries traditionally considered dangerous such as manufacturing and construction [5]. Injuries and illnesses in healthcare accounted for 19.9% of the total for all industries. During 2019, in hospitals alone, non-fatal injury or illnesses resulting in days away from work reached 129.7 per 10,000 full-time equivalent (FTE) workers. In 2020, the rate increased to 371.7 per 10,000 FTE workers. [6]. Data on workers' compensation claims estimated the average loss per claim settled for hospital workers' injuries in 2011 was \$15,860. During 2011, injuries and illnesses cost the healthcare industry \$13.1 billion and more than 2 million lost workdays [7]. Nursing and residential care facilities had the highest injury or illness incidence in 2020, with 791.7 cases per 10,000 FTE workers being injured on the job [6]. In addition, high financial and societal costs exist when replacing HCP who leave the profession because of workplace injury or illness.

Priorities for the [NIOSH Healthcare and Social Assistance Program](#) include the prevention of illnesses caused by hazardous drugs and other agents through respiratory and dermal exposure and infectious agents. Dermal and respiratory exposure can be mitigated using PPE. Well-documented adverse health effects associated with exposure to antineoplastic drugs (drugs that inhibit or prevent the growth and spread of tumors or malignant cells) include acute effects such as nausea, headache, skin and eye irritation, and hair loss, as well as long-term effects such as DNA damage, miscarriage, leukemia, and other cancers [8] [9] [10] [11] [12] [13]. The current NIOSH list of antineoplastic and other hazardous drugs in healthcare settings comprises nearly 220 drugs and continues to grow [14]. NIOSH reports 8 million U.S. HCP being potentially exposed to hazardous drugs, including pharmacy and nursing personnel, physicians, operating room personnel, environmental services workers, workers in research laboratories, veterinary care workers, and shipping and receiving personnel [15]. A recent NIOSH study found that some nurses, including those expecting children, did not wear protective gloves and gowns while handling or administering such drugs [16]. Twelve percent of nonpregnant nurses and 9% of pregnant nurses indicated that they never wore gloves, and 42% of nonpregnant nurses and 38% of pregnant nurses reported never using a gown. PPE such as gloves, gowns, and goggles remain critical components, often considered the minimum required protective equipment, for handling and administering hazardous drugs [17].

NIOSH found that over 400 HCP reported acute illnesses or injuries related to disinfectant exposure from 2002 to 2007 in four states [18]. A 2021 systematic review using meta-analysis estimated that nurses, compared to those in other occupations, face an increased risk of new-onset asthma and bronchial hyperresponsiveness-related symptoms [19]. In this same category of risk, environmental services workers represent the most common occupation (24%), followed by nursing and medical assistants (16%), technicians (15%), and nurses (11%). HCP account for about 16% of all occupational asthma cases, with up to 24% of these cases caused by exposure to cleaning agents [20]. HCP face one of the highest rates of occupational asthma at 8.8%, compared to 7.2% among all workers [20] [21].

Other respiratory hazards for healthcare workers include surgical smoke and waste anesthetic gases. Several studies report toxic, mutagenic, and potentially infectious effects from smoke generated from lasers or electrosurgical devices during surgery [22] [23] [24]. The Occupational Safety and Health Administration (OSHA) estimates exposure of 500,000 workers to surgical smoke each year [25]. Studies show associations between anesthetic or analgesic gases and vapors that escape during dental and medical procedures and impaired cognition and manual dexterity as well as adverse reproductive outcomes [26] [27]. An estimated 250,000 U.S. HCP may be exposed to these waste anesthetic gases, putting them at risk of developing adverse health effects [28].

Infectious diseases pose an ongoing concern among HCP. Some such as tuberculosis have been around for many decades while others have emerged in recent years, including the 2009 H1N1 pandemic influenza during which [at least four nurses died](#), [Ebola virus disease](#), [Middle Eastern Respiratory Syndrome](#), and the [SARS-CoV-2 virus that causes COVID-19](#). Recent infectious disease outbreaks disproportionately infected HCP as compared to the general public [29] [30] [31] [32]. Even pathogens for which effective vaccines exist (e.g., rubeola virus) may cause epidemics among the general population when population-level immunity wanes [33]. Multidrug-resistant organisms present a growing challenge for HCP, with 88 cases of multidrug-resistant tuberculosis and one case of extensively drug-resistant tuberculosis identified in the United States in 2015 [34].

In data across U.S. industries, healthcare occupations have one of the highest rates of musculoskeletal injuries attributable to overexertion. BLS data from 2014 show a rate of 33 per 10,000 full-time workers for overexertion injuries averaged across all industries. By comparison, BLS data show an overexertion injury rate twice that average for hospital workers (68 per 10,000), over three times that average for nursing home workers (107 per 10,000), and over five times that average for ambulance workers (174 per 10,000) [35]. Manual lifting, moving, and repositioning of patients, residents, or clients (i.e., manual patient handling) represents the single greatest risk factor for overexertion injuries in healthcare workers. Nursing aides, orderlies, and attendants had the highest rates of musculoskeletal disorders among all occupations in 2010.

