42 CFR part 84 - Testing Modes

Application Note AFT-002

Introduction

Testing to meet the requirements of the United States 42 CFR part 84 standard consists of two parts: loading and quality control tests. Loading tests must be performed on 20 filters by the manufacturer followed by submitting the testing data to the National Institute for Occupational Safety and Health (NIOSH) along with a new set of 20 filters that are tested by NIOSH at their site. All of these tests must pass the requirements of the category that the submission specifies. Along with loading tests, a quality control plan must be submitted that specifies the ongoing quality control testing that will be used to assure the quality of respiratory protection provided by the respirator. This plan must be reviewed and approved by NIOSH before the manufacturer can incorporate it into their manufacturing process.

Certification Loading Tests

Gravimetric Tests

The aerosol concentration is determined using gravimetric tests in order to know how much aerosol mass has challenged a filter. This test consists of challenging a high efficiency filter with an aerosol and measuring the mass collected on the filter by weighing it prior and after the test. By knowing the flow rate and time (to determine the volume of aerosol), the mass per unit volume of aerosol can be determined by using the following formula:

$$Concentration(mg/m^3) = \frac{Mass(mg)}{Flow\ rate(m^3/\min) * Time(\min)}$$

It is recommended that the aerosol concentration is determined daily when loading tests are being conducted because with time, mass concentration varies. This is especially true of the NaCl salt aerosol where evaporation can change the concentration of the salt solution and new salt solutions are frequently created.

Determining Loading Test Time and Accumulated Mass

To know how much time it will take to load a filter to a specific mass level (for a loading test) or to calculate the accumulated mass on the filter, the following formulas are used:

$$T = \frac{M*1000}{C*Q_f} \qquad M = \frac{C*Q_f(average)*T(elapsed)}{1000}$$

where:
T = Time (minutes)
M = Mass of particle (mg)
C = Aerosol Concentration (mg/m^3)
Q_f = Flow rate (L/min)

Respirator Filter Testing

A respirator is tested at 85 ± 5% L/min and is challenged with 200±5 mg of the test aerosol. When a respirator consists of a single filter the flow rate is 85 L/min. For respirators that use a pair of filters, the individual filters are tested at 42.5 ± 5% L/min and are loaded to 100 mg (flow and mass loading is split equally between the two filters). The penetration is to be monitored throughout the test. The TSI model 8127 (oil only) or the model 8130 (salt and oil) testers are usually accomplished by using the printed output or collecting the serial data (from RS-232 port into a computer). For more information, please visit the references at the end of this application note.

N-Series Respirators

Since exposure to high humidity can degrade some types of electrostatic filter media, the 42 CFR part 84 standard requires pre-conditioning of the N-Series respirators prior to loading tests. The R and P series respirators do not require this conditioning since oil aerosol is much more degrading to media than conditioning with humidity. The respirator filters are conditioned at 85 ± 10% relative humidity and 38 ± 2.5°C for 25 ± 1 hr. After conditioning, the filters must be tested immediately or sealed in a gas tight container for a maximum of ten hours.

During the tests, each respirator filter unit is challenged with an aerosol concentration not exceeding 200 mg/m^3 (typical NaCl concentrations are from 12 – 20 mg/m^3). The specification requires that sodium chloride test aerosol shall have a particle size distribution with count median diameter of 0.075±0.020 μm (size distribution can be determined using differential mobility analyzers, e.g., TSI Model 3936 SMPS) and a standard geometric deviation not exceeding 1.86. The NaCl aerosol must be at 25±5 °C, have a relative humidity of 30±10%, and it must be neutralized to the Boltzmann equilibrium state. The 42 CFR part 84 standard requires loading with 200 mg of salt and that can take over two hours at typical salt concentrations. The minimum efficiency (maximum penetration) is the value that must meet the efficiency limit for the filter rating that is being sought. The penetration of the filters can be measured, recorded or printed until the full 200 mg of aerosol has been loaded onto the filter. NIOSH uses a procedure (see references at end of this application note) where they only conduct full 200 mg tests on three filters followed by shorter tests on the remaining filters (when efficiency increases during loading). For the sample of 20 filters or filter cartridges to demonstrate acceptable performance, each filter must meet or exceed the specific collection efficiency limit (≥95% for N95, ≥99% for N99, and ≥99.97% for N100).

P- and R-Series Respirators

The P and R series respirators are to be tested with dioctyl phthalate (DOP) as the challenge aerosol. During the tests, each respirator filter unit is challenged with an aerosol concentration not exceeding 200 mg/m^3 (typical DOP concentrations are ~100 mg/m^3). The specification requires that DOP test aerosol shall have a particle size distribution with count median diameter of 0.185±0.020 µm and a standard geometric deviation not exceeding 1.60. The DOP aerosol must be at 25±5 °C. It must be neutralized to the Boltzmann equilibrium state.

The 42 CFR part 84 standard for R- series respirator filters requires loading with 200±5 mg of DOP (similar to the N- series tests with salt). Because of the higher aerosol concentration with DOP a typical loading test takes about 22 minutes. For the filter rating that is being sought, the minimum efficiency (maximum penetration) is the value that must meet the efficiency limit. For the P-series respirators, the procedure is somewhat different. The test starts the same as the R- series respirators, but if the penetration is not stable (as defined by the NIOSH standard testing procedures), or efficiency is decreasing at a load level of 200 mg, the test continues. For P-series filters, if the filter efficiency is decreasing when the 200±5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency. The last five data point readings are used to determine if the filter has reached a point at which "no further decrease in efficiency" has occurred. The NIOSH STP document has ranges, for each efficiency level, to determine if this point has been reached. If the filter efficiency is judged to be still increasing, the NIOSH procedure specifies to complete additional loading in 30 mg steps. For each step, five readings are compared to determine whether the increase exceeds the limit. The filter fails if penetration continues to increase at a 400 mg load level. For the sample of 20 filters or filter cartridges to demonstrate acceptable performance, each filter must meet or exceed the specific collection efficiency limit (≥95% for R95 or P95, ≥99% for R99 or P99, and ≥99.97% for R100 or P100).

Quality Control Tests

Quality Control tests are typically a short initial efficiency test on a filter or respirator canister. The level of penetration for each filter would depend on the filter loading behavior. For filters where the initial penetration is the maximum value, a penetration level close to the efficiency range limit would be possible. For filters that increase penetration when loaded the initial penetration would need to be at a level where the expected increase (from the initial value) would still be below the limits. These values and the sampling selection is part of what must be approved by NIOSH in the certification submission process.

With the TSI model 8127 and 8130, these initial penetration tests can be performed in as little as 12 seconds. These tests can be done with the same aerosol that is used in the loading tests but using the FILTER TEST mode instead of the LOADING TEST mode of the filter tester. The filter flow, resistance and penetration values are output from the tester along with a PASS/FAIL indication (if specified by the user). This data can then be used for statistical process control of the manufacturing process.

References

NIOSH Procedure RCT-APR-STP-0057, 0058, 0059 (Rev 1.1, 24 Aug 2005)
NIOSH Procedure RCT-APR-STP-0051, 0052, 0053, 0054, 0055, 0056, (Rev 1.1, 24 Aug 2005)

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