

Frameworks for

PROTECTING WORKERS AND THE PUBLIC

from Inhalation Hazards

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Statement of Task

- Determine the **need for guidance** for the public and workers facing inhalation hazards outside of workplaces with respiratory protection programs based on an assessment of existing knowledge regarding the necessary factors to ensure respiratory protection is effective for its intended use and the identification of gaps in existing standards/guidance.
- Describe current and potential **options for oversight** and approval of respirators for these populations.
- Make recommendations for a **framework of responsibilities and authorities** to provide a unified and authoritative source of information and effective oversight in the development, approval, and use of respirators.



Study Catalyst and Background



Catalyst

- Historically, respiratory protection has been used in occupational settings with well-defined hazards.
- Threats from inhalation hazards (e.g., wildfire smoke, airborne infectious agents) increasingly extend to populations that have previously not used respiratory protection.
- These inhalation hazards have significant impacts on the health of the nation.
- Systems are needed to ensure all requiring respiratory protection have access to appropriate devices and guidance to ensure their effective use.



Terminology

- For the purposes of this report, the term *respiratory protective device* (RPD) is used to describe any personal device that provides protection against inhalation hazards when used effectively.
 - Function-based definition
 - Devices may offer personal protection and/or source control at varying levels, depending on both the device and the hazard in question
 - Intended to accommodate future devices that do not fit into existing categories
 - Terminology will likely continue to be refined



Terminology Continued

Air-Purifying Respirators		
		
Elastomeric Facepiece Respirator	Filtering Facepiece Respirator	Powered Air-Purifying Respirator
Medical Mask	Barrier Face Covering (complies with ASTM F3502-21)	Face Covering
		

In contrast to respirators, medical masks, face coverings, and barrier face coverings have a primary purpose of providing *source control* (reduction of the release of infectious agents from the wearer).

Findings: Gaps and Challenges



Gaps and Challenges in Respiratory Protection for the Public and Workers

- System in place only for selected workers.
 - Those covered by a Respiratory Protection Program mandated by OSHA or other federal agencies.
 - Conformity assessment processes in place
 - Certification of respirators through NIOSH/NPPTL
- For other workers and the public—systems not in place
 - Diversity in demographics, vulnerabilities, susceptibilities
 - Exposure scenarios are broad and poorly characterized
 - Highly fragmented regulatory landscape

➔ **The needs of many workers and the public are not being met, and significant disparities exist.**



Gaps and Challenges Specific to Workers

- Current system of workplace protections, including OSHA requirements, do not cover all workers who need respiratory protection for inhalation hazards.
- NIOSH approves respirators for use in respiratory protection programs (RPPs), but not for use outside of RPPs. Level of protection for all workers against potential hazards not assured.
- Risks of workplace exposures of current concern (e.g., wildfire smoke and infectious aerosols) are difficult to estimate and requirements and standards for these exposures in occupational settings are lacking.



Gaps and Challenges Specific to the Public

- A comprehensive regulatory framework and authority for respiratory protection for the public are lacking.
- Many devices used by the public are not covered by a certifying body or formal oversight designed to ensure that the devices are effective for their intended use.
- There is no formal system for coordinating the development, distribution, and use of respiratory protection by the public. State and local public health agencies are involved but without central guidance.
- The elements of occupational respiratory protection programs are not practicable for the public.