PPT are critical to preventing these risks among HCP. HCP rely on traditional PPE such as gloves, gowns, respirators, surgical masks, aprons, footwear covers, head covers, goggles, and face shields, as well as new innovative PPE such as exosuits, to reduce their exposure to hazards faced in healthcare settings. Improving the effectiveness of these PPE and advancing the development and use of PPT can achieve enhanced protection of HCP.

*Objective 1: Conduct workplace exposure assessments and subsequent hazard evaluations to inform PPT policy, standards, and conformity assessment needs*

### **Knowledge Gaps**

Because of the variety of hazardous chemicals and biological pathogens present in various healthcare settings, characterizing HCP occupational exposures involves intensive use of

resources. Subsequent hazard evaluations also pose different sets of challenges as the exposure time and concentrations vary widely throughout job classifications and facilities.

The healthcare industry has recognized these challenges as endemic for decades, and they remain a concern to this day in many healthcare settings, including acute care, long-term care, and outpatient oral care facilities. Differences in these healthcare settings influence the design, execution, and findings of hazard evaluations. However, recent assessments of widespread infectious disease show higher infection rates for HCP compared to individuals from their surrounding communities [29] [30] [31] [32], with some infections leading to HCP death [36].

Assessing the biological hazards of the workplace exposure portfolio also poses challenges. Most sampling methods, by design, evaluate biological concentrations in a room or area rather than specific personal exposures, which makes joining specific exposure levels to adverse health outcomes challenging [37]. Together, the diversity of pathogens, inconsistencies in workers' exposures, difficulties in evaluating those exposures, and the challenges of hazard evaluations create challenges for the development of effective PPT policies and standards.

These ongoing challenges demonstrate the need to identify and quantify the personal exposures throughout the industry, as well as investigate possible links between those exposures and negative health outcomes. Addressing this knowledge gap will provide the information necessary to mitigate these exposures more effectively through engineering and administrative controls while aiding in the development of effective PPT policy and standards for those remaining exposures.

### *Priorities and Targets*

1. Expand the evidence base used to inform the level of protection necessary to protect HCP in various hazard exposure scenarios for infectious diseases.

Target 1: Conduct case studies to inform the mean airborne and surface concentrations and duration of exposure that may be expected for “small- ” (e.g., influenza virus) and “large-sized” (e.g., tuberculosis droplet nuclei) infectious pathogens in acute, long-term, and dental care settings.

Target 2: Conduct a systematic literature review to identify potential adverse health effects resulting from exposure scenarios identified in Target 1 and address remaining knowledge gaps with *in vitro* and *in vivo* studies.

Target 3: Conduct a systematic literature review to recommend minimum protections necessary (e.g., assigned protection factor, filtration efficiency, and fit testing requirements) for various healthcare exposure scenarios.

*Objective 2: Develop, evaluate, and continually innovate PPE performance requirements and test methods through the integration of advanced PPT and design guidance*

**Knowledge Gaps**

When using PPE to protect the health and safety of HCP, they must have confidence in product effectiveness. Conformity assessment leverages established test methods to verify that PPE conform to published performance requirements so that safety professionals who select them, and the workers who rely on them, can do so with assurance of consistent, necessary protective capabilities [38]. A conformity assessment (CA) program can instill this confidence in PPE users. CA programs range from first-party testing or inspection with a supplier's declaration (the type of CA program suited for healthcare PPE) to testing by a third-party laboratory (with preference for accreditation). These requirements and standards provide context to establish the specific requirements used to evaluate a product's performance. However, the current healthcare PPE CA programs do not contain all the performance tests necessary to ensure that PPE will adequately protect healthcare workers.

The outbreaks of the 2003 severe acute respiratory syndrome (SARS), the 2009 H1N1 influenza, and the 2014 Ebola virus created a heightened awareness for protecting today's HCP. As a result, NIOSH sponsored studies by the National Academies of Sciences, Engineering, and Medicine (NASEM) on the use and effectiveness of powered air-purifying respirators (PAPRs) and the use of elastomeric half-mask respirators (EHMRs) in healthcare [39] [40]. The development of test methods must be completed before these respirators may be routinely used in healthcare settings.

These settings also have needs for improving the fit of, and fit testing for, respirators [41]. Fit testing represents a major barrier to the effective implementation of respirators. Employers identify the cost and logistics associated with fit testing as a primary challenge. Besides fit testing and costs, recruiting human subjects for testing when the possibility exists for infectious disease transmission such as during a pandemic stands as another significant challenge. The ability of NIOSH to rely upon humanlike robotic technologies for testing associated with its approval and research efforts would notably increase the rate of output and reduce the potential risk to human subjects by eliminating the reliance on human subjects. Finally, healthcare settings have a need for innovation in fit testing to include rapid fit testing methods for use in medium- and large-sized facilities (e.g., acute care facilities) and table-top methods that can be deployed to small community healthcare settings (e.g., pharmacies and nursing homes).

