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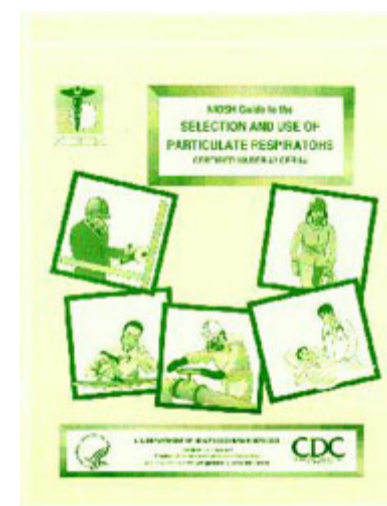
NIOSH Guide to the Selection and Use of Particulate Respirators

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Certified Under 42 CFR 84

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Foreward

In June 1995, the National Institute for Occupational Safety and Health (NIOSH) updated and modernized the Federal regulation for certifying air-purifying particulate respirators [42 CFR Part 84]. The respirators certified under this new regulation are tested under much more demanding conditions, and they provide increased worker protection. These new respirators also provide significant cost savings: Estimates indicate that the health care industry alone will save millions of dollars as a result of this new generation of practical and efficient respirators.

This guide was designed to explain the new regulation and to provide valuable information for selecting and using the new respirators certified by NIOSH.

We greatly appreciate the assistance of respirator manufacturers and others in making this information available to all employers and respirator program managers. We believe this information will help protect the health and lives of U.S. workers who wear particulate filter respirators.

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Abbreviations

APF	assigned protection factor
CFR	Code of Federal Regulations
DFM	dust, fume, and mist
DHHS	U.S. Department of Health and Human Services
DM	dust and mist
DOP	dioctyl phthalate

HEPA filter	high-efficiency particulate air filter
HR	hazard ratio
IDLH	immediately dangerous to life and health
MMAD	mass median aerodynamic diameter
MSHA	Mine Safety and Health Administration
NaCl	sodium chloride
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PAPR	powered air-purifying respirator
PEL	permissible exposure limit
REL	recommended exposure limit
SCBA	self-contained breathing apparatus
TB	tuberculosis

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I. Summary for Respirator Users

This summary presents a brief overview of what the respirator user needs to know about the new categories of particulate respirators certified by the National Institute for Occupational Safety and Health (NIOSH).

NIOSH has developed a new set of regulations in 42 [CFR*](#) 84 (also referred to as "Part 84") for testing and certifying nonpowered, air-purifying, particulate-filter respirators. The new Part 84 respirators have passed a more demanding certification test than the old respirators (e.g., dust and mist [DM], dust, fume and mist [DFM], spray paint, pesticide, etc.) certified under 30 CFR 11 (also referred to as "Part 11").

Changes in the new regulations involve only nonpowered, air-purifying, particulate-filter respirators. Certification requirements for all other classes of respirators (e.g., chemical cartridges, self-contained breathing apparatus [SCBA], airlines, gas masks without a particulate filter, powered air-purifying respirators [PAPRs] equipped with high-efficiency particulate air [HEPA] filters, etc.) have been transferred to Part 84 without change. Until further notice, the Occupational Safety and Health Administration (OSHA) is allowing the continued use of Part 11 particulate-filter respirators. Under Part 84, NIOSH is allowing manufacturers to continue selling and shipping Part 11 particulate filters as NIOSH-certified until July 10, 1998.

The new Part 84 regulation provides for nine classes of filters (three levels of [filter efficiency](#),[†] each with three categories of resistance to [filter efficiency degradation](#)[‡]). The three levels of filter efficiency are 95%, 99%, and 99.97%. The three categories of resistance to filter efficiency degradation are labeled N, R, and P. The class of filter will be clearly marked on the filter, filter package, or respirator box. For example, a filter marked N95 would mean an N-series filter that is at least 95% efficient. Chemical cartridges that include particulate filter elements will carry a similar marking that pertains only to the particulate filter element.

