National Academy of Medicine Workshop
Current Issues in the Assessment of Respiratory Protective Devices: Non-traditional workers and Public Use

Session 4A: Assessment Pathways for Respiratory Protective Devices for Non-Traditional Workers

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Session Objectives

- Review the current NIOSH Respiratory Approval Program and conformity assessment process for the occupational use of respirators.
- Explore how existing conformity assessment processes and standards align with the health and safety requirements of non-traditional user groups and how these processes function to deliver technologies to the end user while balancing speed of delivery with safety.
- Discuss what opportunities exist to develop or support conformity assessment processes for respiratory protective devices and control strategies, such as cloth face coverings, that are responsive to the specific requirements of these user groups.
- Discuss conformity assessment models used in other countries, by third-party organizations, and in private industry for the occupational and non-occupational use of respirators and barrier masks.

NIOSH Personal Protective Technology Program
National Personal Protective Technology Laboratory

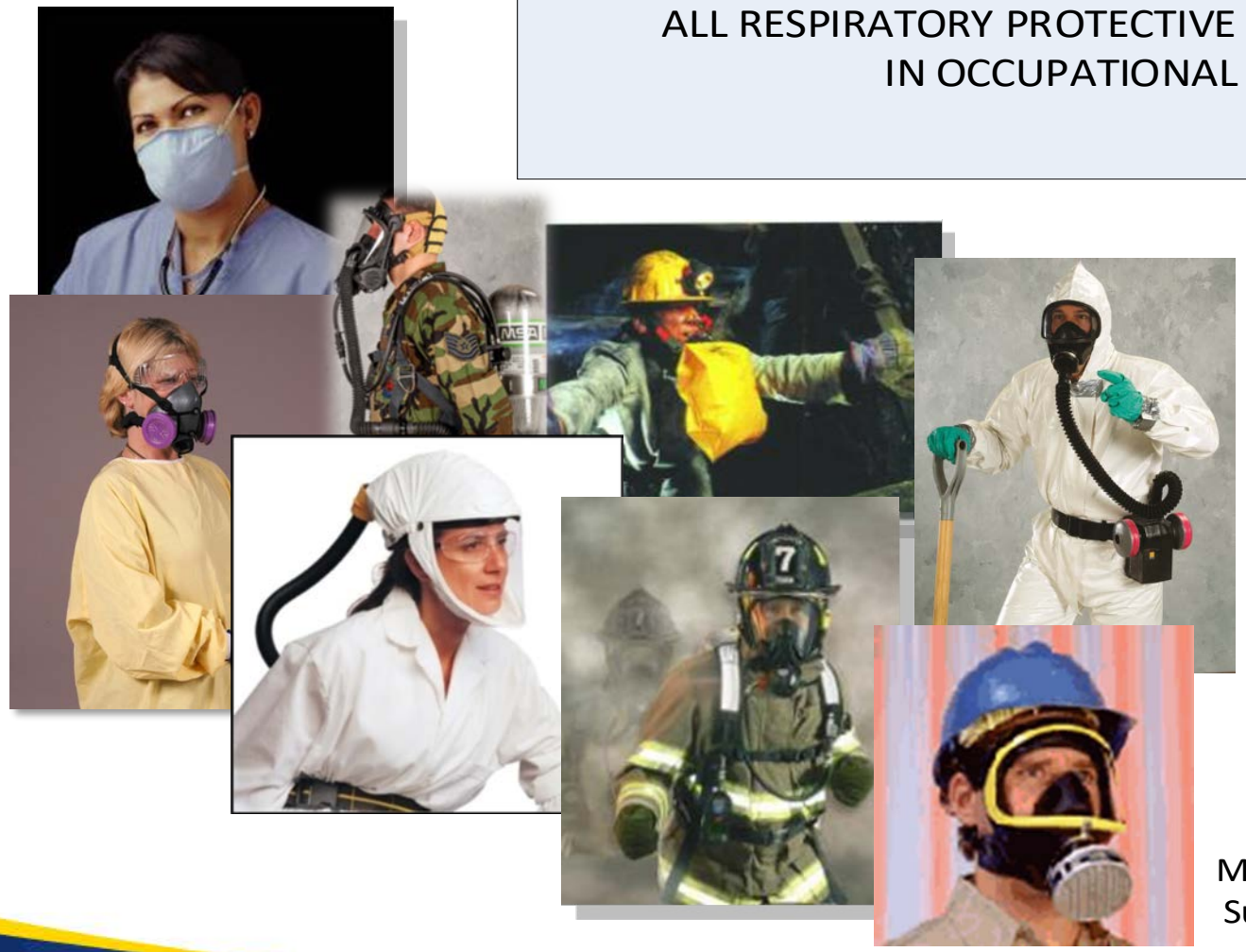



The MISSION of NPPTL and the PPT program is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies (PPT).