Workplaces also increasingly employ direct-reading sensors as health and safety tools that may detect and monitor face seal leakage continuously in real time, reducing the burden of fit testing. Sensors may also be useful in improving the overall effectiveness of other types of healthcare PPE. Development of new test methods and protocols would support feasibility assessments related to the use of these technologies.

Source control (i.e., to filter respiratory secretions to prevent disease transmission to others) remains an infection control strategy with the additional potential benefit of ultimately reducing

the overall exposures to HCP. However, until 2020, no standard existed to which these products could be tested and evaluated to demonstrate performance, and some entities claimed that products with the primary purpose of providing source control may also provide some level of personal respiratory protection. As a result, ASTM International (formerly American Society for Testing and Materials) developed and published a [voluntary consensus standard for face coverings](#) in an unprecedented timeline of only a few months. As a member of the technical committee overseeing this standard, NIOSH became one of many stakeholders with an interest in ensuring that new, sound scientific evidence be incorporated into revisions of this standard. Developing guidance for appropriate use of resulting products remains a critical goal.

Some situations require HCP to wear multiple types of PPE simultaneously. For example, treatment of Ebola patients required HCP to wear up to seven different types of PPE from head to toe (e.g., boot coverings, coveralls, respirator, gloves, and eye protection). Additional research is needed in test methods, selection guidance, and the interoperability of individual components of ensembles for healthcare. Contemporary issues include those related to heat stress [42], component interfaces (e.g., glove-gown or respirator and eye protection) [43], and the need to integrate more efficient measurement technologies [44].

Finally, as noted earlier, manual lifting and handling patients continues to be a major source of injuries for HCP. Exosuits represent a rapidly advancing form of PPT that may reduce musculoskeletal disorder or injury risk to HCP [45]. Advancing exosuit technologies and understanding the safety and efficacy of these devices can prevent injuries in numerous healthcare settings, such as acute care, rehabilitation, and long-term care facilities, where other controls may not be feasible.

### *Priorities and Targets*

1. Conduct research on NIOSH-approved respirators not traditionally used in healthcare to inform policy solutions that may be adopted by NIOSH's RAP.

Target 1: Assess the adequacy of existing test methods to validate their utility in healthcare or identify and develop additional performance requirements and test methods for PAPR, EHMR, and the mostly commonly utilized filtering facepiece respirators (FFR) for use in healthcare settings.

2. Demonstrate the utility of novel or innovative respirator design components and features that may be leveraged by manufacturers to enhance PPE protections or user adherence and comfort.

Target 1: Develop a Sensor Integration Roadmap and initiate identified activities.

Target 2: Demonstrate the feasibility of using sensor technologies to provide real-time, field-based respirator fit and/or filter penetration data.

Target 3: Explore novel or innovative head suspension and facepiece designs or features that may provide improved fit characteristics, communication, comfort, or other desirable performance enhancements.

3. Advance the use of innovative technologies to optimize respirator fit assessments.

Target 1: Evaluate an advanced humanlike articulated headform as a means for replacing the human subject when realistic respirator seal characteristics are a necessary component of a laboratory assessment.

Target 2: Facilitate the development and evaluation of a digital, smart-device-deployed application that scans user faces to identify an individual's facial sizing—as described by the NIOSH Bivariate Panel and NIOSH Principal Component Analysis Panel—to predict the fit of respirators for users.

Target 3: Evaluate the utility of sensors for FFRs to be used within field-based test methods to provide real-time data that inform user seal checks, respirator fit during use, outward leakage during use, and how fit testing requirements may evolve as this technology penetrates the market.

4. Provide evidence-based guidance for PPE intended to provide source control and some level of respiratory protection for infectious diseases spread through respiratory secretions.

Target 1: Develop and evaluate a test method to assess sneeze and cough hazards.

Target 2: Evaluate face coverings, masks intended for medical purposes, and respirators to determine the level of source control to be expected and to inform test method development.

Target 3: Provide research, technical support, and guidance to establish and continually improve the ASTM F3502-21 Barrier Face Covering voluntary consensus standard that assesses outward filtration efficiency, user comfort, and fit for face coverings.

Target 4: Conduct proof-of-concept studies towards the goal of designing next-generation face coverings that effectively reduce person-to-person transmission.

5. Provide evidence-based guidance to improve performance requirements, test methods, and design guidance for the use of two or more PPT components at once (includes respirators, eye and face protection, gowns, gloves, head covers, aprons, and footwear covers).

Target 1: Develop requirements and test methods to assess the performance at the interface of ensemble components and to inform design guidance for PPT interface regions.

Target 2: Improve the efficiency of existing laboratory-based test methods for the penetration of blood, bodily fluids, and bloodborne pathogens.

Target 3: Develop test methods that are then used to evaluate the efficacy of using respirators in combination with eye and face protection.

Target 4: Provide research, technical support, and guidance to establish a voluntary consensus standard that assesses comfort and wearability and integrate the developed standard within NIOSH guidance.

