

The Evolving National Landscape for Respiratory Protection

Maryann D'Alessandro NIOSH Board of Scientific Counselors Meeting

April 20, 2022



Overview

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 Draege



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)





Trademarks and certification marks currently registered with USPTO



This is an example of a misrepresentation of NIOSH approval. SafeShield's marketing of model FS-N95 is misleading and may cause users to believe it is NIOSH approved. SafeShield references certification to NIOSH CFR 42.84 180-181 and TEB-APR-57069.71 his information is inaccurate, safeShield is not a NIOSH approval holder or private label assignee, and model FS-N95 is NOT NIOSH approved. (12/1/2021)

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

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 <u>NIOSH Counterfeit/Misrepresented Respirator webpage</u>
- 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

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

- 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

Completed ISEA Activities

 NORA Councils
 NOF

 ISEA
 ISEA

 NASEM COPPE
 NIO

 Lit Review
 Equition

1

Document the existence and characteristics of

protections and scope initial effort

gaps and challenges related to equitable PPE

> NORA Councils ISEA NIOSH Partnership for Equitable PPE Protection

FRN

Crowdsourcing Ideas

Crowdsourcing Challenge – Summer 2022 Workshop planned Oct/Nov 2022

This will be an iterative process

2	3	4	5	6
ldentify and organize collaborators across the PPE community	Identify viable solutions and approaches to address gaps and challenges	Establish a prioritization framework for meeting gaps and challenges	Identify and describe roles for members of the PPE community and establish participant buy-in as needed	Establish a roadmap with (1) timelines for each gap and challenge, (2) linkages to PPE community member roles, and (3) metrics for success

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

CDC

2010



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OCCUPATIONAL HEALTH NURSES AND RESPIRATORY PROTECTION INTERNET

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2015

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2020





Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses

The National Academics of SCIENCES • ENGINEERING • MEDICINE CONSENSUS STUDY REPORT

SNSENSUS STUDT REPORT

Frameworks for PROTECTING WORKERS AND THE PUBLIC

from Inhalation Hazards



CDC Foundation

Together our impact is greater

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 Workerand 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



Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations

SCIENCES - ENGINEERING - MEDICINE

	CONSENSUS STUDY REPORT
Frameworks for	Frameworks for
PROTECTING	PROTECTING
WORKERS AND	WORKERS AND
THE PUBLIC	THE PUBLIC
from Inhalation Hazards	from Inhalation Hazards

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

> The National Academics of SCIENCES - ENGINEERING - MEDICINE CONSEINSUS STUDY REPORT

Frameworks for PROTECTING WORKERS AND THE PUBLIC from Inhalation Hazards Rec 6-1 Ensure that Occupational Safety 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 6-4 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

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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

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Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations

> Frameworks for PROTECTING WORKERS AND THE PUBLIC from Inhalation Hazards

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Rec 6-3

Improve the Timeliness and

Capacity of NIOSH's

Respirator Conformity

Assessment Processes

Rec 6-5

Recommend only NIOSH

Approved Respirators in

Guidance for Workers Facing

Inhalation Hazards

Rec 6-8 Launch Expanded <u>NIOSH</u>

Research and Surveillance

Programs

Two recommendations focus on building a strong scientific foundation

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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

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

Rec 7-1

Establish a Coordinating Entity to Oversee the Framework for Respiratory Protection for the Public

Rec 7-4

Rec 7-3 Assign and Coordinate Roles and Responsibilities for Framework Functions Establish a Capability to Oversee Standards Development for and Approval of Respiratory Protection Devices for the Public

Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations

SCIENCES + ENGINEERING + MEDICINE
CONSENSUS STUDY REPORT
Frameworks for PROTECTING WORKERS AND THE PUBLIC from Inhalation Hazards

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

SCIENCES - ENGINEERING - MEDICINE
CONSENSUS STUDY REPORT
Frameworks for PROTECTING WORKERS AND THE PUBLIC from Inhalation Hazards

Two recommendations emphasize the need to evaluate hazards and identify the devices that need to be used for the 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	Rec 7-4 Establish a Capability to Oversee Standards Development for and Approval of Respiratory Protection Devices for the Public		
Rec 7-5 Establish and Use a Standardized Process for Determining the Public Need for Respiratory Protection	Rec 7-6 Use Hazard and Risk Evaluations to Determine th Necessary Respiratory Protection Devices for the Public		

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Rec 75 Establish and Use a Standardized Process for Determining the Publits 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

CONSENSUS STUDY REPORT	1
Frameworks for PROTECTING WORKERS AND THE PUBLIC from Inhalation Hazards	

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

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Rec 77 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
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

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CONSENSUS STUDY REPORT
Frameworks for PROTECTING WORKERS AND THE PUBLIC from Inhalation Hazards

One recommendation for public use is ensuring Continuous Improvement

General Public

Frameworks for Protecting Workers and the Public from	Rec 6- Ensure that Occupation Administration (OSHA) Requirements App	-1 nal Safety and Health Respiratory Protection ly to All Workers	Rec 7-2 Ensure Collaboration and Coordination between the Coordinating Entities for the Worker and Public Framework	Rec 7-2 re Collaboration and dination between the inating Entities for the and Public Frameworks Rec 7-1 Establish a Coordinating Entity to Oversee the Framework for Respiratory Protection for the Public		
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	Rec 6-7 Support the Development of Targeted and Tailored Guidance and Training for Workers	Rec 6-9 Conduct Research on M Respiratory Protection (RPP) Requiremen	lodels for Con Program tow ts Fr	Rec 7-9 tinuously Evaluate Progress ard Goals, and Enhance the amework's Operations		

NASEM Recommendations

Expanded Workforce: Workers without Respiratory Protection Programs

General Public

Frameworks for Protecting Workers and the Public from Inhalation Hazards Recommendations

> Frameworks for PROTECTING WORKERS AND THE PUBLIC from Inhalation Hazards

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Rec 7-6

Use Hazard and Risk

Evaluations to Determine the

Necessary Respiratory

Protection Devices for the

Public

Rec 7-5 Establish and Use a Standardized Process for Determining the Publics Need for Respiratory Protection

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Led by other federal agencies
 Aligned with NIOSH KSAOs

NASEM Recommendations

Rec 7-2

Expanded Workforce: Workers without Respiratory Protection Programs

General Public

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PPE Interest at the highest federal level

NIOSH-led efforts

NPPTL is leading National PPE efforts



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



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EPA



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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