The new classes of nonpowered particulate respirators require new decision logic for selection of the proper respirator. The selection process for using the new particulate classification is discussed fully in Section II (Detailed Guidelines for Use) and outlined as follows:

1. The selection of N-, R-, and P-series filters depends on the presence or absence of oil particles, as follows:
 - If no oil particles are present in the work environment, use a filter of any series (i.e., N-, R-, or P-series).
 - If oil particles (e.g., lubricants, cutting fluids, glycerine, etc.) are present, use an R- or P-series filter. **Note:** N-series filters cannot be used if oil particles are present.
 - If oil particles are present and the filter is to be used for more than one work shift, use only a P-series filter.

Note: To help you remember the filter series, use the following guide:

- N for **Not** resistant to oil,
 - R for **Resistant** to oil
 - P for oil **Proof**
2. Selection of filter efficiency (i.e., 95%, 99%, or 99.97%) depends on how much filter leakage can be accepted. Higher filter efficiency means lower filter leakage.
 3. The choice of facepiece depends on the level of protection needed—that is, the assigned protection factor (APF) needed.

*Code of Federal Regulations. See CFR in references.

[†]Filter efficiency is the stated percentage of particles removed from the air.

[‡]Filter efficiency degradation is defined as a lowering of filter efficiency or a reduction in the ability of the filter to remove particles as a result of workplace exposure.

II. Detailed Guidelines for Use

A. Purpose

The purpose of this user's guide is (1) to familiarize respirator users with the new Part 84 certification regulations for particulate respirators, and (2) to provide guidance for the selection and use of the new particulate respirators. The new regulation became effective on July 10, 1995, and replaces the old Part 11 regulation under which NIOSH and the Mine Safety and Health Administration (MSHA) jointly certified respirators before that date.

These guidelines are written for those responsible for establishing and administering an acceptable respiratory protection program. These individuals should be knowledgeable about the basic elements of a respiratory protection program as required in the OSHA respiratory protection standard [29 CFR 1910.134] and as recommended in the *NIOSH Guide to Industrial Respiratory Protection* [NIOSH 1987], the *American National Standard for Respiratory Protection* (ANSI Z88.2-1992) [ANSI 1992], and the *American Industrial Hygiene Association Respiratory Protection Manual* [AIHA 1993].

B. Background

The old Part 11 respirator certification regulation [30 CFR 11] was promulgated in 1972. Some of the particulate filter certification tests dated from Bureau of Mines procedures during the 1930s and were never significantly updated. New research, testing, and manufacturing technology have made the particulate filter certification procedures in Part 11 outdated.

Only certifications of nonpowered, air-purifying, particulate-filter respirators are affected by this change from Part 11 to Part 84. Powered, air-purifying, particulate-filter respirators will be addressed in a future revision to Part 84. The remaining portions of Part 11 are incorporated into Part 84 without change. This limited revision provides for certification tests using a worst-case penetrating aerosol (i.e., an aerosol that produces maximum filter penetration) so that the new certified filters can be used against any size of particulate in the workplace. Other respirator testing and certification procedures will be addressed through a series of future changes to Part 84.

On July 10, 1995, 30 CFR 11 was replaced by 42 CFR 84 as an active regulation. As of that date, NIOSH no longer accepts applications for new approvals or for extension of approvals under Part 11 regulations. All nonpowered, air-purifying, particulate-filter respirators approved under Part 84 must meet the new performance standard. However, the new regulation permits the manufacture and sale of nonpowered particulate respirators certified under Part 11 until July 10, 1998. This 3-year period will provide time for manufacturers to have new respirators approved and manufactured to meet demand. OSHA, MSHA, and other regulatory agencies have the authority to set a use deadline for 30 CFR 11 filters purchased before July 10, 1998.

A new sequence of approval numbers (TC-84A-xxxx) is used for nonpowered particulate respirators certified under Part 84. All other respirator types will continue to use the sequence of approval numbers previously used for Part 11 because the requirements for these other types have not changed. For example, the number series TC-13F-xxxx indicates an SCBA that is certified under the provisions of either the old Part 11 or the new Part 84. Similarly, PAPRs for particulates that are certified under the new Part 84 will continue to be numbered with the sequence TC-21C-xxxx (as they were numbered under Part 11) because the certification requirements have not yet changed. [Appendix A](#) shows examples of the old Part 11 and the new Part 84 certification labels.