6. Inform the test methods used to assess individual components of the HCP ensemble.

Target 1: Provide a leadership role including research, technical support, and guidance to advance the [ANSI/ISEA Z87.1](#) (draft, refer to page 3) eye and face protection standard for biological hazards.

Target 2: Ensure that test methods are adequate to assess PPE components against novel/emerging infectious and non-infectious hazards.

Target 3: Provide a leadership role including research, technical support, and guidance to advance ASTM's Respirator Fit Capability voluntary consensus standard for FFRs to also include all other air-purifying respirators (i.e., elastomeric with cartridges and canisters).

7. Support the exploration, development, and integration of innovative technologies to advance HCP ensembles and identify the need for new performance requirements or test methods.

Target 1: Demonstrate the efficacy of various eyewear coatings to reduce fogging when eye and face protection is worn in combination with respirators, surgical masks, or face coverings.

Target 2: Advance the development of mechanized clothing to be used in a healthcare setting by nurses to reduce lower-back loading during patient body manipulations or location transfers.

*Objective 3: Develop and disseminate strategies and tactics to extend PPT supplies during emergencies, disasters, or PPT shortages*

### **Knowledge Gaps**

HCP use N95 FFRs more than any other respirator type. Modeling previously suggested that the demand for respirators used by HCP during an influenza pandemic would far exceed domestic supplies [46]. Some U.S. locales—despite stockpiling programs at local, regional, and national levels—experienced shortages of respirators during the H1N1 influenza pandemic in 2009-2010 and the outbreak of SARS in 2003-2004. PPE orders increased up to 200-fold in October 2014 after the first U.S. Ebola fatality and issuance of updated CDC PPE guidance [47].

In 2020, during the COVID-19 pandemic, the U.S. respirator supply chain demonstrated an inelasticity in relation to a limited surge production capacity for respirators and other PPE types, such as gowns [48]. Further, international manufacturers often serve as primary suppliers of PPE for the U.S. market. Obtaining needed PPE in 2020, especially respirators, proved to be difficult due to limited exports of raw materials and NIOSH-approved respirators produced outside of the United States.

In response to the shortages, NIOSH assisted CDC's pandemic response in developing measures to optimize PPE supplies along the continuum of care using crisis and contingency strategies [49]. These measures included (1) reuse, extended use, and decontamination of FFRs; (2) using respirators (including N95 FFRs and other types) beyond the manufacturer-designated shelf life for healthcare delivery; and (3) using respirators claiming to meet international standards with requirements similar to NIOSH's filtration efficiency and inhalation and exhalation breathing resistance requirements.

In occupational settings where respiratory hazards can be identified in advance of exposure, OSHA requires that employers establish a [respiratory protection program \(RPP\)](#). As a robust

program, the RPP requires significant time and attention from the employer. It includes proper respirator selection, donning and doffing of respirators, fitting respirators, and identifying potential risks to those with pre-existing cardiopulmonary disease. However, HCP who are not typically exposed to respiratory hazards—and therefore not covered under an RPP—may be unexpectedly exposed to a respiratory hazard (e.g., at-home care support during a wildfire, or hospital services staff during an infectious disease outbreak/pandemic). Unfortunately, these workers urgently require respiratory protection, and the employer must sometimes establish an RPP with these workers being continually exposed to a respiratory hazard. A similar situation exists for the general public, which does not have the support that an RPP provides or an established government framework to oversee the comprehensive respiratory protection needs. Thus, a need exists for NIOSH to coordinate with other federal entities to develop and implement strategies to address urgent respiratory protection gaps for HCP not covered by an RPP and for members of the general public, which would reduce transmission rates of infectious diseases and thereby reduce the risk level to HCP.

### *Priorities and Targets*

#### 1. Expand national capacity to provide PPT during demand surges.

Target 1: Establish the standards and a testing and evaluation framework that empower stockpile managers to verify manufacturer performance claims of PPE initially and continually within their facilities.

Target 2: Facilitate coordinated PPT inventory data sharing between software platforms by developing a voluntary consensus standard for PPT nomenclature and data format.

Target 3: Using Target 2 above, develop an interoperable platform to allow stockpiles that implement Target 1 above to share test results with the product manufacturer and further enable product purchasing and rotation coordination between stockpile and health systems.

Target 4: Develop and enhance best practice guidelines on elastomeric half-mask respirators for HCP, including strategies for fit testing, staff training, decontamination, and other logistics.

Target 5: Sponsor studies to evaluate use and distribution of elastomeric half-mask respirators and powered air-purifying respirators and their accessories to address future respirator shortages.

Target 6: Support initiatives to establish a national strategy to rapidly produce and supply PPE conforming to appropriate standards, with readily accessible technical support.

#### 2. Improve the protections provided to HCP when contingency and crisis PPT strategies are implemented.

Target 1: Conduct post-market evaluations of respirators approved to international standards but that are not NIOSH-approved.