General Framework for Respiratory Protection

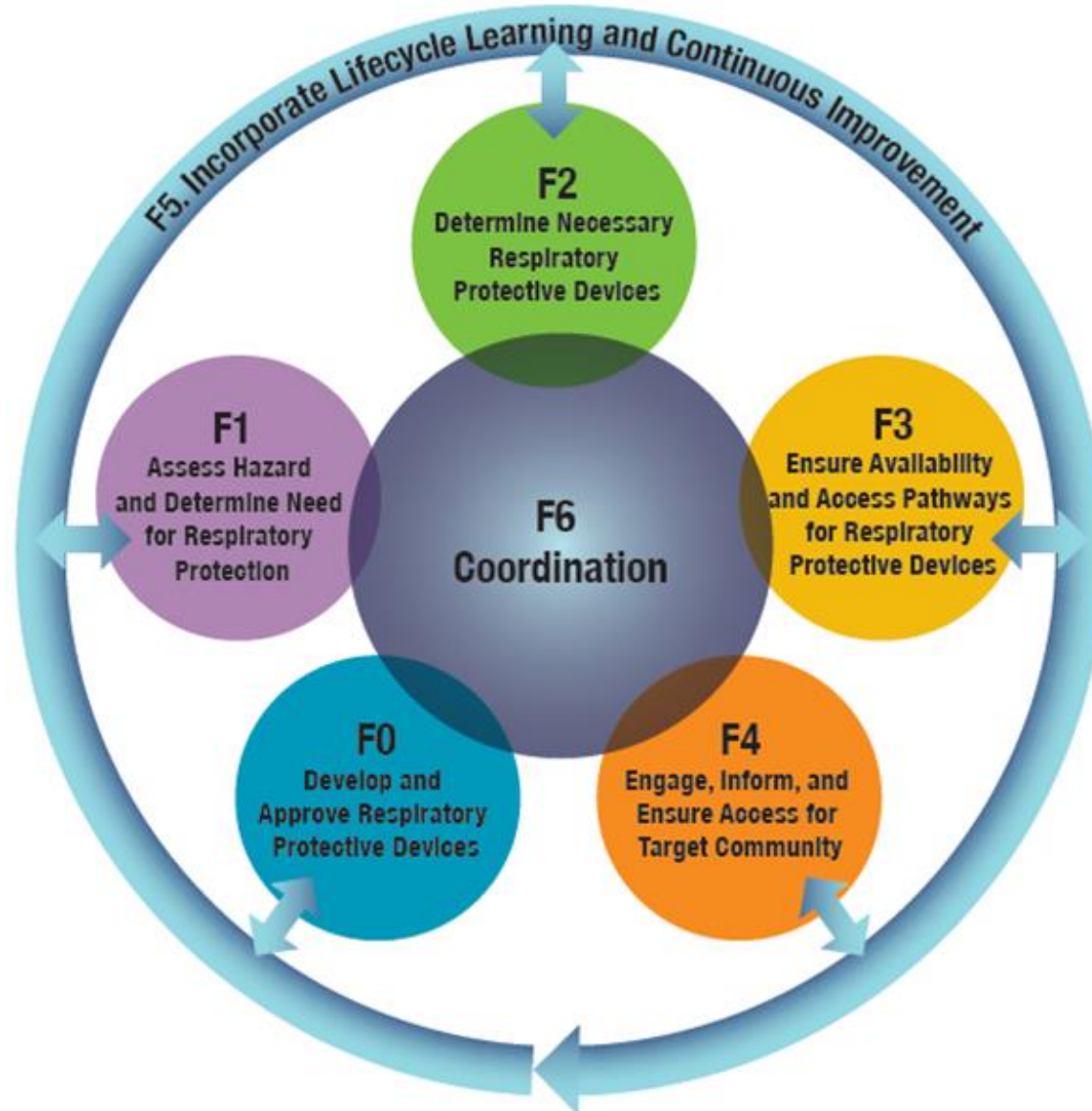


Guiding Principles

- Equity-protection for all
- Systems-based approach
- Respiratory protection is not absolute protection
- Decisions will be made under uncertainty
- Preparedness throughout the frameworks
- Acknowledge and incorporate population heterogeneity



A Framework for Oversight and Guidance for Respiratory Protection



Core Framework Functions

- **Function F0:** Develop and approve respiratory protective devices
- **Function F1:** Assess hazard and determine need for respiratory protection
- **Function F2:** Determine the necessary respiratory protective devices
- **Function F3:** Ensure availability and access pathways for respiratory protective devices
- **Function F4:** Engage, inform, and ensure access for the target community
- **Function F5:** Incorporate lifecycle learning and continuous improvement
- **Function F6:** Coordination