NIOSH HAS RESPIRATOR CONFORMITY ASSESSMENT AUTHORITY
AND
OSHA and MSHA OVERSEE WORKPLACE COMPLIANCE

ALL RESPIRATORY PROTECTIVE DEVICES (RPDs) USED IN OCCUPATIONAL SETTINGS

OSHA's Respiratory Protection Standard 29 CFR 1910.134 requires workplaces using respirators to establish a Respiratory Protection Program.



All N95 filtering facepiece respirators (FFRs)

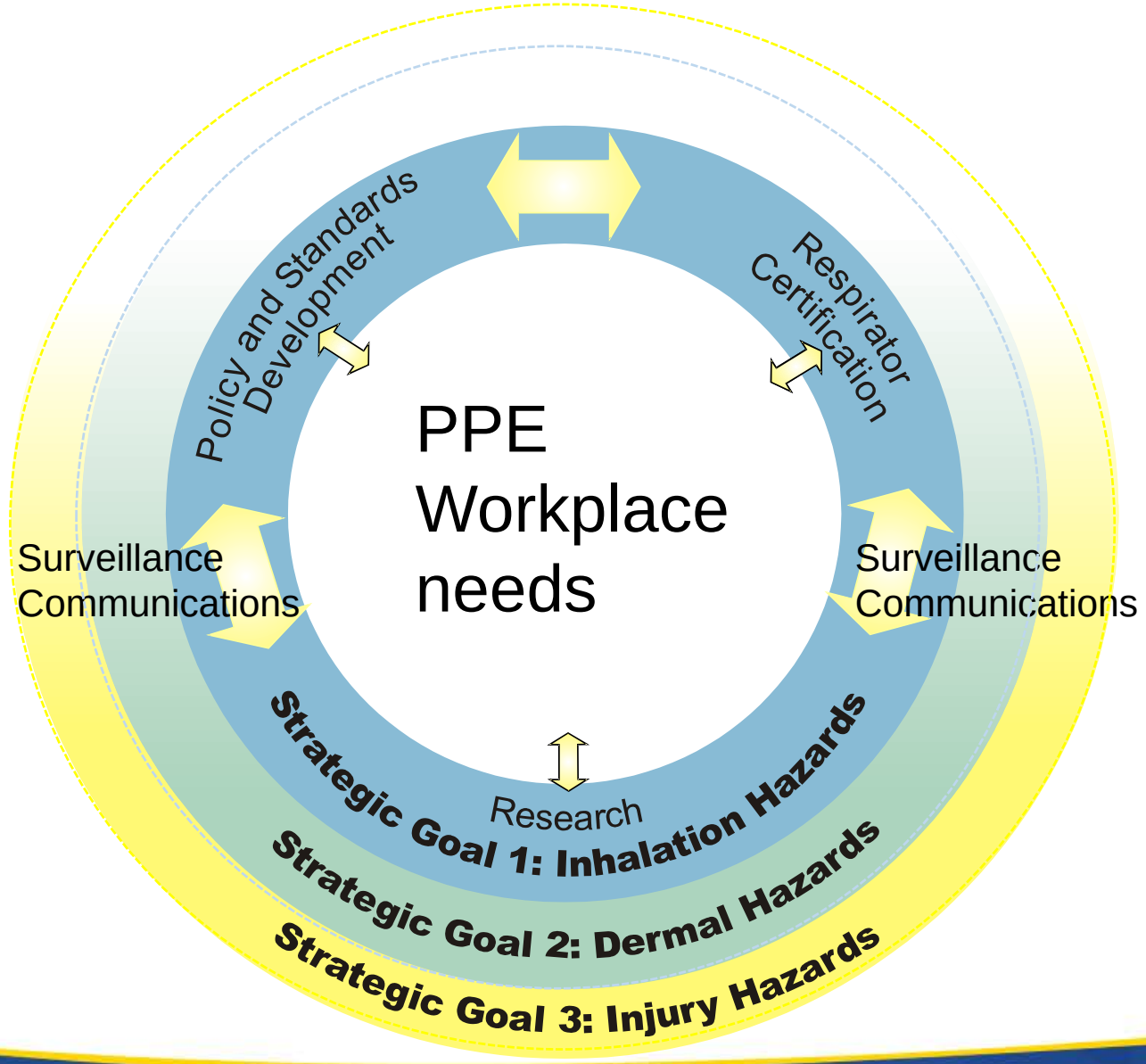
All Surgical N95 Respirators

ALL SURGICAL MASKS

FDA CLEARS MEDICAL DEVICES