Target 2: Develop and evaluate laboratory-based test methods for single- and multi-use PPE decontamination techniques and treatments (e.g., cycles and doses).

Target 3: Develop practical field-based test methods for filter penetration that empower employers to increase confidence in FFRs deployed to the workforce that are of unverified quality (e.g., shipments with unknown origin and after decontamination).

Target 4: Evaluate the effectiveness of past extended use and reuse practices with consideration of PPE performance and the impact these practices have on user performance, acceptance, and adherence.

Target 5: Test novel materials and construction of PPE to optimize performance and HCP use, acceptance, and adherence.

Target 6: Develop evidence-based implementation guidance for extended use and reuse of PPE during PPE shortages.

3. Coordinate with other federal partners to advance respiratory protection for HCP and members of the general public who are not part of a respiratory protection program when sudden respiratory hazards are present.

Target 1: Jointly sponsor a [NASEM consensus study](#) with other federal partners to provide recommendations for how the United States can best identify the need for, and support the use of, respiratory protective devices by the public and HCP who are not part of a respiratory protection program.

Target 2: Provide national leadership to integrate NASEM's recommendations into the U.S. strategy for respiratory protection of these populations.

Target 3: Determine the assigned protection factor that may be expected when fit testing is not feasible or is delayed with and without the use of a standardized sizing guide that matches adult individuals to a respirator size designation.

Target 4: Determine what level of protection may be expected for various FFR filtration efficiencies (e.g., N95) when fit testing is not feasible or is delayed and only a user seal check is performed.

*Objective 4: Develop and disseminate guidance and best practices to inform PPT implementation and enhance user adherence*

### **Knowledge Gaps**

Numerous studies show that HCP have limited understanding of the purpose, selection, maintenance, and proper use of PPE [50] [51] [52] [53] [54] [55]. Like other safety measures dependent on behavior, such as washing hands or wearing seat belts, PPE is most effective when properly used. For example, respirators or surgical gowns should be worn in the presence of hazards and donned and doffed correctly to prevent exposure and provide protection.

Individual behaviors and organizational practices contribute to the safety culture in healthcare settings; on occasion, these cultural practices may run counter to the best interest of HCP self-protection [50]. HCP non-adherence to guidelines, recommendations, policies, and regulations may be affected by time constraints, incomplete knowledge of guidelines and recommendations,

concerns about interference with patient care or occupational duties, perceived discomfort, perceived risk of exposure or consequences of exposure, and lack of emphasis on self-protection [50]. As with other complex organizational problems, no single solution or remedy suffices; however, organizations that seek and adopt ways to achieve incremental improvements in workplace safety can offer enhanced protection for HCP.

Numerous opportunities exist for the development and validation of methods, tools, and interventions to increase HCP knowledge about PPE use. These opportunities can better position health systems to protect their workers in prudent and cost-saving ways during healthcare delivery. Healthcare organizations and HCP with a more comprehensive understanding of current health and safety management practices are well-positioned to support a [systems-based approach](#) as it enables them to identify the most prevalent individual and organizational factors that contribute to low adoption and execution of desired safety practices around PPE use.

NIOSH seeks to reduce the occupational risks HCP face by conducting and supporting a systems approach for PPT. Such an approach considers the inter-relationships between PPE design, use, user guidance, user adherence and the technical methods, processes, techniques, tools, and materials that support the development and use of PPE. Leveraging this knowledge to develop targeted risk management interventions can improve the effective use of PPE in healthcare settings.

Providing HCP and their employers with PPT guidance and information that is up to date and readily and easily accessible fosters the most effective [targeted health and safety practices](#). One consideration when developing guidance is content that addresses the needs of all workers and work circumstances. This may include traditional (e.g., N95 FFR) and non-traditional (e.g., EHMR) healthcare PPE, a variety of healthcare settings (e.g., long-term care facilities), and various types of employment arrangements (e.g., traveling nurses or contracted physicians) [56]. Additionally, as the U.S. healthcare industry continues to embrace non-standard work arrangements (e.g., contract workers), meeting the challenge of training and fitting new employees due to turnover can ensure HCP safely and effectively use PPE. This is particularly evident for PPE such as respirators, where safe and effective use depends upon factors specific to a single individual, such as fit and health status. Finally, as new types of PPE products (e.g., PAPRs, EHMRs, FFRs, and barrier face coverings) enter healthcare settings, identifying best practices for PPE implementation, use, and effectiveness can further protect HCP.

### *Priorities and Targets*

#### 1. Provide mechanisms that improve accessibility to critical PPT guidance.

Target 1: Conduct formative evaluations (pilots or exploratory research) to identify and assess information sources that organizations and HCP use to obtain PPE best practices guidance and establish relationships with the entities that manage the content for these sources.

Target 2: Continue to leverage NIOSH PPT communication channels (e.g., Respiratory Protection Week, PPE CASE Notes, MMWR, and social media) to disseminate best practices and conduct a systematic evaluation of these channels to assess and improve their impact.

