



# The Evolving National Landscape for Respiratory Protection

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NIOSH Board of Scientific Counselors Meeting

April 20, 2022



# Overview

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Current Respiratory Protection Landscape

Emerging issues and National Strategy

The Path Forward?

# NPPTL Mission and Responsibilities

- At the request of Congress, NIOSH established the National Personal Protective Technology Laboratory in 2001 with the mission to....
  - *Prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies*
- Key Responsibilities
  - Conformity Assessment of Respirators
  - Research on Respirators and other types of Personal Protective Equipment
  - Outreach and Communications



Photo credit Moldex



Photo credit Draeger



Photo credit MSA



Photo credit MSA

# The Respirator Conformity Assessment Program is the Cornerstone of NPPTL.

- Respirator approval
  - Over 9000 respirator systems approved
  - 90 manufacturers
  - 25 countries
- Post market evaluation
- Standards development

## Conventional (2020 COVID-19) Operations

- 30 approval decisions per month (~65)
- 400 approval decisions (809)
- 250 quality audits (781)



# Certification Mark Monitoring Activities

## Several USPTO Trademarks and Certification Marks recorded

- NIOSH stylized logo with and without words, NIOSH Approved, N95, N99, N100, P95, P100; other protections pending registration
- Public notice of registering these marks was posted and disseminated
- Working with NIH to trademark “N95” in 18 other countries (4 granted), and “NIOSH APPROVED” in 16 other countries (6 granted)

## Certification mark monitoring

- Responding to public inquiries to verify NIOSH approval authenticity
- Adding products that are counterfeit or misrepresent the NIOSH approval on the [NIOSH Counterfeit/Misrepresented Respirator webpage](#)
- Developed a Customs and Border Protection (CBP) SOP for seizing respirator products with nonconforming use of NIOSH approved respirator marks
- Contracted Underwriters Laboratory to recommend strategies to handle counterfeit respirators; recommendations being evaluated/considered
- Exploring proactive monitoring options



*Trademarks and certification marks currently registered with USPTO*



*Example of what is posted on NIOSH's Counterfeit/Misrepresented Respirator Webpage*

# NIOSH Conformity Assessment Evolution

## **Assessment underway to explore transitioning PPE Conformity Assessment practices to align with the NIOSH National Framework for Conformity Assessment**

- Approval Core Function
- Standards Core Function
- Post Market Core Function
- Non-Traditional Users / Unconventional PPE
- Healthcare & EMS PPE / RPD

# Respirator Research and Standards Development Areas



- **Fit**
  - Facial anthropometrics/headforms
  - Real-time fit monitoring
  - Respirator fit capability
  - Respirator fit/facial anthropometry app
- **Comfort**
  - Physiology studies (N95s, elastomeric, PAPRs)
- **Standards Development**
  - PAPR
  - Combination Unit Respirator
  - Respirator fit capability
  - Standard sizing for children
  - Barrier face coverings
- **Performance & Usability**
  - Simulated workplace protection factor studies
  - Respirator clinical effectiveness
  - SPARTAN (PAPRs)

- **Filtration**
  - Nanoparticles / Bioaerosols
- **Surveillance & Interventions**
  - Respirator Survey
  - Respirator evaluation & interventions
  - Best practices for EHMRs, PAPRs, N95s
  - EHMR in healthcare & first responder settings
  - Point of use Filter Penetration Testing
- **Influenza Pandemic / Reuse**
  - Elastomeric respirator research and demonstration studies
  - Splash/spray resistance & flammability
  - General public use of barrier face coverings and respirators
  - Clinical reuse/**extended use** of N95s
  - Extended use/reuse of EHMR
  - Decontamination method development and assessment for N95s, EHMRs, PAPRs

## NPPTL Impact

NPPTL research is addressing critical workplace needs



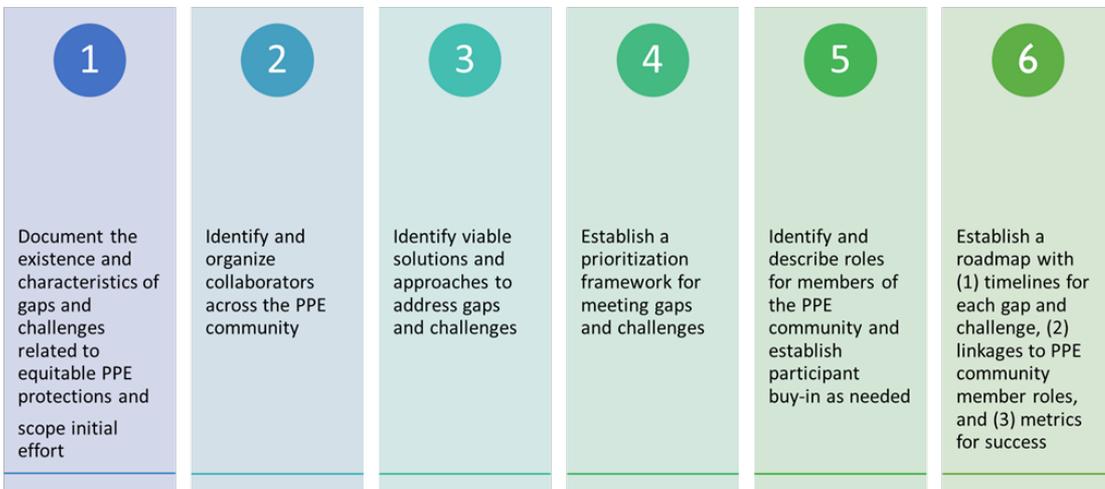
# Draft NIOSH Healthcare Personal Protective Technology Targets for 2020 to 2030

