The Use and Effectiveness of Powered Air-Purifying Respirators in Health Care

NIOSH Respirator Certification Standards

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Objective and Take home message

**Objective**

- Educate the committee on what a PAPR is
- Describe respiratory protective device regulatory requirements and regulatory flexibility

**Take home message**

- NIOSH may have the regulatory flexibility to use existing authorities to certify powered respirators designed to meet healthcare needs
A PAPR is defined by the standards it has to meet

- **OSHA Definition (29 CFR 1910.134 (b))**
  - *Powered air-purifying respirator (PAPR)* means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

- **NIOSH Definition (42 CFR 84.2(z))**
  - Powered air-purifying respirator means a device equipped with a facepiece, hood, or helmet, breathing tube, canister, cartridge, filter, canister with filter, or cartridge with filter, and a blower.
  - Further defined by technical requirements.
OSHA defines Assigned Protection Factors (APF) for all respirator classes including PAPRs

APF = 25/1000*

* Manufacturer must demonstrate performance at level of protection of 1000 or greater to receive APF of 1000

Workers with facial hair may only use PAPRs with loose-fitting hoods or helmets

APF = 1000
Identification of 42 CFR 84 PAPR Certification Standards

• NIOSH PAPR standards are contained in various Subpart paragraphs in 42 CFR 84 and/or described in NIOSH published supplemental documents:
  – Standard Application Procedures
  – Standard Test Procedures
  – NIOSH policy documents
  – Letters to Manufacturers
  – User Notices
NIOSH 42 CFR 84 technical requirements applicable to PAPR

- **Subpart I**
  - canister providing gas mask level protection
  - a particulate filter combined with a gas mask canister protection

- **Subpart L**
  - a chemical cartridge level protection
  - a particulate filter combined with a chemical cartridge protection

- **Subpart KK**
  - particulate filter protection only
  - most applicable for healthcare workers for patient care and increased use scenarios (e.g. pandemic)
Performance characteristics vary among various tested parameters

- Flow rates are same for Powered APR or Non-Powered APR test conditions
  - Silica dust test set at manufacturer’s maximum operational flow rate for 4 hours of continuous operation
  - Particulate filter efficiency at minimum regulatory operational flow rate
- Constant rated airflow
  - 115 LPM minimum flow rate for tight-fitting facepiece
  - 170 LPM minimum flow rate for loose-fitting hood, helmet
- Breathing resistance evaluated at 85 LPM continuous flow rate regardless of type*

* HCW work rate activities generally are considered low, but 85 LPM is generally considered moderate to high work rate.
42 CFR 84 provides NIOSH the limited authority to certify new respirator types

- 84.60 authorizes NIOSH to approve all described respirator types,
- 84.63 authorizes NIOSH to apply additional requirements to assure the quality, effectiveness and safety of any respirator,
- NIOSH has approved breath-response PAPRs using these authorities.
Criteria for certifying a breath-responsive PAPR created in April 2000 using existing regulatory authorities.

- Established new class as Breath-Responsive PAPR under 84.60 and 84.63 authorities.
- Includes variable airflow less than minimum constant airflow.
- NIOSH determined Pressure Demand operational requirements for supplied-air respirators to be appropriate metric.
Further examine authorities in NIOSH respirator standard to allow HCW respirators with non-traditional PAPR flow rates.

- Consider potential for new respirator types with alternative flow rate capabilities
- Reengage stakeholders to discuss regulatory options for respirators equipped with battery-powered blowers
Potential next steps

- Assess potential for new respirator class structure needed for alternate performance requirements
- Develop strategies for selection and use of alternate flow rate levels, matching respiratory needs and addressing comfort and tolerability concerns
- Conduct workplace studies to assess net effect of alternative PAPR flow rates on HCW protection
- Inform improvements in NIOSH regulations with assessment of ISO RPD requirements
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