Target 3: Facilitate discussions with continuing education, recertification, and licensure bodies to integrate PPE best practices into required, formal education curriculum or modules.

Target 4: Expand NIOSH's web-based tool, [PPE-Info](#), to provide selection logic support and direct links to manufacturer products that claim to meet relevant standards to include face coverings.

2. Develop and improve implementation guidance for PPT best practices.

Target 1: Conduct workforce or workplace studies to evaluate current on-the-job training techniques and processes and develop interventions to enhance the effectiveness of this training for various levels of nursing support, to include non-traditional employment arrangements (e.g., traveling nurses or contracted physicians).

Target 2: Conduct a review of PPT best practices for routine and crisis operations to identify strategies and opportunities where the two may align, thereby reducing the need to implement a change in practice during future crises.

Target 3: Document the knowledge, attitudes, and behavioral practices of HCP around PPE perceptions, adoption, and sustained use to inform interventions and practices in long-term care, at-home care, and dentistry settings.

Target 4: Update NIOSH's Respiratory Protection Toolkit to include contemporary content related to reusable respirators, crisis strategies and non-traditional employment arrangements (e.g., traveling nurses or contracted physicians).

3. Provide evidence-based guidance regarding the use of respiratory protective and source control devices not traditionally used in the U.S. healthcare settings.

Target 1: Adapt the implementation guidance developed to enable the use of elastomeric half-mask respirators in healthcare during PPE shortages to support routine use of these respirators.

Target 2: Develop implementation guidance for routine use of powered air-purifying respirators in healthcare settings.

Target 3: Conduct face covering effectiveness studies at hospital facilities where source control is needed to inform use guidance and the ASTM consensus standard for face coverings.

*Objective 5: Provide national leadership to inform the design and execution of NIOSH's RAP and other PPT conformity assessment schemes*

### **Knowledge Gaps**

Conformity assessment leverages established test methods to verify that PPE conform to published performance requirements so that safety professionals who select them, and the workers who rely on them, can do so knowing that needed protective capabilities are consistently present [38]. As stated by NASEM: "for the consumer or worker, conformity assessment

provides confidence in the claims made about the product by the manufacturer and may assist the consumer with purchasing decisions in determining the fitness of a product for its intended use” [57]. A comprehensive and tailor-made conformity assessment program is the most effective way to manage risks associated with potentially non-conforming PPE and instill user confidence in the PPE.

No single regulatory body, official guidance, or mandating authority is charged with assessing conformity of all types of PPT. Historically, NIOSH has served as a national leader in PPE conformity assessment by overseeing the agency’s RAP (codified at 42 Code of Federal Regulations (CFR) Part 84) and supporting or conducting research to inform worker safety regulations, PPE performance standards, and infection prevention guidance. In 2017, NIOSH published its [National Framework for Personal Protective Equipment Conformity Assessment - Infrastructure](#) [38], which guides conformity assessment program owners to optimize conformity assessment practices using a risk-based approach.

In 2017, NIOSH’s RAP convened an Action Planning Team to assess the RAP and identify specific action items that would optimize its performance. NIOSH presented these action items to the International Safety Equipment Association—the largest industry association for respirator manufacturers—and further revised them before finalizing its RAP Action Plan in 2018 and presenting it at a [meeting with respirator manufacturers](#).

In 2020 and 2021, NIOSH’s RAP experienced an unprecedented number of applications that outpaced human capital resources. NIOSH received a high number of applications from those inexperienced with the process who required much more support than applicants already familiar with the process. The additional support needed by the new applicants, in combination with the unprecedented number of applications received, posed a substantial (and unsustainable) resource challenge to NIOSH. Additionally, global travel limitations impacted the Program’s ability to perform manufacturing site audits or initial manufacturing site qualifications.

To address these challenges, NIOSH implemented a variety of policy and human capital solutions to (1) accelerate application turnaround times for high-priority respirator types, (2) evaluate manufacturing sites virtually, and (3) provide information to fill knowledge gaps for new applicants. Importantly, as NIOSH plans for transitioning back to conventional operations, it plans to assess the root causes (policy and standards gaps or resource limitations) for the challenges experienced. Further, NIOSH also plans to review the near-term solutions implemented to address these challenges to determine the potential value if they were continued in the current (or an adapted) form.

Conformity assessment challenges also exist for non-respiratory PPE. For example, the language in current standards continues to preclude third parties such as stockpiles from performing post-market quality assurance evaluations on critical PPE items such as surgical and isolation gowns [58]. This poses a particular concern as US. Strategic National Stockpile, state, and private stockpiles depleted their inventory in early 2020 and subsequently needed to purchase millions of gowns with no ability to verify the initial or ongoing quality of these products. Additionally, challenges related to product labeling and packaging for surgical and isolation gowns and face

coverings continue to be noted by stakeholders—e.g., group purchasing organizations and stockpiles. Challenges include labeling insufficiently durable to environmental conditions during shipment nor accessible to those managing and distributing large shipments and pallets. Further, individual product labels are sometimes misleading—e.g., claiming conformity for the material when the fully assembled and constructed product did not conform.