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

# NIOSH efforts to address equitable PPE for all workers

Ongoing/Completed Activities



FRN  
NORA Councils  
ISEA  
NASEM COPPE  
Lit Review

FRN  
NORA Councils  
ISEA  
NIOSH Partnership for Equitable PPE Protection

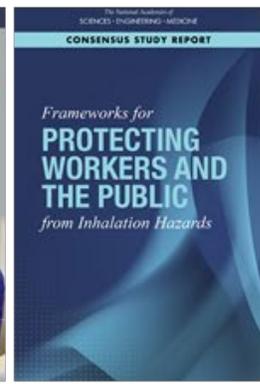
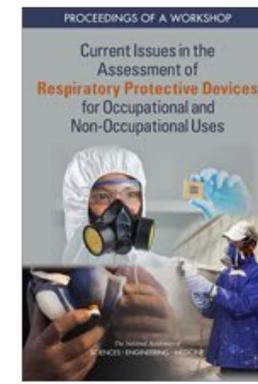
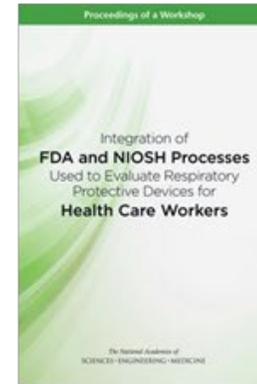
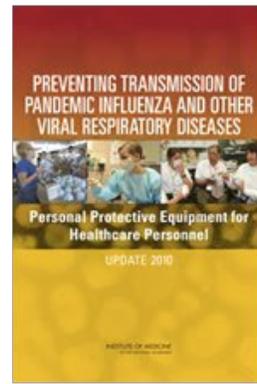
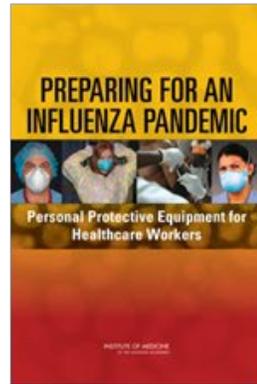
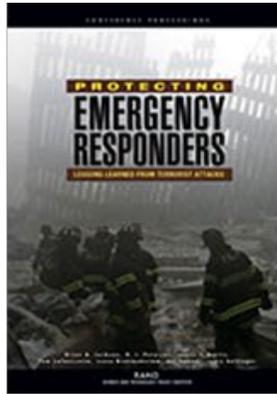
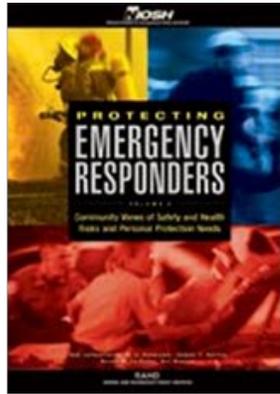
Crowdsourcing Ideas

Crowdsourcing Challenge – Summer 2022  
Workshop planned Oct/Nov 2022

# NIOSH is preparing to launch PPT Centers of Excellence

- **2008 Recommendation for PPT Centers of Excellence (COEs)**
  - Pursued in 2011, but no funding
  - Pursued priority elastomeric respirator grant in 2015
  - 2020 proposed legislation described PPT COEs
- **Early 2021**
  - Stakeholders provided input on COE needs and structure
- **Nov 2021 – Jan 2022**
  - FRN and docket active for comments
  - 46 comments that supported establishing COEs received
- **Public Safety and Healthcare and Social Assistance were predominant sectors**

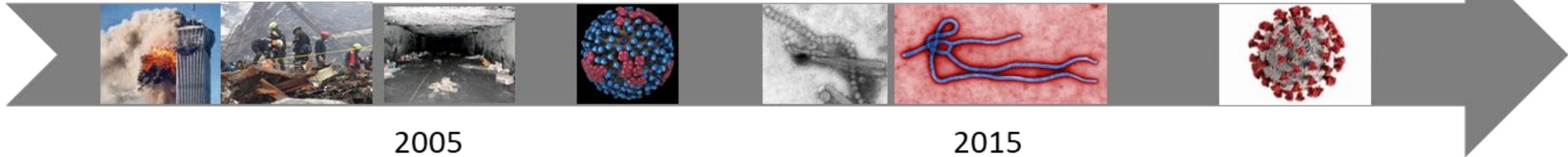
# The Respiratory Protective Device landscape has been shaped by Public Health Emergencies and Workplace Needs



