



# Regulation Update – 42 CFR 84

*Occupational Health and Environmental Safety Division*

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## Summary

This rule replaces MSHA regulations at 30 CFR Part 11 (30 CFR 11) with new public health regulations at 42 CFR Part 84 (42 CFR 84). NIOSH will have exclusive authority for testing and certification of respirators with the exception of certain mine emergency devices. The rule revises test requirements for particulate filter respirators and prefilters for gas and vapor respirators. Testing requirements for future approvals of the following respirators or filters are eliminated:

- Single use dust/mist respirators
- Dust/mist respirators
- Dust/mist/fume respirators
- Radon daughter respirators
- Pesticide prefilters, and
- Paint spray prefilters.

Under the new particulate filter tests these classes of respirators are replaced with nine new classes of air-purifying particulate filters. All filter tests use the most penetrating aerosol size, 0.3 µm aerodynamic mass median diameter, so any of these filters may be used no matter what the aerosol size, according to NIOSH. Table 1 summarizes the new filter classifications and their uses.

**Table 1. Filter Classifications Under 42 CFR 84**

<b>42 CFR 84</b>		<b>AEROSOL TEST</b>	
<b>Minimum Efficiency</b>	<b>NaCl Non-oil aerosols*</b>	<b>DOP includes oil aerosols*</b>	<b>DOP includes oil aerosols</b>
95%	N95	R95	P95
99%	N99	R99	P99
99.97%	N100	R100	P100

\* May have time use restriction on this filter series

The rule provides for a three-year transition period to allow for a gradual shift from 30 CFR 11 particulate respirators to newly approved (42 CFR 84) respirators. Approval holders will be allowed to manufacture and sell Part 11 filter respirators until July 10, 1998.

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## Introduction

On June 8, 1995, the National Institute for Occupational Safety and Health (NIOSH) published a final rule changing certification requirements for particulate respirators. This action is the first of a series of modules that will incrementally revise current respirator approval requirements for all respirators. Except for particulate filter respirators, most requirements of the existing approval regulations (30 CFR 11) are incorporated into the new regulations without change. Other related issues addressed include:

- a transition period for gradual phase-out of 30 CFR 11 approved particulate respirators,
- only approving new powered air-purifying respirators (PAPRs) with high efficiency particulate air (HEPA) filters until the PAPR module is developed,
- elimination of specific test procedures for pesticide and paint spray prefilters, and
- revision of particulate filter tests for combination gas masks.

The regulation was published in the *Federal Register*, 60 *Fed. Reg.* 110; 30336-30398 (June 8, 1995). The effective date for 42 CFR 84 is July 10, 1995.

This summary of the respirator approval changes was prepared by 3M OH&ESD. It does not represent an official or legal, or necessarily complete, interpretation of the standard. If specific questions arise, the regulation itself should be reviewed and relied on rather than this summary.

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## Background

Prior to 42 CFR 84, the rules and procedures for approval of respiratory protective devices were found in 30 CFR 11. These rules evolved from rules and procedures developed by the U.S. Department of Interior, Bureau of Mines (BOM). Until 1972, BOM was solely responsible for testing and approving respirators. In 1972, 30 CFR 11 was published jointly by the BOM and NIOSH. Over time, BOM's responsibilities for respirator testing and approval were transferred to the Mine Safety and Health Administration (MSHA). Also in the *Federal Register* of June 8, 1995, MSHA transferred the requirements for approval of respirators from 30 CFR 11 to NIOSH. NIOSH published the new requirements as 42 CFR 84. This final rule places responsibility for certifying most respirators with NIOSH. NIOSH and MSHA will continue to jointly review and approve respirators used for mine rescue and other mine emergencies. These respirators include:

- filter self-rescuers,
- self-contained self rescuers (SCSRs),
- mine rescue apparatus (long duration, closed and open circuit devices), and
- other self-contained breathing apparatus (SCBA).

In addition, MSHA will continue to test electrical and electronic components of respirators for use in potentially explosive atmospheres in gassy underground mines and issue a separate approval under 30 CFR Part 18 for such respirator components.

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## Transition Period

NIOSH is allowing three years for the phasing out of CFR 11 approved particulate respirators. As of the effective date of 42 CFR 84, NIOSH will no longer accept applications for new approvals or extensions of approval under 30 CFR 11. All applications received after the effective date of part 84 will be tested to the provisions of 42 CFR 84. A subpart KK containing part 11 requirements for particulate respirators has been added to the part 84 final rule to provide for extensions of approvals needed to address respirator recall and retrofit matters that are associated with health and safety issues for workers. Respirators listed as certified under the provisions of 30 CFR 11, subparts K (particulate respirators) or M (pesticide respirators), may not be sold or shipped by the approval holder as NIOSH/MSHA certified respirators effective July 10, 1998. Continued use of distributed particulate respirators is under jurisdiction of the Occupational Safety and Health Administration (OSHA) and MSHA and therefore is not affected by this rule. Because certifications will not be revoked for 30 CFR 11 devices sold and shipped by the approval holder prior to July 10, 1998, NIOSH anticipates that OSHA and MSHA would permit continued use of those part 11 respirators. A new approval number series will be initiated for products certified under the technical requirements of part 84. Those respirators not affected by this rulemaking will continue to receive approval numbers in the same format designation (TC number) as issued under 30 CFR 11.