Finally, questions remain about the quality and performance of gloves and other PPE types (e.g., gowns) used when handling hazardous drugs (e.g., antineoplastic or chemotherapy drugs) or drugs with the potential for dermal absorption such as fentanyl and its analogs. Several studies indicate that antineoplastic drugs may permeate gloves, including nitrile gloves [59] [60] [61]. Further, researchers know little about the protective ability of gloves against continually changing formulations of drugs as well as their precursors and analogs. NIOSH’s review of available products found five glove models where the manufacturer claimed protection against one drug (i.e., fentanyl), but test methods to assess product performance and validate these claims are lacking [62]. Characterizing the performance of gowns and other PPE used to prevent exposure to hazardous drugs with the potential for dermal absorption can be used to inform the conformity assessment.

### *Priorities and Targets*

1. Optimize NIOSH RAP operations by integrating modern and innovative technologies and artificial intelligence approaches.

Target 1: Develop and implement an “information enterprise system” with input from stakeholders to enhance records management, efficient internal operations, manufacturer tracking of approvals and applications, user access to respirator approval information, and communication between NIOSH and applicants through the incorporation of artificial intelligence.

Target 2: Integrate the use of remote, digital technologies to enhance reviews and assessments of proposed or active manufacturing sites.

2. Implement policy solutions within NIOSH’s RAP that advance the state of respiratory protection in the United States.

Target 1: Continue coordination efforts with the Food and Drug Administration to expand the respiratory protection available to HCPs and to streamline approvals/decisions for respirators used in healthcare.

Target 2: Continue to update requirements and test methods (federal and consensus) for powered air-purifying respirators to establish evidence-based standards that enable the safe and effective use of these respiratory protective devices in healthcare settings (e.g., where there is a need for a sterile field and communication).

Target 3: Integrate ASTM’s Respirator Fit Capability Standard into the regulatory framework of NIOSH’s RAP.

Target 4: Assess the outcome of Objective 1 from these NIOSH Healthcare PPT Targets to determine the need for additions or revisions to U.S.-based conformity assessment frameworks.

3. Identify the need for additional standards solutions to enhance respirator protections in the United States.

Target 1: Conduct surveillance to assess exposure hazards and PPE usage characteristics for HCP working in facility types where limited PPE usage research has been conducted (e.g., outpatient settings) and healthcare occupational groups where limited PPE usage research has been conducted (e.g., home healthcare support in remote work locations).

Target 2: Evaluate the impact of current regulations on respirator innovation.

Target 3: Develop a Roadmap to address any issues identified from Targets 1 and 2 above.

4. Implement changes to practices, procedures, and informational products used by the NIOSH RAP to optimize performance.

Target 1: Enhance existing post-market respirator testing and evaluation to include evaluating respiratory protective devices at the point-of-use (e.g., evaluate the effect of storage conditions), leveraging the PPT nomenclature and data format standard and resulting software platforms mentioned previously (refer to Objective 3, Priority 1, Targets 2 and 3).

Target 2: Leverage the PPT nomenclature and data format consensus standard to provide greater connectivity between the NIOSH RAP's Certified Equipment List and third-party vendor platforms for PPE inventory management.

Target 3: Develop NIOSH-accredited third-party facility knowledge, skills, and abilities for NIOSH respirator testing and quality assurance capabilities to enhance NIOSH agility during surge events and improve efficiencies and support technology innovators during routine demands, to provide trusted testing support, and develop a strategy for leveraging and maintaining trust with these laboratories (per [federal guidance](#)).

Target 4: Establish a sustainable approach to routinely review and update the NIOSH Standard Testing Procedures with consideration for the latest technological advancements.

Target 5: Develop and formalize crisis strategy practices, procedures, and informational products that the Program will implement when an emergency is declared.

5. Inform the design of conformity assessment programs where NIOSH is not the scheme owner or where no current scheme owner exists.

Target 1: Provide leadership through research, technical support, and guidance to optimize the conformity assessment schemes for HCP ensembles and components (e.g., surgical and isolation gowns).

Target 2: Provide leadership through research, technical support, and guidance to establish a conformity assessment scheme for face coverings that provide source control to reduce the spread of infectious disease.

Target 3: Assess the effectiveness of existing product and package labeling requirements for PPE used by HCP to document the ability of PPE selectors, purchasers, distributors, and users to accurately discern the appropriate use conditions for a given product.

### *Objective 6: Expand U.S. capacity for PPT research and innovation*

#### **Knowledge Gaps**

In 2008, [the NASEM recommended](#) that NIOSH “establish and sustain extramural PPT Centers of Excellence (COEs). These PPT COEs could be developed to “work closely with the NIOSH intramural research program to improve PPT, increase field research, and explore and implement research to practice interventions.” Realization of this recommendation would establish a strong extramural community and provide the opportunity to extend scientific inquiry into the behavioral sciences and other types of expertise not yet well developed within NIOSH’s Personal Protective Technology Program, including its NPPTL.