2000

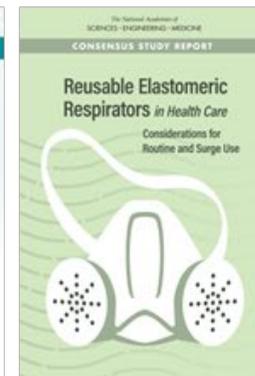
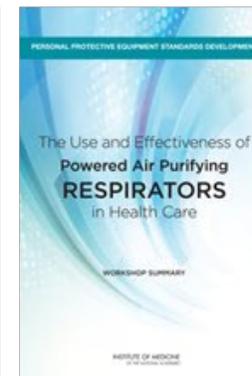
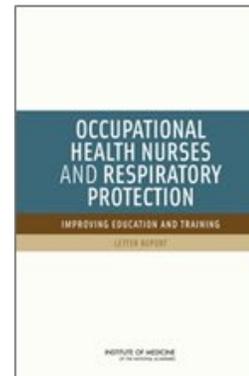
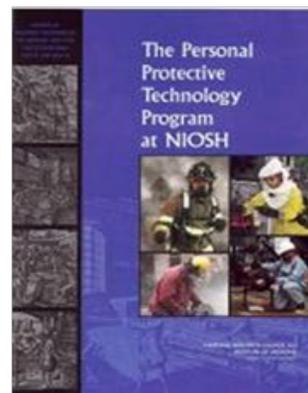
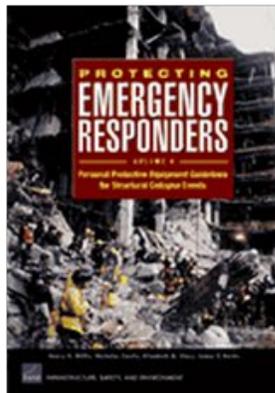
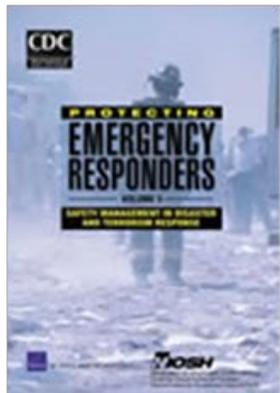
2010

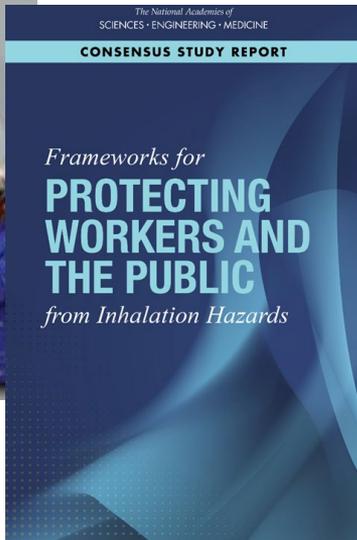
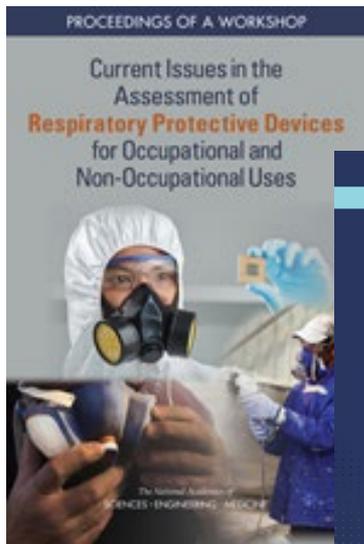
2020



2005

2015





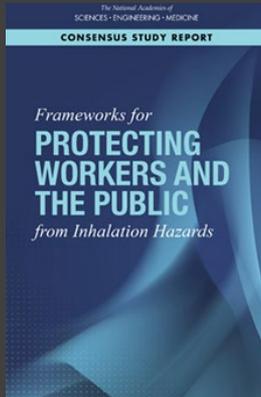
## National Academies Consensus Report on Frameworks for Protecting Workers and the Public from Inhalation Hazards