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## Filter Classification

This rule establishes three series of filters; N, R, and P. Each series has three levels of filter efficiency; 95 %, 99%, and 99.97%. These are the minimum efficiencies to be demonstrated by each filter. Hence, there are nine classes of filters altogether. Filters will be identified as:

- N95, R95, and P95: 95% filter efficiency level
- N99, R99, and P99: 99% filter efficiency level
- N100, R100, and P100: 99.97% filter efficiency level

The P100 filter will be color-coded magenta.

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## Test Requirements

The new certification tests use the most penetrating aerosol size, 0.3  $\mu\text{m}$  aerodynamic mass median diameter, of either a mildly degrading particulate, sodium chloride (NaCl), or a highly degrading oil, dioctylphthalate (DOP). The efficiency of the filter shall be monitored and recorded throughout the test period. The N-series respirators will be tested to a maximum loading level of 200 mg NaCl per respirator. The minimum efficiency for the filters tested must be equal to or greater than the filter efficiency criterion listed above for the filter class for which approval is sought. 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 shall be taken out of their packaging and placed in an environment of  $85 \pm 5$  % relative humidity at  $38 \pm 2.5^\circ\text{C}$  for  $25 \pm 1$  hours. These preconditioning requirements apply only to N-series filters. This requirement is to address the effect of humidity on the filter's efficiency because the sodium chloride aerosol is less severe than DOP in reducing filter efficiency.

The R-series respirators will be tested to a maximum loading of 200 mg DOP per respirator. The minimum efficiency for the filters tested must be equal to or greater than the filter efficiency criterion listed above for the filter class for which approval is sought.

For P-series filters, if the filter efficiency is decreasing when the 200 mg of DOP challenge point is reached, the test shall be continued until there is no further decrease in efficiency. The minimum efficiency for the filters tested must be equal to or greater than the filter efficiency criterion listed above for the filter class for which approval is sought.

Airflow resistance tests were modified from 30 CFR 11 by deleting the final inhalation resistance requirements. The airflow resistance through the filter is not determined after the loading tests. According to NIOSH, this is because the filter efficiency tests are not designed to simulate loading of the filter at the worksite. Therefore final inhalation test requirements are not appropriate with the introduction of these new tests. [At 10 times the PEL for lead, assuming a moderate breathing rate of 10 M<sup>3</sup> per 8 hour day for a worker, it would take 40 days for a respirator to become loaded with 200 mg of lead.]

Table 1 summarizes 42 CFR 84 filter classification with respect to the various filter efficiency tests.

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## **Respirator Limitations & Use**

Since filter classification of N, R, and P does not provide information as to where to use a specific filter, NIOSH plans to issue a Users Notice or Guide to explain the use of respirators certified under 42 CFR 84. This guide is anticipated to be either an update or supplement to the NIOSH Respirator Decision Logic. Thus, it would not be a legal document as published in the *Federal Register*. It would be published as a NIOSH recommendation. OSHA and MSHA regulate the use of all respirators in the workplace.

Respirators certified according to 42 CFR 84, subpart K, are designed and limited for use as respiratory protection against atmospheres with particulate contaminants that are not immediately dangerous to life or health and that contain adequate oxygen to support life. The N-series filters are restricted to use in those workplaces free of oil aerosols. The R- and P-series filters are intended for removal of any particulate that includes oil-based liquid particles.

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## **Use of Particulate Respirators for Protection Against TB**

All nine classes of particulate respirators to be certified under the provisions of the new particulate filter tests (filter efficiency) in part 84 meet or exceed the performance recommendations contained in the CDC "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994". According to NIOSH it is not necessary to subject filter respirators to a bioaerosol as a condition of certification. By using test aerosols of the most penetrating size range as required in part 84, the efficiency- level determination of the certification testing will be the lowest obtainable for any size aerosol. Therefore, the efficiency level against any bioaerosol for any certified respirator will meet or exceed the certified efficiency level. [OSHA regulates the use of respirators in health-care facilities and at this time OSHA still requires HEPA filter respirators to be used.]

## **Powered Air-Purifying Particulate Respirators**

Filters for powered air-purifying respirators (PAPRs) are not affected under the changes to 42 CFR 84. The requirements for PAPRs will be addressed in a forthcoming module. In the interim, powered air-purifying particulate respirators equipped with HEPA filters will be approved under the provisions of 42 CFR 84 subpart KK. Approvals of new PAPRs for particles will only be certified with high efficiency (HEPA) filters as tested under 30 CFR 11. New approvals for PAPRs with dust/mist or dust/fume/mist filters will not be granted.

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## **Pesticide Respirators**

The requirements for pesticide respirators from 30 CFR 11 were not included in 42 CFR 84. This rule eliminates the pesticide respirator category and the tests specific to these respirators. Pesticide respirators certified under 30 CFR 11 may not be sold or shipped by the approval holder as NIOSH/MSHA certified respirators after July 10, 1998. These respirators are subjected to the same requirements discussed previously under "Transition Period".

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## **Paint Spray Respirators**

The test requirements specific to paint spray respirators are also eliminated under 42 CFR 84. Filters used in conjunction with chemical cartridges, including those that might be used for spray paint will be tested under the same provisions as particulate respirators.

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## **Combination Gas Masks**

Combination gas masks are respirators using a canister containing filters for protection against particles in combination with gases, vapors, or gases and vapors. The filters in these devices shall also comply with the requirements of the new part 84 particulate filters except for the airflow resistance test. Airflow resistance requirements of 30 CFR 11 apply as incorporated into 42 CFR 84.