Several recent efforts also recognize the need for greater PPT research and innovation capacity where recommendations align with NIOSH’s unique capabilities, as detailed below.

- In December 2020, the Federal Emergency Management Agency announced a [Plan of Action](#) to establish a national strategy for the manufacture, allocation, and distribution of medical devices to respond to COVID-19 as part of a [Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic](#).
- In January 2021, President Biden signed [Executive Order 14001](#), resulting in the July 2021 [National Strategy for a Resilient Public Health Supply Chain](#), where Resiliency Recommendation 4 is to “launch a new public health supplies innovation center and product standardization task force.”
- Also in January 2021, the [National Strategy for the COVID-19 Response and Pandemic Preparedness](#) was published, with Goal 4 being, “immediately expand emergency relief and exercise of the Defense Production Act,” with subsequent text discussing both[?] PPE as a critical supply and specific needs to address shortages.
- In September 2021, the White House released [American Pandemic Preparedness: Transforming our Capabilities](#), where the first goal under Building Core Capabilities was to have effective, comfortable, and affordable PPE and where a sub-goal focused on PPE innovation.
- Additionally, the White House Implementation Plan for Countering Biological Threats and Pandemic Preparedness (forthcoming publication) identifies the need to promote a science and technology base to support biodefense. PPE serve a crucial role in meeting this objective.

Meeting the objectives outlined in these various strategy documents requires not only greater national capacity for PPT research and innovation, but also equitable PPE protections for HCP who rely on PPE for protection. Addressing gaps in PPE use, availability, accessibility, acceptability, and knowledge that exist for only a subset of PPE users with shared characteristics may reduce inequities related to PPE. These worker populations may include, but are not limited to, workers who are of an atypical size; who are members of a gender, racial, ethnic, or linguistic

minority group; who conduct non-traditional healthcare worker activities; or who are members of sub-disciplines that are not the primary focus of the current PPT activities within their larger field. For example, a recent study found that housekeeping staff employed in healthcare settings had the highest rate of SARS-CoV-2 seroprevalence (34.5%)—a rate higher than that observed for HCP working in intensive care settings (14.8%) [63]. Examples of challenges faced by some members of these populations include difficulty finding a single-use FFR that fits their facial dimensions, PPE limitations when religious practices require growing facial hair or wearing a head wrap, language difficulties and cultural differences when reading guidance documents, and limited scientific studies or training modules that address hazard scenarios experienced by a small sub-population of workers.

### *Priorities and Targets*

#### 1. Expand private sector engagement in PPT research and technology development.

Target 1: Establish PPT COEs within the academic community to support a pipeline of PPT researchers by establishing laboratory capabilities, administering academic training, and fostering outreach and continuing education specific to PPT.

Target 2: Establish a new NPPTL Program that leverages both Broad Agency Announcement and Request for Proposal contract types to engage technology developers, engineering firms, suppliers, and manufacturers to advance the development and production of next-generation PPT for HCP.

Target 3: Once established, leverage the NPPTL RAP and PPT COEs to drive innovative PPT design to include novel materials, construction, use of sensors, and usability issues.

Target 4: Guide PPT COEs to develop the national capacity for: (1) research and development of new technologies and approaches to PPT, including sensor technology to increase efficacy; (2) human factors or ergonomics approaches to evaluating the factors that influence the adoption and usage of PPE such as performance, comfort, fit, and usability; (3) sociotechnical systems analyses of the influences of factors such as health and safety management systems, safety culture, and regulatory requirements; and (4) innovative approaches to the design, manufacture, and maintenance of PPE that enhance factors such as the effectiveness and acceptance of PPE in varied user populations, availability, and the ability to rapidly customize and produce PPT during crises.

Target 5: Leverage the research conducted by the newly established PPT COEs to establish evidence-based PPT guidance.

#### 2. Towards the goal of providing equitable PPE protections for all U.S. workers, address existing gaps in PPE use, availability, accessibility, acceptability, and knowledge.

Target 1: Establish relationships with the research community that address PPE equity challenges and challenges for workers whose jobs place them at higher levels of risk.

Target 2: Conduct literature reviews and engage with members of the PPE community to identify PPE availability, accessibility, knowledge, and use challenges that allow PPE equity challenges to persist or allow challenges for high-risk workers to persist.

Target 3: Integrate test procedures and tasks into existing and newly developed projects to address the unique needs of both PPE users experiencing inequitable PPE protections, and workers whose jobs place them at high risk, where appropriate.

Target 4: Leverage ASTM's Respirator Fit Capability Standard to identify populations of workers who may not have adequate options for respiratory protection and recommend possible strategies to close this gap.

Target 5: Publish a national strategy to provide equitable PPE protections for all U.S. workers by (a) identifying and prioritizing goals into near-, mid-, and long-term efforts and (b) providing a roadmap and timelines for how members of the PPE community can work in coordination to systematically address all gaps and challenges.

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