### • Recommendations

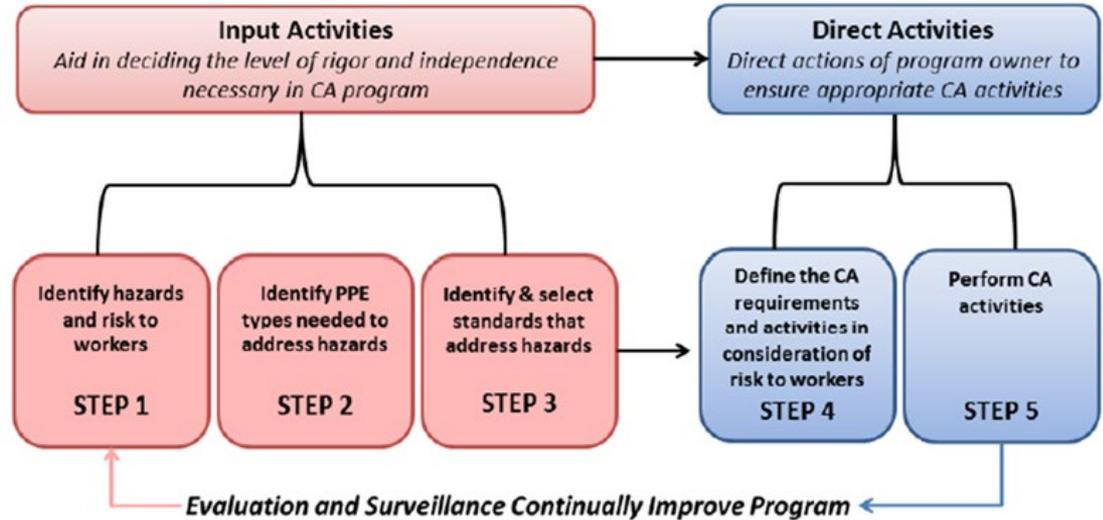
- Applying the Framework to Meet the Respiratory Protection Needs of Workers
- Applying the Framework to Meet the Respiratory Protection Needs of the Public
- Coordination Between Worker- and Public-Focused Frameworks



# A Framework for Oversight and Guidance for Respiratory Protection



NIOSH  
Conformity  
Assessment  
Framework,  
NIOSH Pub.  
2018-102 is  
similar to the  
NASEM  
Framework



## Expanded Workforce: Workers without Respiratory Protection Programs

Rec 6-1  
Ensure that Occupational Safety  
Administration (OSHA) Respiratory  
Protection Requirements Apply to All  
workers

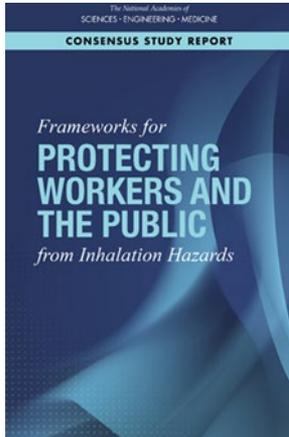
- Build on the foundation of OSHA RPPs and NIOSH/NPPTL as the approving authority for respirators.
- OSHA should be the coordinating entity
- Broaden worker coverage through changes to OSH Act language and interpretation
- Establish new OSHA standards for triggering coverage
- Expand NPPTL conformity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

## General Public

Rec 7-1  
Establish Coordinating Entity to Oversee  
the Framework for Respiratory  
Protection for the Public

- 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

## Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations



**Expanded Workforce:  
Workers without Respiratory Protection Programs**

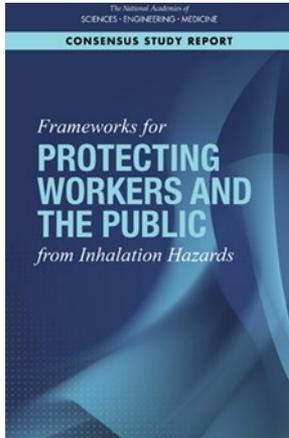
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Rec 6-2  
Ensure Protection from  
Inhalation Hazards for Workers  
Not Covered by Federal or State  
Occupational Safety and Health  
Authorities

Rec 6-4  
Establish Comprehensive  
Workplace Exposure Standards  
that Serve to Trigger Respiratory  
Protection Program  
Requirements

**Three  
recommendations  
focus on ensuring  
protection from  
inhalation hazards for  
all workers**

Frameworks for  
Protecting  
Workers and the  
Public from  
Inhalation Hazards  
Recommendations



**Expanded Workforce:  
Workers without Respiratory Protection Programs**

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Ensure that Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to All Workers

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

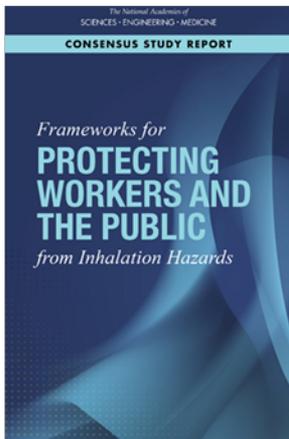
Rec 6-3  
Improve the Timeliness and Capacity of NIOSH's Respirator Conformity Assessment Processes

Rec 6-4  
Establish Comprehensive Workplace Exposure Standards that Serve to Trigger Respiratory Protection Program Requirements

Rec 6-5  
Recommend only NIOSH Approved Respirators in Guidance for Workers Facing Inhalation Hazards