Manufacturers must list Surgical N95s with FDA

NPPTL's responsibilities vary across its three strategic goals.



Conformity Assessment is important to address worker health and safety.

"Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled"

ISO/IEC 17000:2004 Conformity assessment Vocabulary and general principles

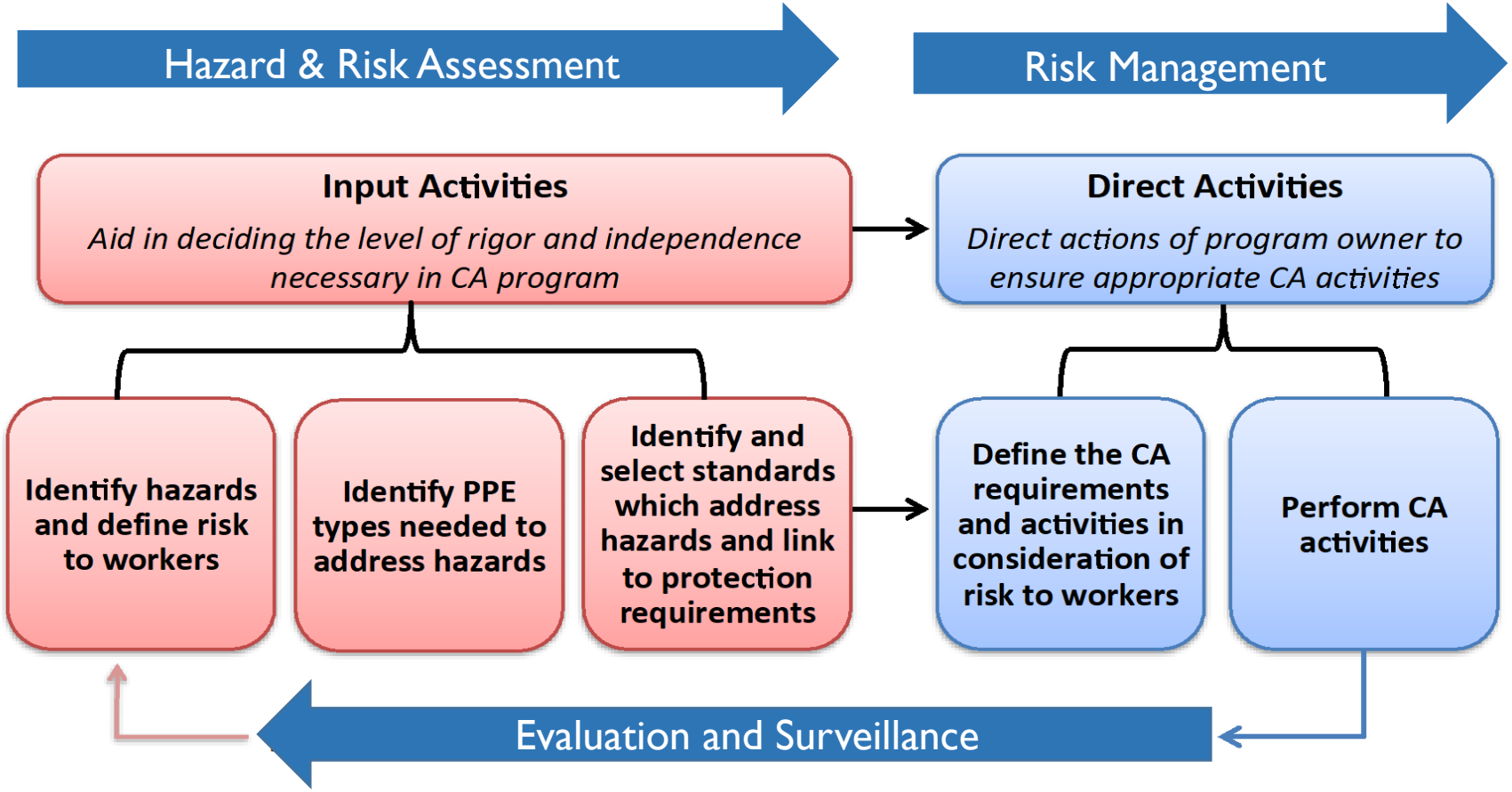
- Help regulators ensure that health, safety or environmental conditions are met
- Provide consumers with added confidence
- Give the company a competitive edge

