



TC 94 / SC 15 Respiratory Protective Devices

Comparison of NIOSH Regulation 42 CFR Part 84 to ISO RPD Performance Standards

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NIOSH and ISO RPD standards development history

- **NIOSH**

- 42 CFR Part 84 was promulgated in 1995
- CBRN requirements were developed beginning in 2001
- Based on design, function and performance

- **ISO**

- ISO TC94 SC15 was established in 2002
- Based on performance

TC94 / SC15 RPD Standards Status

- **32 ISO standards or technical specifications are being developed**
 - 18 International Standards
 - 14 Technical Specifications
- **13 of the 32 have been approved and published**

The respirator performance standards, ISO 17420-1 & 2, are still in a committee draft stage, and are subject to change.

Conformity Assessment Requirements

- **NIOSH**

- 42 CFR part 84 contains conformity assessment framework for the certification body, including quality assurance, respirator certification requirements, and post market evaluations

- **ISO**

- performance standards do not contain any conformity assessment, quality assurance or certification requirements

Respirator Performance

- **NIOSH**

- Requirements are for complete respirator configurations
- Each respirator must meet all applicable requirements and have its own approval

- **ISO**

- Requirements are for complete respirators with one exception, filtering respirators using a standardized connector
- Each respirator must meet all the applicable requirements

NIOSH Classification

- **NIOSH classifies respirators by:**
 - Configuration
 - Gas mask – chin style or body mounted
 - Facepiece type
 - Half-mask, full facepiece, hood, helmet
 - Mode of operation
 - Air-purifying – particulate and/or gas/vapor filtering
 - Powered, non-powered
 - Supplied-air – constant flow, demand, pressure demand
 - Self-contained breathing apparatus - open circuit, closes circuit
 - Use
 - Escape only
 - Abrasive blasting

ISO Classification

- **ISO classifies respirators by:**
 - Mode of operation - filtering verses supplied breathable gas
 - Protection class
 - Workrate class
 - Facepiece type by area of coverage and loose or tight-fitting
 - Special application(s)

Performance Differences Mode of Operation

- **NIOSH has different requirements based on design within the mode of operation**
 - Filtering verses chemical cartridge verses gas mask
 - Continuous flow, verses demand, verses pressure demand supplied air respirators
 - Closed-circuit verses open circuit self-contained breathing apparatus
- **ISO has the same basic requirements for all respirators within each mode of operation**

Performance Differences

Protection class

- **NIOSH**

- Requires laboratory qualitative fit test on most respirator types
- Requires quantitative fit tests on CBRN respirators
- Does not assign any protection class or level and does not imply the workplace protection level

- **ISO**

- Requires a quantitative Total Inward Leakage test on all respirators to establish a numerical protection class (PC1 to PC6)
- The PC number will be used as a basis for determination of the protection level expected in the workplace

Performance Differences

Work rate and Flow rate Testing

- **NIOSH**

- Requires tests at various flow rates depending on the component or configuration being tested
- Requires a higher workrate for SCBA jointly approved to NIOSH and to NFPA

- **ISO**

- Requires tests on some components at different flow rates
- Has 4 classes of work rate based on an ISO human factors Technical Specification ISO TS 16975-1, and requires specific tests to validate the work rate class

Performance Differences Breathing Resistance

- **NIOSH**

- Has different requirements for breathing resistance measured at a fixed flow, based on respirator types and mode of operation

- **ISO**

- Has requirements for peak pressure (pressure differential), measured while the respirator is being cycled at the maximum work rate of its class

Performance Requirement Differences

Particle filters

- **NIOSH**

- Minimum efficiency levels are:
 - N95, 99, 99.97%, based on 200mg aerosol load with NaCl at 85 lpm flow
 - R or P95, 99, 99.97%, based on 200 mg aerosol load with DOP at 85 lpm flow
- Performance requirement for filters intended for reuse after a single shift is not addressed