**Two recommendations focus on Generating and using NIOSH approved RPDs**

Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations



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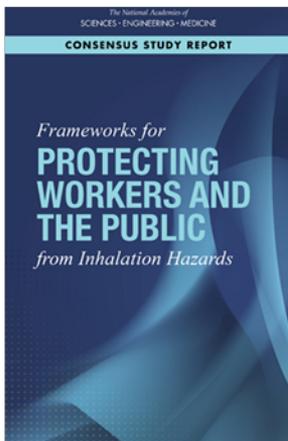
Rec 6-5  
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Rec 6-6  
Prepare to Meet Expanded Worker Respiratory Protection Needs

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

**Two recommendations focus on Meeting Expanded Worker Needs for Device Access, Guidance, and Training on Use**

Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations



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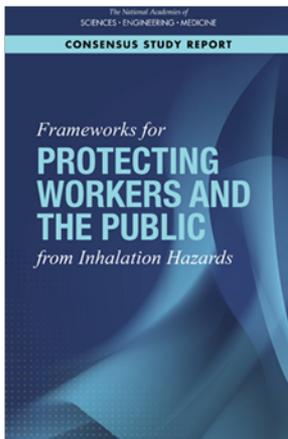
Rec 6-8  
Launch Expanded NIOSH Research and Surveillance Programs

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

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

**Two  
recommendations  
focus on building a  
strong scientific  
foundation**

Frameworks for  
Protecting  
Workers and the  
Public from  
Inhalation Hazards  
Recommendations



General Public

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

Rec 7-3  
Assign and Coordinate Roles and Responsibilities for Framework Functions

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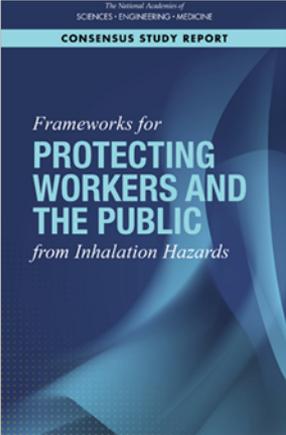
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**Two recommendations focusing on establishing authorities and mechanisms for coordination for the general public.**

Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations



## General Public

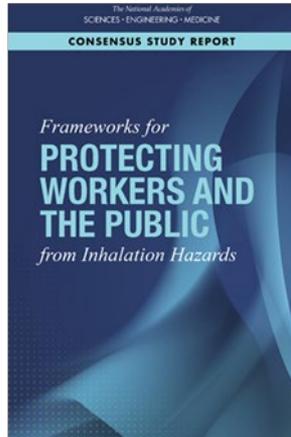
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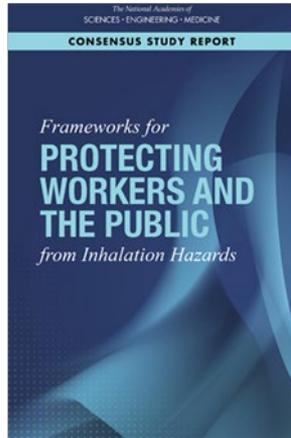
Rec 7-4  
Establish a Capability to  
Oversee Standards  
Development for and Approval  
of Respiratory Protection  
Devices for the Public

**One recommendation  
focuses on establishing  
an oversight authority  
for devices intended  
for public use.**

Frameworks for  
Protecting  
Workers and the  
Public from  
Inhalation Hazards  
Recommendations

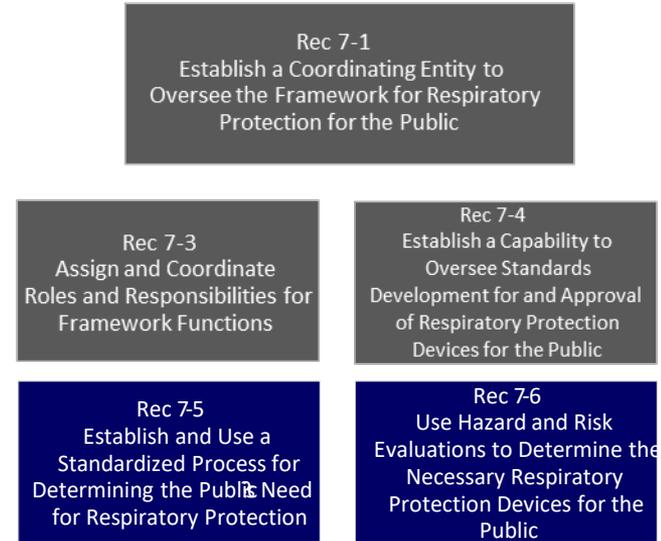


Frameworks for  
Protecting  
Workers and the  
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Inhalation Hazards  
Recommendations

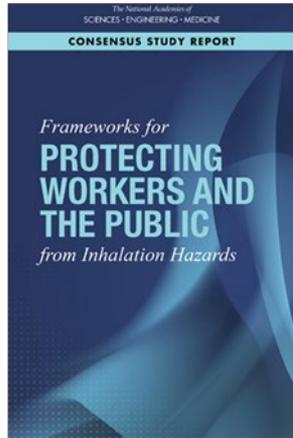


**Two recommendations emphasize the need to evaluate hazards and identify the devices that need to be used for the public.**

