



NIOSH Pre-Submission Testing for Respirators



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NIOSH Certification

National Institute of Safety and Health (NIOSH) evaluates and approves all respirators intended for use in healthcare and other workplace settings within the United States. As a part of the assessment process, NIOSH conducts comprehensive in-house testing. However, prior to application submission, preliminary testing (or “pre-submission testing”) must first be completed by the manufacturer or a third-party laboratory to verify that minimum performance requirements are met.

Pre-submission testing must follow strict guidelines as outlined in the Code of Federal Regulations (CFR). To avoid application delays or rejections, manufacturers should ensure that all appropriate pre-submission testing is completed with adequate documentation and that only high-quality testing is conducted.

Required testing may include Sodium Chloride, Dioctyl Phthalate, inhalation/exhalation, and valve leak tests to assess filtration, breathability, and leakage. For surgical N95s, which are concurrently regulated by the FDA as class II medical devices, additional pre-submission testing includes flammability, fluid resistance, and biocompatibility.

Types of NIOSH-Certified Respirators

Pre-submission testing requirements vary by respirator type. NIOSH categorizes filters based on the resistance to filter efficiency degradation (i.e., oil resistance) of the filtering media and the particle filtration efficiency. There are three categories for NIOSH-certified, nonpowered, air-purifying, particulate-filter respirators:

N - Not resistant to oil
N95, N99, and N100 filter at least 95%, 99%, and 99.97% of airborne particles

R - Somewhat resistant to oil
R95, R99, and R100 filter at least 95%, 99%, and 99.97% of airborne particles

P - Strongly resistant to oil (oil proof)
P95, P99, and P100 filter at least 95%, 99%, and 99.97% of airborne particles

N-Series masks are appropriate for use in the absence of oil particles (e.g., lubricants, cutting fluids, glycerin, etc.). In the presence of oil particles, R- or P-series filters should be used. If a filter will be used for multiple shifts when oil is present, P-series filters are most appropriate for use.

Pre-Submission Testing Requirements

All testing must comply with NIOSH Standard Testing Procedures (STPs) and use appropriate instrumentation as outlined in 42 CFR Part 84 and NIOSH Procedures TEB-ABR-STP-0003, 0004, 0007, and 00051-59. Nelson Labs has extensive experience in this testing as well as other testing for filters and filtration devices.

Category	Filter Class	Particle Filtration Efficiency Test		Breathability Test		Valve Leak Test - NRC125
		Test Agent	Efficiency	Inhalation	Exhalation	If applicable
N-Series	N95 N99 N100	NaCl	≥95% ≥99% ≥100%	≥35mm	≥25mm	≥30mL/min
R-Series	R95 R99 R100	DOP	≥95% ≥99% ≥100%	≥35mm	≥25mm	≥30mL/min
P-Series	P95 P99 P100	DOP	≥95% ≥99% ≥100%	≥35mm	≥25mm	≥30mL/min

Testing Methodology

Particle Filtration Efficiency Testing - Sample Size = 20 respirators

Filtration efficiency testing is conducted to determine the percentage of particles filtered by the respirator, using either Sodium Chloride (NaCl) or Dioctyl Phthalate (DOP) as the test agent. Sodium chloride is considered only slightly degrading to filter efficiency and is used to test N-series respirators. Dioctyl Phthalate (DOP) is considered very degrading and is used to test R-Series and P-series respirators.

- **NRC110 – NaCl**
- **NRC115 – DOP**

Breathability Testing - Sample Size = 3 respirators

To determine breathability, two tests—exhalation and inhalation resistance—are performed to mimic airflow resistance while breathing in and out. Low levels of exhalation and inhalation resistance represent ease of breathing for the user.

- **NRC120 – Inhalation & Exhalation**

Valve Leak Testing - Sample Size = 3 respirators

Valve leakage testing is only necessary if the product contains an exhalation valve, which allows air to flow out of the respirator during exhalation and prevents inward flow during inhalation. Respirators with exhalation valves protect the user from the outside environment only.

- **NRC125 – Valve Leak Test**



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+1 (801) 290-7500 | www.nelsonlabs.com | sales@nelsonlabs.com

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