Recommendations for Applying the Framework to Meet the Respiratory Protection Needs of Workers



Overview

- Build on the foundation of OSHA RPPs and NIOSH/NPPTL
- OSHA should be the coordinating entity
- Broaden worker coverage through changes to OSH Act language and interpretation
- Establish new OSHA standards for triggering coverage
- Expand NPPTL capacity and NIOSH research



Ensuring Protection from Inhalation Hazards for All Workers

Recommendation 6-1: Ensure That Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to All Workers

- **Congress** should revise the OSH Act to address gaps in OSHA coverage
- **OSHA** should revise its statutory interpretations regarding definitions of employers and employees

Recommendation 6-2: Ensure Protection from Inhalation Hazards for Workers Not Covered by Federal or State Occupational Safety and Health Authorities

- **State legislatures** should require employers to protect workers who are not currently under OSHA jurisdiction from inhalation hazards through legislation and regulations



Ensuring Protection from Inhalation Hazards for All Workers Continued

Recommendation 6-4: Establish Comprehensive Workplace Exposure Standards That Serve to Trigger Respiratory Protection Program Requirements

- **OSHA** should establish and regularly update science-based, comprehensive workplace exposure standards for PM indicators and airborne infectious disease agents that would trigger RPP requirements
- **Congress** should set deadlines for OSHA's promulgation of these standards
- **OSHA** should expand its technical assistance capabilities to assist employers unfamiliar with RPP requirements
- **OSHA** and **NIOSH** should develop comprehensive guidelines for workers who are at high risk of exposure to these hazards in the interim



Generating and Using NIOSH-Approved Respirators

Recommendation 6-3: Improve the Timeliness and Capacity of the National Institute for Occupational Safety and Health's (NIOSH's) Respirator Conformity Assessment Processes

- **NIOSH** should expand **NPPTL** and use consensus standards and 3rd party testing to improve timeliness of respirator approvals and surge capacity

Recommendation 6-5: Recommend only National Institute for Occupational Safety and Health (NIOSH)–approved Respirators in Guidance for Workers Facing Inhalation Hazards

- **Agencies providing guidance for workers** facing inhalation hazards should recommend only NIOSH-approved respirators



Meeting Expanded Worker Needs for Device Access, Guidance, and Training on Use

Recommendation 6-6: Prepare to Meet Expanded Worker Respiratory Protection Needs

- **OSHA** and **NIOSH** should evaluate expanded worker needs for respiratory protection and guide **ASPR** on stockpiling and distribution guidelines.

Recommendation 6-7: Support the Development of Targeted and Tailored Guidance and Training for Workers

- **OSHA, NIOSH, EPA, NIEHS, and other federal agencies** should expand grant programs and other support mechanisms for the development of tailored and culturally appropriate guidance and training materials for employers and workers



Building a Strong Scientific Foundation

Recommendation 6-8: Launch Expanded National Institute for Occupational Safety and Health (NIOSH) Research and Surveillance Programs

- **NIOSH** should expand its surveillance and intramural and extramural research programs to better understand risks to workers from inhalation hazards and to advance the development and effective use of respiratory protection
- **Congress** should ensure the necessary appropriated funding

Recommendation 6-9: Conduct Research on Models for Respiratory Protection Program (RPP) Requirements

- **NIOSH** should assist **OSHA** in evaluating the effectiveness of different RPP models and RPP requirements for different scenarios for occupational exposure to inhalation hazards



Recommendations for Applying the Framework to Meet the Respiratory Protection Needs of the Public



Overview

- A coordinating entity is needed along with an interim office to get started
- Capability needed for standards development and implementation
- Approach needed to gauge risk and identify appropriate devices
- Devices to be available for all people with appropriate guidance on their use



Establishing Authorities and Mechanisms for Coordination

Recommendation 7-1: Establish a Coordinating Entity to Oversee the Framework for Respiratory Protection for the Public