**General Public**



Frameworks for  
Protecting  
Workers and the  
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Recommendations



**Two recommendations focus on Ensuring device availability and access and developing appropriate guidance to support device use.**

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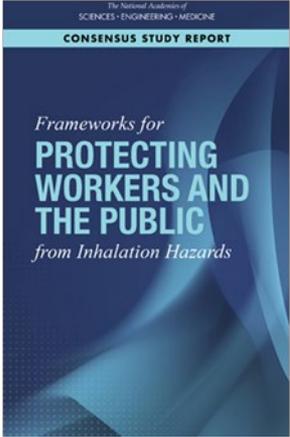
**Rec 7-5**  
Establish and Use a  
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Determining the Public Need  
for Respiratory Protection

**Rec 7-6**  
Use Hazard and Risk  
Necessary Respiratory  
Protection Devices for the  
Public

**Rec 7-7**  
Ensure Availability of and  
Access to Respiratory  
Protective Devices

**Rec 7-8**  
Develop Culturally  
Appropriate Guidance and  
Training on the Use of  
Respiratory Protective Device  
for the Public

Frameworks for  
Protecting  
Workers and the  
Public from  
Inhalation Hazards  
Recommendations



**One recommendation  
for public use is  
ensuring Continuous  
Improvement**

**General Public**

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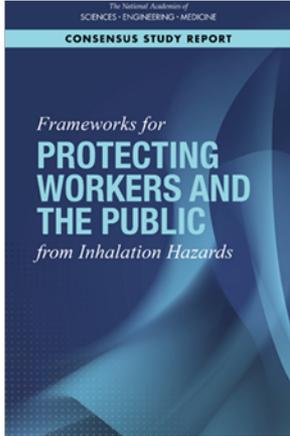
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**Rec 7-9**  
Continuously Evaluate Progress  
toward Goals, and Enhance the  
Framework's Operations

# Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations



## Expanded Workforce: Workers without Respiratory Protection Programs

## General Public

<p>Rec 6-1 Ensure that Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to All Workers</p>	<p>Rec 7-2 Ensure Collaboration and Coordination between the Coordinating Entities for the Worker and Public Frameworks</p>	<p>Rec 7-1 Establish a Coordinating Entity to Oversee the Framework for Respiratory Protection for the Public</p>
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<p>Rec 6-2 Ensure Protection from Inhalation Hazards for Workers Not Covered by Federal or State Occupational Safety and Health Authorities</p>	<p>Rec 6-3 Improve the Timeliness and Capacity of NIOSH's Respirator Conformity Assessment Processes</p>
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Rec 7-3  
Assign and Coordinate Roles and Responsibilities for Framework Functions

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Rec 6-4  
Establish Comprehensive Workplace Exposure Standards that Serve to Trigger Respiratory Protection Program Requirements

Rec 6-5  
Recommend only NIOSH Approved Respirators in Guidance for Workers Facing Inhalation Hazards

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Rec 7-6  
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Rec 6-6  
Prepare to Meet Expanded Worker Respiratory Protection Needs

Rec 6-8  
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Rec 7-7  
Ensure Availability of and Access to Respiratory Protective Devices

Rec 7-8  
Develop Culturally Appropriate Guidance and Training on the Use of Respiratory Protective Devices for the Public

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

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

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

# NASEM Recommendations

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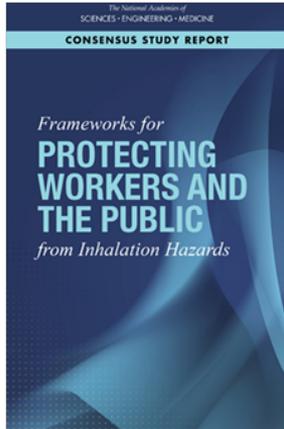
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Continuously Evaluate Progress toward Goals, and Enhance the Framework's Operations

**■** Led by other federal agencies  
**■** Aligned with NIOSH KSAOs

## Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations



# NASEM Recommendations

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Ensure that Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to All Workers

**Rec 7-2**  
Ensure Collaboration and Coordination between the Coordinating Entities for the Worker and Public Frameworks

**Rec 7-1**  
Establish a Coordinating Entity to Oversee the Framework for Respiratory Protection for the Public

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

**Rec 6-3**  
Improve the Timeliness and Capacity of NIOSH's Respirator Conformity Assessment Processes

**Rec 7-3**  
Assign and Coordinate Roles and Responsibilities for Framework Functions

**Rec 7-4**  
Establish a Capability to Oversee Standards Development for and Approval of Respiratory Protection Devices for the Public

**Rec 6-4**  
Establish Comprehensive Workplace Exposure Standards that Serve to Trigger Respiratory Protection Program Requirements

