

42 CFR PART 84 STANDARD

APPLICATION NOTE AFT-001

Introduction

Procedures for testing and certifying air-purifying and particulate respirators changed under a final regulation published June 8, 1995 by the National Institute for Occupational Safety and Health (NIOSH). This new standard, called 42 CFR part 84, replaces MSHA regulation designated 30 CFR part 11 which is based upon testing methods and filtration theory that is more than 20 years old. This action by NIOSH is the first in a series of modules that will incrementally revise current approval requirements for all respirators.

NIOSH certifies three classes of filters, N- (for **Not** resistant to oil), R- (for **Resistant** to oil), and P-(for oil **Proof**) series, with three levels of filter efficiency, 95%, 99%, and 99.97%, in each class based upon 42 CFR part 84. These nine classes of filters are further summarized in the matrix below:

Table 1: Filter Classification under 42 CFR part 84

Minimum Efficiency	N Non oil aerosols	R Includes oil aerosols*	P Includes oil aerosols**
95%	N95	R95	P95
99%	N99	R99	P99
99.97%	N100	R100	P100

* May have a time restriction when oil aerosols are present

** Used according to manufacturers time restrictions when oil aerosols are present

Test Requirements for 42 CFR part 84

Certification Tests

The 42 CFR part 84 certification tests use the most penetrating aerosol size, 0.3 μm aerodynamic mass median diameter, of either a mildly degrading particulate such as sodium chloride (NaCl), or a highly degrading oil such as Dioctyl Phthalate (DOP). The efficiency of the filter is monitored and recorded throughout the test period.



The N- series respirators are tested to a maximum loading level of 200 mg of NaCl aerosol per respirator. The minimum efficiency for which approval is sought must be equal to or greater than the filter efficiency criterion for the filter class. For example, after being loaded with 200 mg of NaCl, an N95 particulate filter must demonstrate filter efficiencies greater than or equal to 95%. Prior to filter efficiency testing of N-series filters, the filters are taken out of their packaging and placed in an environment of 85 + 5% relative humidity at 38 + 2.5° C for 25 + 1 hours. This requirement addresses the effect of humidity on the filter's efficiency because the NaCl aerosol is less severe than DOP in reducing filter efficiency. Please refer to NIOSH document [RCT-APR-STP-0057, 0058, 0059](#) (Revision 1.1, Date 24 Aug 2005) describing detailed procedures for testing N-series respirators.

Similarly, the R- series respirators are tested to a maximum loading of 200 mg of DOP aerosol per respirator. The minimum efficiency for which approval is sought must be equal to or greater than the filter efficiency criterion for the filter class. For P- series filters, the filter is also tested with DOP aerosol but if the filter efficiency is decreasing when the 200 mg of DOP aerosol challenge point is reached, the test shall be continued until there is no further decrease in efficiency. The minimum efficiency for which approval is sought must be equal to or greater than the filter efficiency criterion for the filter class. Please refer to NIOSH document [RCT-APR-STP-0051, 0052, 0053, 0054, 0055, 0056](#) (Revision 1.1, Date 24 Aug 2005) describing detailed procedures for testing R- and P-series respirators.

NIOSH certification approval process mandates that 20 filters will be tested at the NIOSH facility (for each filter seeking approval). The minimum efficiency of each of the 20 filters will be determined and recorded and should be equal to or greater than the filter efficiency criterion listed for each level in order to be approved.

Quality Control Tests

As a part of each application for 42 CFR part 84 approval, a quality control plan must be submitted and approved by NIOSH, to assure the quality of respiratory protection provided by the respirator. This quality control plan shall include a procedure for the selection of a sample of respirators and the components for testing. Loading tests, like those required for approval, may be a part of a quality control plan, but shorter, none destructive quality control tests are the main component of most quality control plans. The TSI model 8127 and 8130 can perform an initial penetration test, suitable for quality control testing, in as little as 12 seconds. These tests can be done with the same test conditions as used in the loading tests.

TSI 8127/8130 and 42 CFR part 84 Compliance

The data in Table 2 describes the test requirements that are described in the 42 CFR part 84. The table also provides in detail the apparatus and parameter set forth in the standard and the applicability of TSI products (Model 8127, 8130, and 3936) in fulfilling those requirements.

Table 2: Test Requirements for 42 CFR part 84

Test/Parameters	Requirements	TSI 8127	TSI 8130
Test Classification			
Loading tests	<ul style="list-style-type: none"> Aerosol concentration: < 200 mg/m³ Target loading: 200±5 mg (N- and R- categories) Collection efficiency: 95%, 99% and 99.97% (in each N-,P-,R- categories) 	✓	✓
Quality control tests	Manufacturer defined filter efficiency checks (subject to NIOSH approval)	✓	✓
Test Parameter			
DOP aerosol*	<ul style="list-style-type: none"> Count Median Diameter (CMD): 0.185 ± 0.02 µm Geometric Standard Deviation (σ_g): < 1.6 	✓	✓
NaCl aerosol*	<ul style="list-style-type: none"> Count Median Diameter (CMD): 0.075 ± 0.02 µm Geometric Standard Deviation (σ_g); < 1.86 	Not Applicable	✓
Aerosol detection	Light scattering photometers	✓	✓
Challenge flow rate	85 L/min (± 5%)**	✓	✓
Aerosol temperature	25 ± 5°C	✓	✓
Relative humidity	30 ± 10 %	Not Applicable	✓

* Particle size distribution can be measured using TSI 3936 Scanning Mobility Particle Sizer™

** For a single filter respirator (flow rate decreases with multiple respirators)

As evident from the table, both 8127 and 8130 filter testers meet the rigorous requirements of 42 CFR part 84. A large number of filter manufacturers have used these filter testers for their filter development and manufacturing programs. Incorporation of 8127/8130 filter testers have provided a leverage to these manufacturers in getting closer to NIOSH approval for their respirators, as NIOSH also uses the same filter testers for their certification process. This drastically (or almost completely) eliminates any variation in test results performed at manufacturer locations versus the tests performed at NIOSH.



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