

RESPIRATOR TESTS AND REQUIREMENTS

42 CFR Part 84 – Respirators

The Sodium Chloride Aerosol testing (NaCl)- NIOSH procedures TEB-APR-STP-0059 (N95) and TEB-APR-STP-0058 (N99).

Inhalation and Exhalation Resistance testing – NIOSH procedures NIOSH TEB-APR-STP-007 and STP-003

Note: surgical respirators require Synthetic Blood Penetration (ASTM F1862) and Flammability (16 CFR Part 1610) as additional tests

Valve leakage testing for respirator (NIOSH TEB-APR-STP-0004)

Overview of NIOSH Respirator Testing Requirements (42 CFR Part 84)

In order to certify respirators you must follow the guidelines set for in the Code of Federal Regulation (CFR), 42 CFR Part 84. It details the test procedure, requirements and all the documentation that must be met to file an application with NIOSH. Before respirators can be submitted to NIOSH for certification, manufacturers must have data showing that they have passed a pre-submission test following the procedure listed in 42 CFR Part 84. These tests can be performed by manufacturer or a third-party laboratory.

There are three tests that need to be performed to meet the pre-submission testing requirements.

1. The Sodium Chloride Aerosol testing is conducted to determine the percentage of particles filtered by the respirator. $\geq 95\%$ filtration efficiency for N95 respirators
2. The Inhalation and Exhalation Resistance testing is conducted to measure the breathability of the respirator. For NIOSH acceptance, the inhalation resistance cannot exceed 35 mm water column height pressure. For NIOSH acceptance, the exhalation resistance cannot exceed 25 mm water column height pressure.
3. The Valve Leakage testing measures the amount of leakage between the valve and the valve seat. For NIOSH acceptance, the leakage between the valve and the valve seat cannot exceed 30 milliliters per minute.
NIOSH requires that twenty respirators be evaluated for filtration efficiency, three respirators for exhalation resistance, three respirators for inhalation resistance, and three valves for valve leakage (unnecessary if the respirator does not have a valve). If your product conforms to one of the NIOSH ratings, then an additional group of respirators can be submitted to NIOSH to begin the certification process.