NIOSH

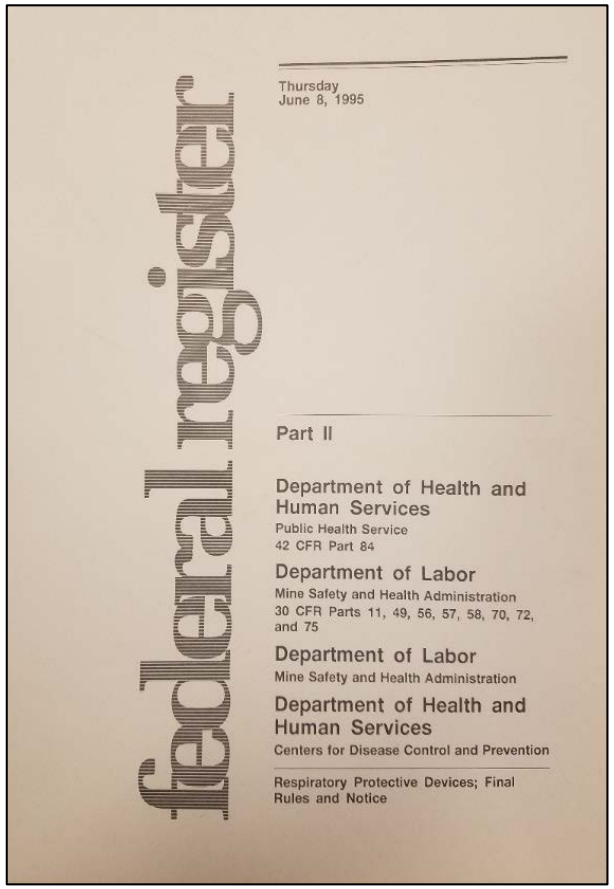
NIOSH and FDA

NIJ

The framework establishes a set of principles and provides guidance for PPE conformity assessment.



NPPTL executes NIOSH's authority to approve respirators—42 CFR Part 84.



Two regulatory agencies require the use of NIOSH-approved respirators

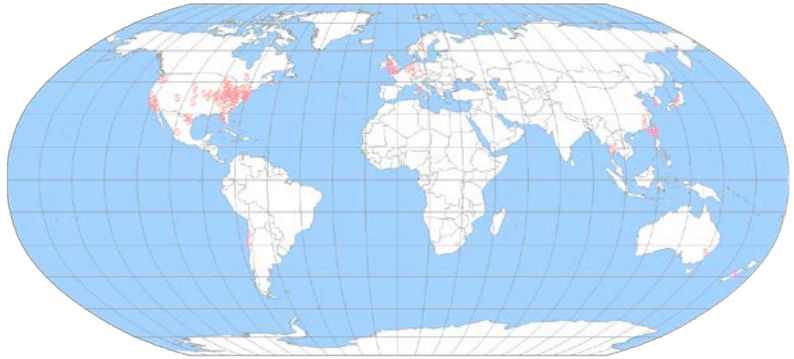
Occupational Safety and Health Administration (OSHA)

Mine Safety and Health Administration (MSHA)

NPPTL has protected workers from job hazards by developing standards and certifying over 9000 respirators.