- **Congress** should establish a coordinating entity within HHS with the necessary responsibility, authority, and resources to provide a unified and authoritative source of information and effective oversight of RPDs for the public
- **HHS** should establish an interim office to take on priority near-term tasks of the coordinating entity
- **The White House** should establish an interagency task force to ensure coordination

Recommendation 7-3: Assign and Coordinate Roles and Responsibilities for the Framework Functions

- **The coordinating entity** should assign and organize roles and responsibilities of federal and other stakeholders
- **Congress** should address gaps in authorities



Establishing an Oversight Authority for Devices Intended for Public Use

Recommendation 7-4: Establish a Capability to Oversee Standards Development for and Approval of Respiratory Protective Devices Used by the Public

- **Congress** should mandate that **HHS** establish and resource a laboratory responsible for overseeing standards development, conformity assessment, and approval for RPDs intended for use by the public
- Could be NPPTL or a new laboratory within HHS



Evaluating Hazards and Identifying Devices when Needed

Recommendation 7-5: Establish and Use a Standardized Process for Determining the Public's Need for Respiratory Protection

- **The coordinating entity** should work with **CDC**, **EPA**, and other federal stakeholders to establish and apply a standardized scientific review and evaluation process to identify inhalation hazards that warrant public use of RPDs

Recommendation 7-6: Use Hazard and Risk Evaluations to Determine the Necessary Respiratory Protective Devices for the Public

- The **recommended laboratory** (Rec 7-4) should make recommendations to the **coordinating entity** on approved RPDs that best meet the needs of the public based on hazard/risk evaluations (Rec 7-5)



Ensuring Device Availability and Access and Developing Appropriate Guidance to Support Use

Recommendation 7-7: Ensure Availability of and Access to Respiratory Protective Devices

- **The coordinating entity** should organize efforts to make RPDs available and accessible to the public, interfacing with **ASPR, OSHA, FEMA, and the White House** to ensure adequate supplies

Recommendation 7-8: Develop Culturally Appropriate Guidance and Training on the Use of Respiratory Protective Devices by the Public

- **CDC** should lead the development of culturally appropriate guidance and training related to the use of RPDs by the public
- **The coordinating entity** should facilitate the engagement of and gathering of input from key stakeholders



Ensuring Continuous Improvement

Recommendation 7-9: Continuously Evaluate Progress toward Goals, and Enhance the Framework's Operations

- **The coordinating entity** should, based on ongoing monitoring and evaluation:
 - Develop plans with objectives and milestones
 - Regularly assess and publicly report on progress
 - Ensure funding allocation enables goals to be achieved
 - Coordinate linkages across partners
 - Conduct periodic exercises to evaluate preparedness
 - Lead the development of a strategic research agenda



Recommendation for Coordination Between Worker- and Public-Focused Frameworks



Coordinating Between Frameworks

Recommendation 7-2: *Ensure Collaboration and Cooperation between the Coordinating Entities for the Worker and Public Frameworks*

- **DOL/OSHA** and **HHS** should ensure that mechanisms are established to support collaboration and cooperation as the two frameworks are implemented
- This should be included among requirements for regular assessment and reporting (Recommendation 7-9)



Moving Forward

- COVID-19 and annual wildfires have underscored that the threat from inhalation hazards extends far beyond the groups of workers traditionally required to use respirators under a respiratory protection program.
- We cannot know what's coming next but we must be better prepared.
- This will require action at the highest levels of government.