**Rec 6-5**  
Recommend only NIOSH Approved Respirators in Guidance for Workers Facing Inhalation Hazards

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

**Rec 7-6**  
Use Hazard and Risk Evaluations to Determine the Necessary Respiratory Protection Devices for the Public

**Rec 6-6**  
Prepare to Meet Expanded Worker Respiratory Protection Needs

**Rec 6-8**  
Launch Expanded NIOSH Research and Surveillance Programs

**Rec 7-7**  
Ensure Availability of and Access to Respiratory Protective Devices

**Rec 7-8**  
Develop Culturally Appropriate Guidance and Training on the Use of Respiratory Protective Devices for the Public

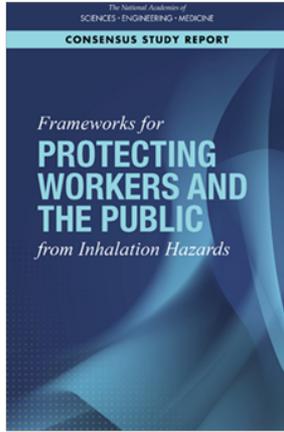
**Rec 6-7**  
Support the Development of Targeted and Tailored Guidance and Training for Workers

**Rec 6-9**  
Conduct Research on Models for Respiratory Protection Program (RPP) Requirements

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

- Led by other federal agencies
- Aligned with NIOSH KSAOs
- Immediate action needed

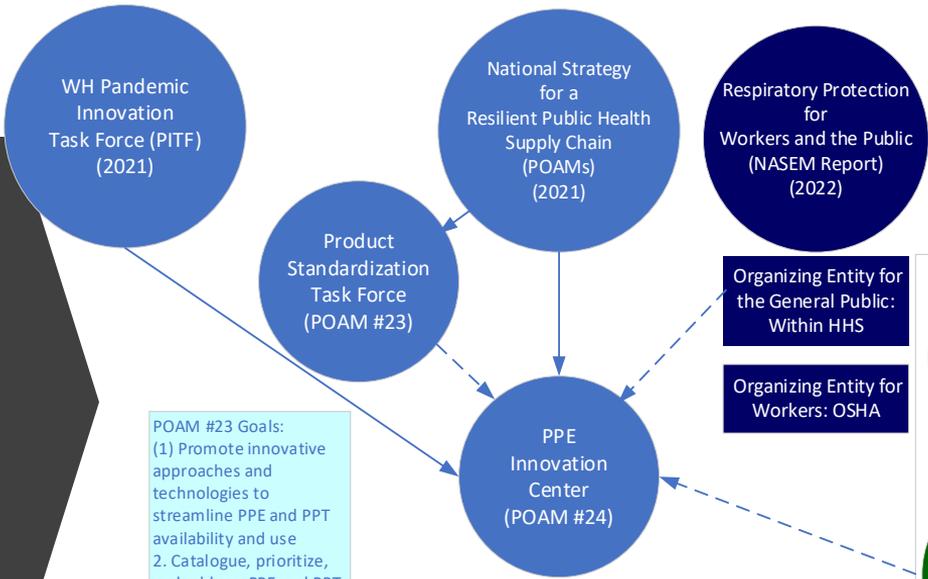
## Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations



## PPE Interest at the highest federal level

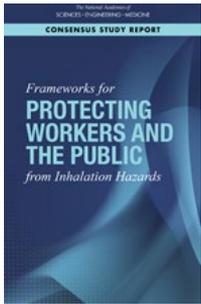
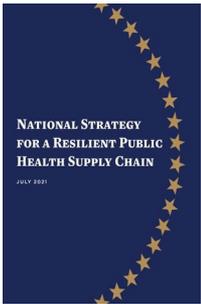
## NIOSH-led efforts