- **ISO**

- Minimum efficiency levels are:
 - 80, 95, 99, 99.9, 99.99%, based 150mg aerosol load with both NaCl **and** paraffin oil, at peak of their work rate flows
- A degradation test is required for filters intended for reuse after a single shift

Performance Differences gas/vapor cartridges and canisters

- **NIOSH**

- Requires three capacities based on type;
 - Cartridges,
 - Chin style gas mask canisters
 - Front or back mounted gas masks canisters
- Does not require a test for instantaneous breakthrough at high flows, except for CBRN canisters
- Performance requirement for cartridges or canisters intended for reuse after a single shift is not addressed
- Pre-conditioning is equilibration, wet and/or dry, except CBRN which uses wet or dry challenge agents

Performance Differences gas/vapor filters

- **ISO**

- Allows for smaller capacities, but checks for instantaneous breakthrough at the peak flow of the designated workrate class
- Requires a migration test for filters intended for reuse after a single shift
- Testing is conducted using a wet and/or dry challenge
- Pre-conditioning includes vibration and shock, but not wet or dry equilibration

Performance Differences PAPR or Assisted filtering devices

- **NIOSH**

- Requires different flow rate for filter testing depending on facepiece types (tight-fitting or loose-fitting)
- Requires a silica dust loading for 4 hours

- **ISO**

- Requires testing filters at the interactive flow rate of the PAPR
- Requires the PAPR to perform at its workrate class
- Has no time restriction
- Requires a warning device

Performance Differences

SCBA Duration

- **NIOSH**

- Requires specific time durations for self-contained breathing apparatus based on a 40 liter minute volume and requires the SCBA to be labeled as such, e.g. 30 min.
- Requires specific quantities of breathable gas for closed-circuit escape respirators

- **ISO**

- Requires the usable capacity of breathable gas to be either calculated or measured and the respirator to be classified and labeled as such, e.g. S1200 (1200 liters of breathable gas)

Performance Differences Human Subject Tests

- **NIOSH**

- Requires human-subject tests on some respirator types at room temperature
- Requires a human-subject test on SCBA at lowest temperature as specified by the manufacturer

- **ISO**

- Requires human subject tests on all respirators at two temperatures, -5° and +35°C (23° and 95°F)

Performance Differences

Positive and Negative Pressure

- **NIOSH**

- Refers to respirators as negative pressure or positive pressure and has requirements for continuous positive pressure in some respirator facepieces

- **ISO**

- Does not refer to either positive or negative pressure and lacks a requirement for measuring or detecting positive or negative pressure inside the facepiece

ISO Special Application Performance Requirements

- **Tasks which require respirators with enhanced requirements have been identified as Special Applications. They are:**
 - Firefighting, CBRN response, Marine operations, Mining, Abrasive blasting, Welding and Escape
 - Within each major category are specific tasks, e.g. Wildlands firefighting, Structural firefighting, Rescue
- **Special application performance requirements are specific to the task, e.g., flame engulfment for structural firefighting.**

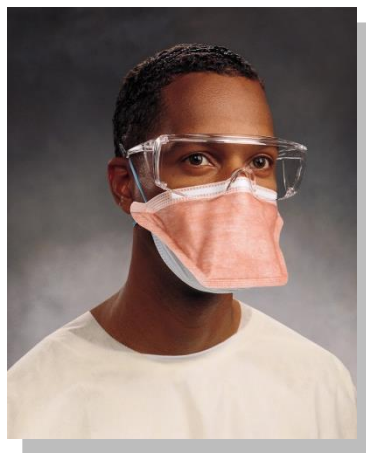
ISO Special Application Performance Requirements cont.

- **Special application respirators have to meet their special application requirements in addition to all of the “basic” requirements unless there is a special application requirement that supersedes the basis requirement**
- **Special application respirators may have required minimum protection classes and work rate classes**

NIOSH Next Steps

- **Assess ISO requirements as compared to current 42 CFR part 84 requirements**
- **Investigate the pros and cons of incorporating the ISO performance standards as the NIOSH respirator requirements, including validation of test methods**
- **Make recommendations to update 42 CFR part 84 requirements**

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