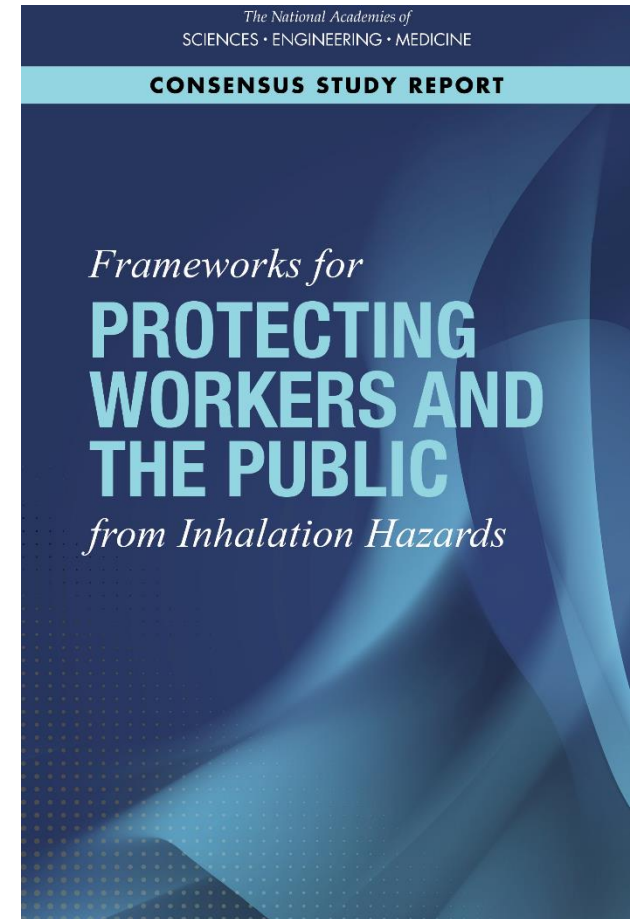


Report and Dissemination Materials

Materials available on the National Academies Press webpage:

- PDF Report
- Report Highlights
- Slide set

[http://www.nationalacademies.org/
respiratory-protection](http://www.nationalacademies.org/respiratory-protection)



Thank You!



Mask Oxen Achieving Herd Immunity

Courtesy of Bruce Lippy, Committee Member

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Supplementary Slides



Expertise, Resources, and Authorities: Functions F0-F2

Function	Expertise	Resources and Authorities
Function F0: Develop and approve respiratory protective devices	<ul style="list-style-type: none"> • Respiratory protection • Product development, including knowledge of market forces and incentives • Conformity assessment • Standards development 	<ul style="list-style-type: none"> • Access to testing laboratories • Access to standards development organizations • Regulatory authority to approve devices • Enforcement mechanisms for corrective action for nonconforming products (including recall authority)
Function F1: Assess hazard and determine need for respiratory protection	<ul style="list-style-type: none"> • Hazard monitoring • Hazard and exposure assessment • Risk evaluation and hazard control 	<ul style="list-style-type: none"> • Access to a multidisciplinary group to monitor the hazard, conduct hazard assessment, and judge the acceptability of risks • Hazard monitoring infrastructure
Function F2: Determine the necessary respiratory protective devices	<ul style="list-style-type: none"> • Respiratory protection: hazard-based assessment and determination of level of protection • Product development, including knowledge of market forces and incentives 	<ul style="list-style-type: none"> • Relationships with manufacturers • Access to the Certified Equipment List

Expertise, Resources, and Authorities: Functions F3-F5

Function	Expertise	Resources and Authorities
Function F3: Ensure availability and access pathways for respiratory protective devices	<ul style="list-style-type: none"> • Supply chain management • Understanding of diverse population needs related to access to respiratory protective devices 	<ul style="list-style-type: none"> • Relationships with manufacturers • Relationships with state, local, tribal, and territorial authorities responsible for distributing devices • Access to Strategic National Stockpile (SNS) information • Authorities related to the SNS, including purchasing and distribution
Function F4: Engage, inform, and ensure access for the target community	<ul style="list-style-type: none"> • Public health messaging and risk communication • Sociobehavioral science • Health equity • Guidance development 	<ul style="list-style-type: none"> • Networks to reach target audiences • Authority to approve guidance
Function F5: Incorporate lifecycle learning and continuous improvement	<ul style="list-style-type: none"> • Inhalation hazards and respiratory protection • Sociobehavioral science • Implementation science • Continuous improvement 	<ul style="list-style-type: none"> • Research infrastructure • Infrastructure to monitor and evaluate for ongoing improvement purposes