Australia	Brazil	Canada	Chile	China	Colombia	Czech Republic
England	Germany	India	Ireland	Italy	Japan	Korea
Latvia	Mexico	Poland	Singapore	Slovenia	Sweden	Switzerland
Taiwan	Thailand	UAE	USA	Vietnam		

- 101 approval holders
  - 15 countries
- 192 manufacturing sites
  - 26 countries



NPPTL improved the quality of the Nation's inventory of respiratory protection for workers in all industry sectors by making 552 respirator approval decisions and completing 254 respirator audit activities in 2019.

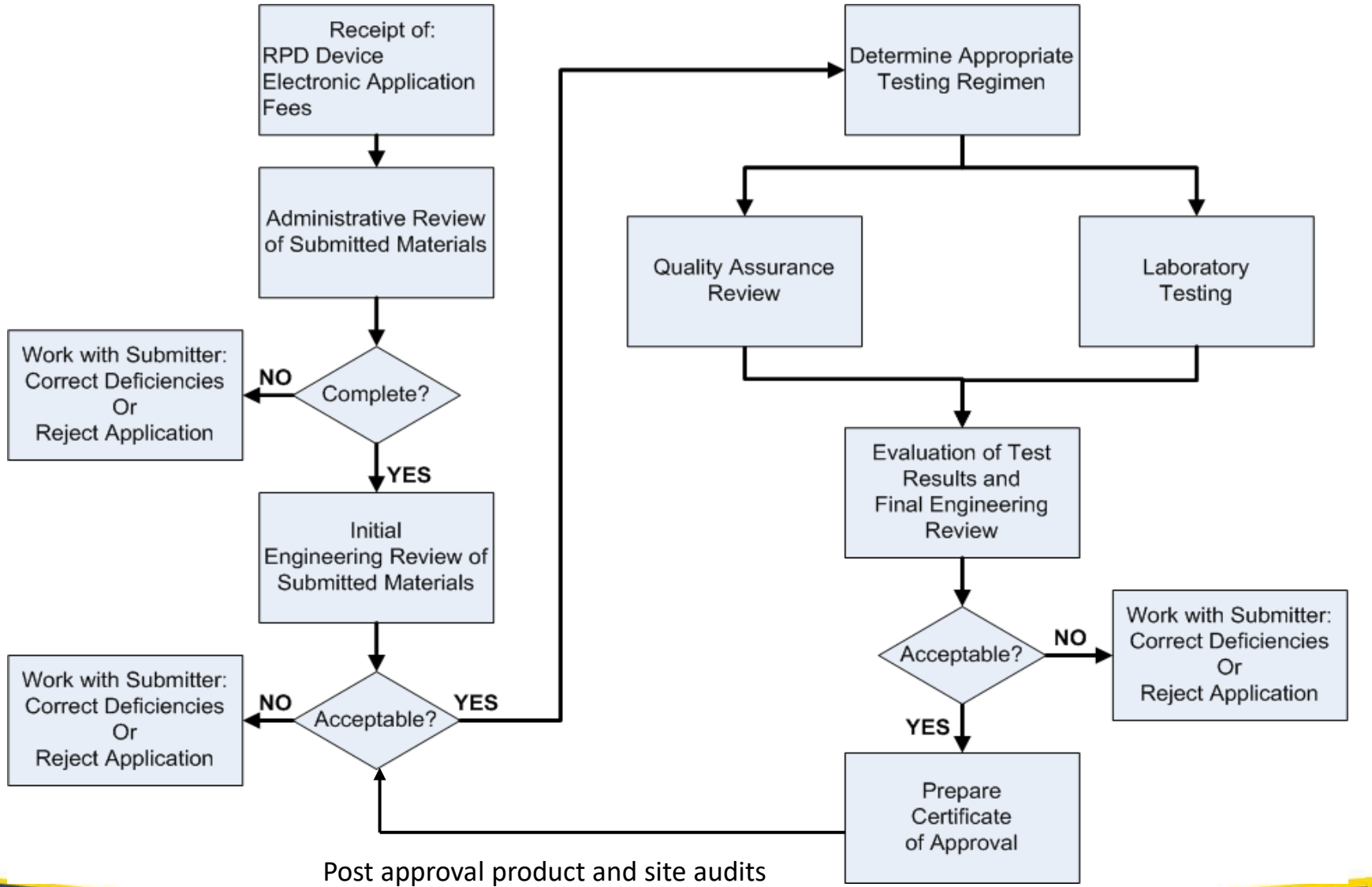
In support of the COVID-19 Response, NPPTL has issued 498 respirator approval decisions and completed 538 respirator audit activities since January 1, 2020