**NPPTL is leading National PPE efforts**

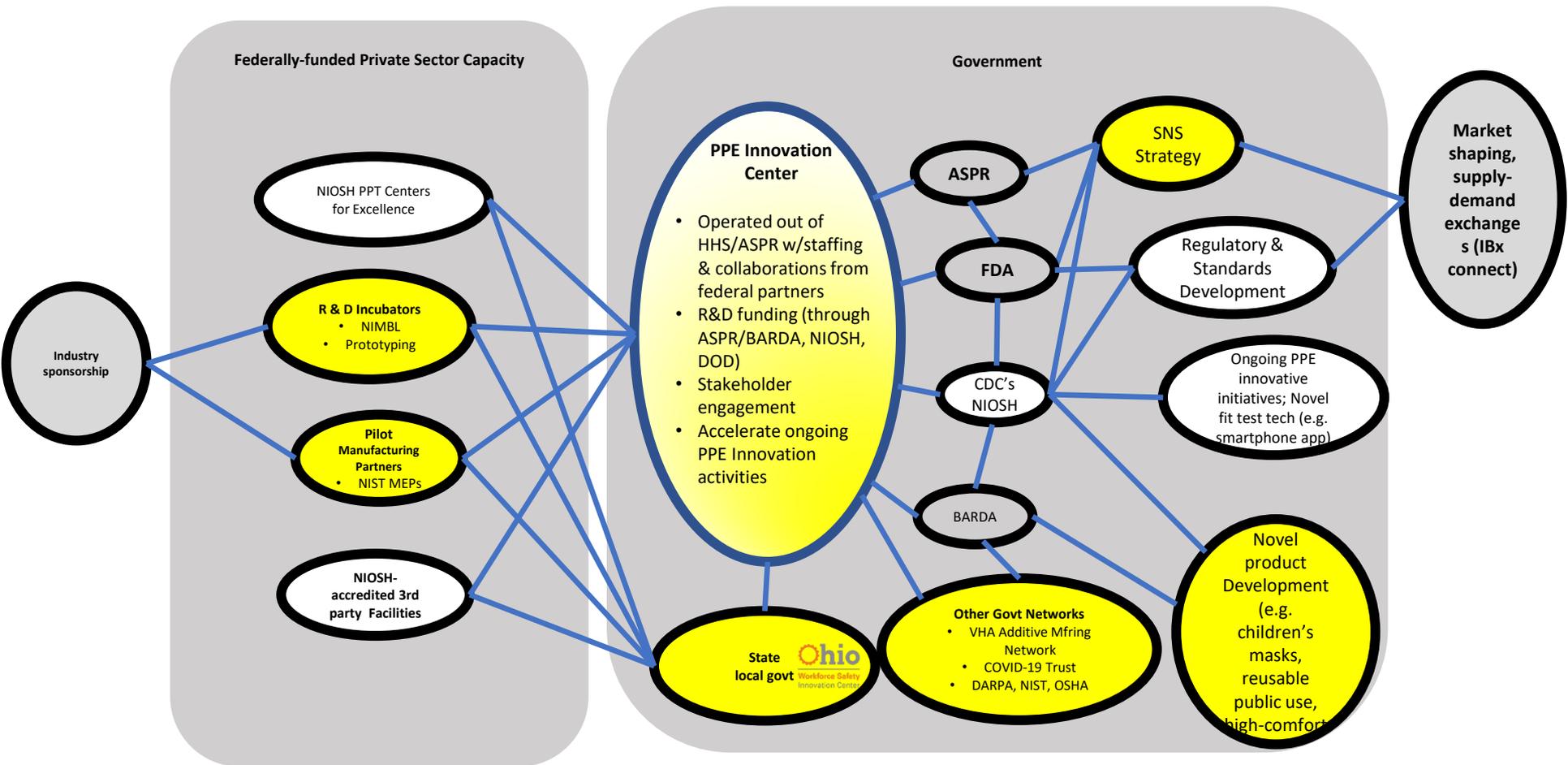


**POAM #23 Goals:**  
(1) Promote innovative approaches and technologies to streamline PPE and PPT availability and use  
2. Catalogue, prioritize, and address PPE and PPT standardization gaps

**POAM #24 Goals:**  
(1) Next generation of masks and respirators  
(2) More resilient PPE supply chains

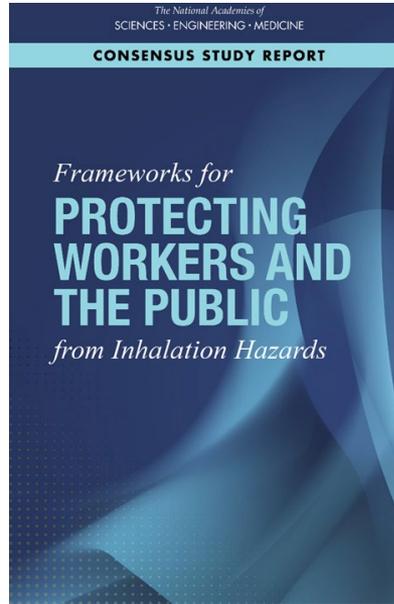


# Federal Vision for the PPE Innovation Center Framework



# NPPTL Actions

- Continue to work on National efforts to implement recommendations
- Work with OSHA to address recommendations associated with RPPs for all workers
- Socialize Draft White Paper to determine NPPTL involvement in general public efforts



# NPPTL questions to the NIOSH BSC

1. How can NIOSH remain the global leader in respiratory protection in its traditional areas of responsibilities given emerging issues and increased expectations resulting from COVID-19?
2. Given the increased number of workers whose respiratory protection needs are not being met, how can NIOSH best position itself to remain the global leader to address these needs?
3. How can NIOSH leverage its workplace expertise to best support the public's evolving respiratory protection needs as underscored by the COVID-19 pandemic?

# Quality Partnerships to Enhance Worker Safety and Health

Visit NIOSH NPPTL:

<https://www.cdc.gov/niosh/npptl/default.html>

[100 Years of Respiratory Protection](#)



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