

Goals for the Workshop

Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers

**National Personal Protective Technology
Laboratory**

The National Academies

500 Keck Street, NW, Room 100

Washington, DC

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National Personal Protective Technology Laboratory Mission

An estimated 20 million workers use personal protective equipment on a regular basis to protect themselves from job hazards.



The **MISSION** of NIOSH NPPTL and the NIOSH PPT Program is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies (PPT).

OSHA and MSHA require the use of NIOSH-certified respirators in the American workplaces requiring RPDs.

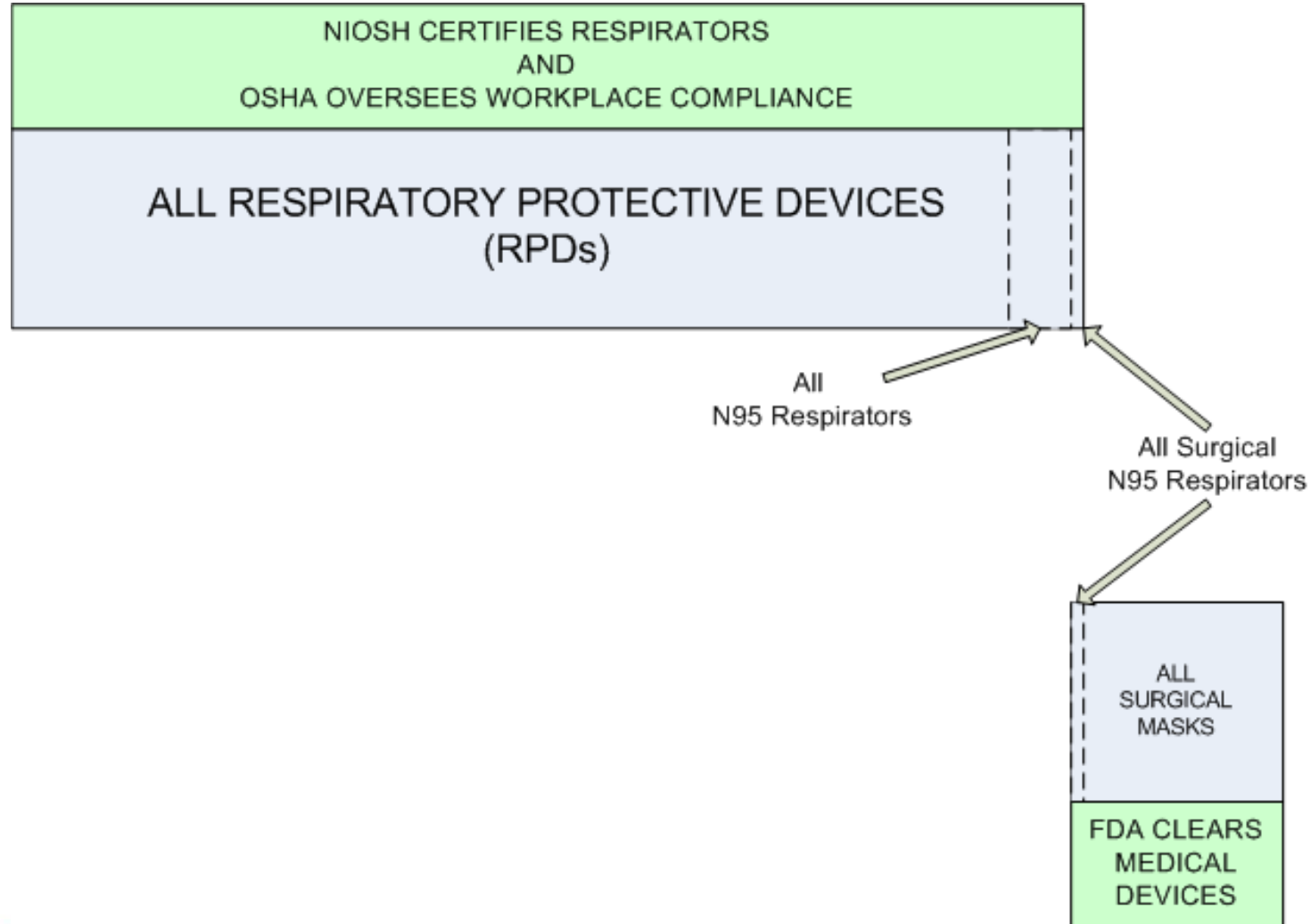
NIOSH has authority to certify respirators

- Authority rooted in creation of the Bureau of Mines, 1910
- BOM, DOI, Coal Mine Safety and Health Act, 1969
- OSH Act of 1970

Title 42, Code of Federal Regulations Part 84 42 CFR 84



NIOSH and FDA only have concurrent authorities for surgical N95 respirators.



NIOSH respirator approval increases the quality and diversity of the national inventory of RPDs in the workplace.



Concurrent authorities have resulted in confusion in the marketplace

- NIOSH and FDA are collaborating to establish an MOU to
 - Develop a process to reduce conflicting and duplicative steps
 - Develop a process to enable stakeholders to easily discern what steps must be taken to satisfy all requirements
 - Improve worker safety
 - Finalize MOU and begin implementation

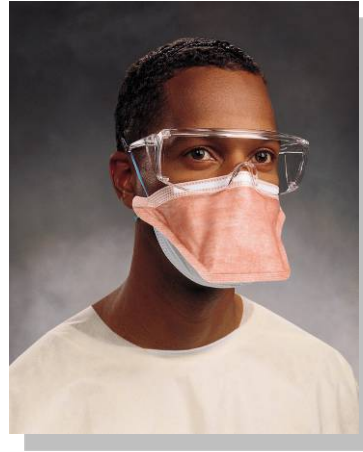


Significant progress has been made on the FDA/NIOSH MOU

Goals for Workshop

- Obtain input from stakeholders on
 - test methods and other features of approval/clearance process
 - approaches to reduce conflicting and duplicative steps
 - pre-approval and post-approval activities
 - approaches to improve workplace safety and health

Quality Partnerships Enhance Worker Safety & Health



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Thank you

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