Types of Certified Respirators

- Air-Purifying Respirators:
  - Powered or Non-Powered
  - Particulate
  - Gas & Vapor
  - Gas masks
  - Combination
- Atmosphere-Supplying Respirators
  - Self Contained
  - Supplied-Air (Airline)
  - Combination

NIOSH Approval Process Overview

NIOSH has a robust respirator approval process that involves many stakeholders.

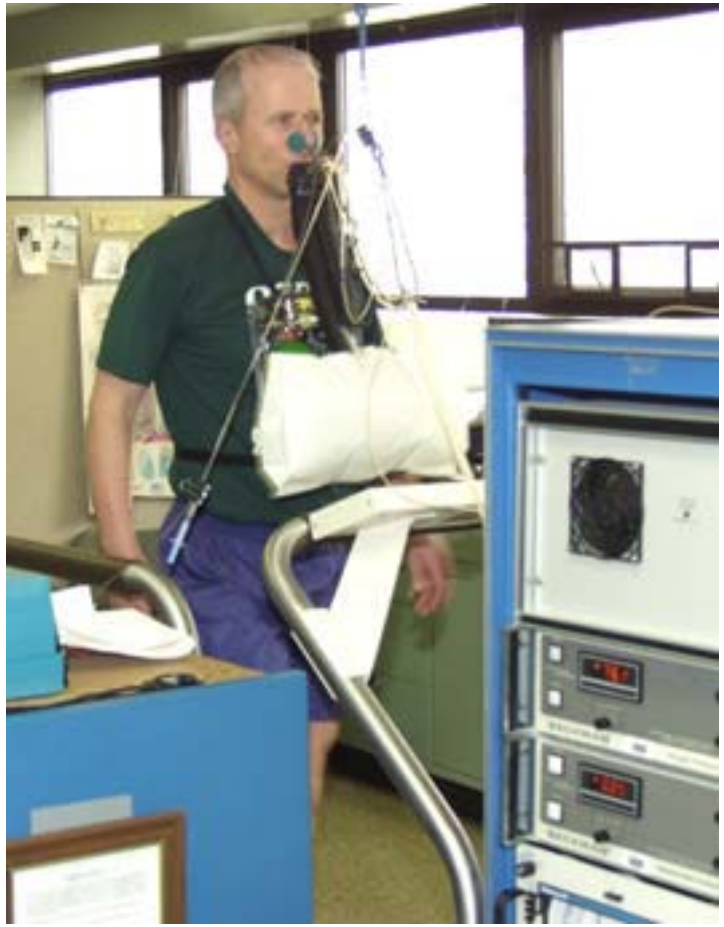


Post approval product and site audits

Post-approval Product Audits

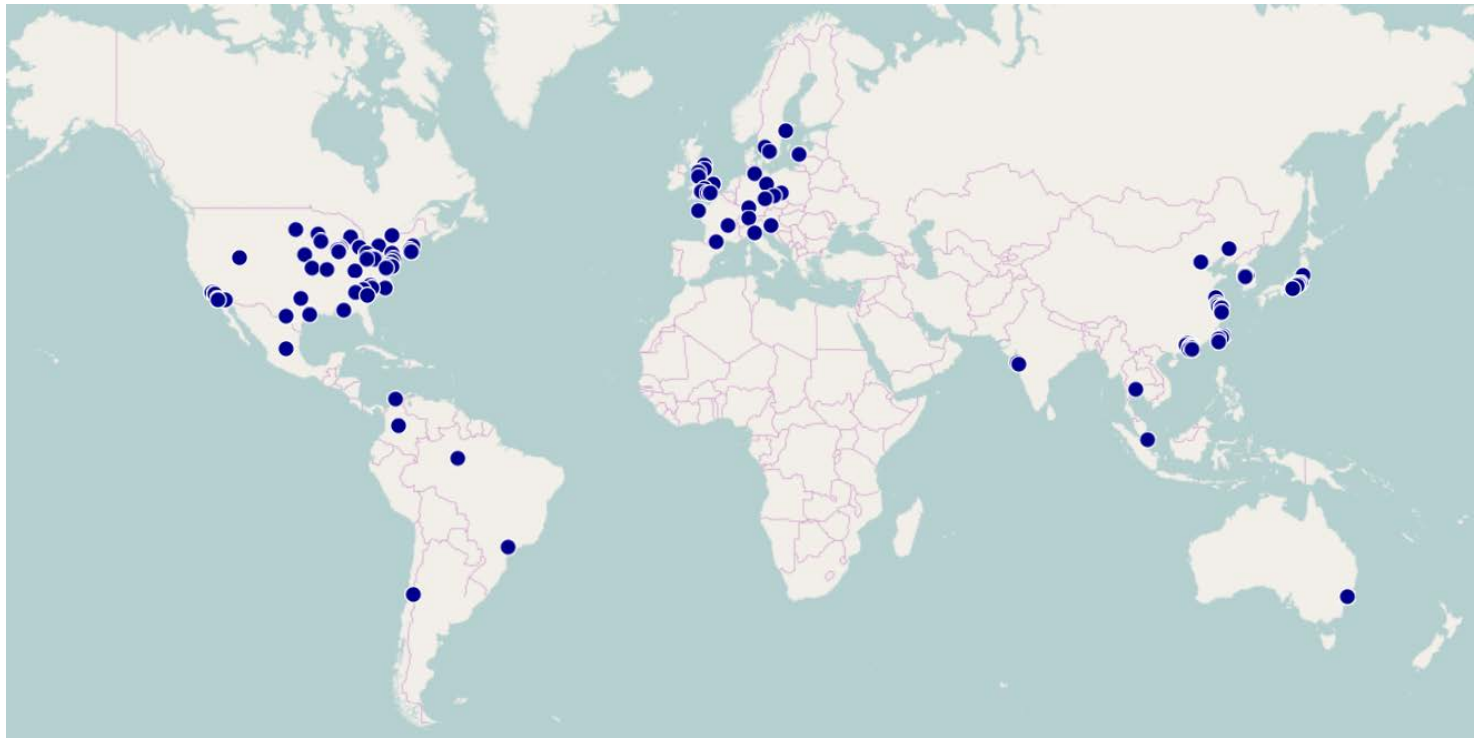
- Historic approach: Approximately 40-50 models selected each year and purchased on the open market
- Products chosen from the Certified Equipment List using criteria such as:
  - Respirator type
  - Time since last tested
  - Problem history
- In recent years purchased products have focused on FFRs.
- Any test failures resolved through a CPIP Investigation
- Current approach: Audit one product per year for each type of product approved.

Post market evaluation activities provide for effective product conformity and use assessments.



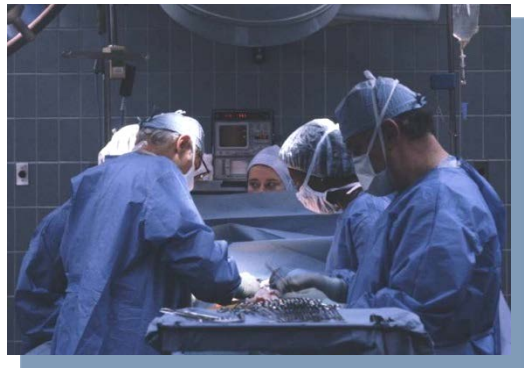
Site Audit Program ensures manufacturer compliance with approved quality system plans and the respirator performance requirements of 42 CFR 84.

- Audit Frequency
  - 2 Years for Production Facilities
  - 4 Years for Corporate Offices
- Audit Duration
  - Facility Size
  - Number of Approvals Held
  - Respirator Complexity
  - Audit/Field Problem History
- Outcomes
  - Approval Holder quality systems and products continue to meet standard.
  - Approval Holders assure quality and reliability of respirators.
  - Workers have stronger assurance of respirator functionality.



Quality Partnerships Enhance Worker Safety & Health



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