All particulate respirators approved under Part 84 will have a certification label bearing the NIOSH and the Department of Health and Human Services (DHHS) emblems, whereas those approved under Part 11 have the emblems of NIOSH and MSHA. This allows the user to distinguish particulate respirators certified before July 10, 1995, under Part 11 from particulate respirators certified after that date under Part 84.

The revised testing requirements for particulate filters are much more demanding than the old Part 11 tests, and they provide much better evidence of the filter's ability to remove airborne particles. The new requirements are consistent with 20 years of advances in respiratory protection technology.

C. 42 CFR 84 Filter Classes

The Part 84 certification regulation provides for nine classes of filters (three levels of filter efficiency, with three categories of resistance to filter efficiency degradation). The three levels of filter efficiency are 95%, 99%, and 99.97%. The three categories of resistance to filter efficiency degradation are labeled N (*Not* resistant to oil), R (*Resistant* to oil), and P (oil *Proof*) (see [Table 1](#)). **These new certification categories apply only to nonpowered, air-purifying, particulate-filter respirators.** PAPRs for particulates will be approved only with high-efficiency filters. PAPRs will not be approved with DM or DFM filters under Part 84. This rule also eliminates the combination categories of paint spray and pesticide respirator approvals; however, other combination respirators (e.g., particulates and acid gases or organic vapors) will be certified under Part 84.

Table 1. – Description of filter classes certified under 42 CFR 84

Class of Filter	Efficiency (%)	Test Agent	Test maximum loading (mg)	Type of contaminant	Service time*
N-Series		NaCl [†]	200	Solid and water-based particulates (i.e., non-oil aerosols)	Nonspecific ^{‡§}
N100	99.97				
N99	99				
N95	95				

Class of Filter	Efficiency (%)	Test Agent	Test maximum loading (mg)	Type of contaminant	Service time*
R-Series		DOP oil**	200	Any	One work shift‡,‡‡
R100	99.97				
R99	99				
R95	95				
P-Series		DOP oil	Stabilized efficiency	Any	Nonspecific‡
P100‡‡	99.97				
P99	99				
P95	95				

*NIOSH will be conducting and encouraging other researchers to conduct studies to assure that these service time recommendations are adequate. If research indicates the need, additional service time limitations may be recommended by NIOSH for specific workplace conditions.

†NaCl = sodium chloride.

‡Limited by considerations of hygiene, damage, and breathing resistance.

§High (200 mg) filter loading in the certification test is intended to address the potential for filter efficiency degradation by solid or water-based (i.e., non-oil) aerosols in the workplace. Accordingly, there is no recommended service time limit in most workplace settings. However, in dirty workplaces (high aerosol concentrations), service time should only be extended beyond 8 hours of use (continuous or intermittent) by performing an evaluation in specific workplace settings that: a) demonstrates extended use will not degrade the filter efficiency below the certified efficiency level, or (b) demonstrates the total mass loading of the filter is less than 200 mg (100 mg per filter for dual-filter respirators).

**DOP oil = dioctyl phthalate.

‡‡No specific service time limit when oil aerosols are not present. In the presence of oil aerosols, service time may be extended beyond 8 hours of use (continuous or intermittent) by (a) demonstrating that extended use will not degrade the filter efficiency below the certified efficiency level, or (b) demonstrating that the total mass loading of the filter is less than 200 mg (100 mg per filter for dual-filter respirators).

‡‡‡The P100 filter must be color-coded magenta. The Part 84 Subpart KK HEPA filter on a PAPR will also be magenta, but the label will be different from the P100 filter, and the two filters cannot be interchanged.

NIOSH established the new test criteria to simulate worst-case respirator use and very severe test conditions. These filters can be used without particle size analysis or filter penetration testing in the workplace. R- or P-series filters should be selected if there are oil (e.g., lubricants, cutting fluids, glycerine) or non-oil aerosols in the workplace. N-series filters should be used only for non-oil (i.e., solid and water-based) aerosols.

Note: To help you remember the filter series, use the following guide:

- N for **Not** resistant to oil,
- R for **Resistant** to oil
- P for oil **Proof**

The filter certification test is called worst-case (i.e., it produces maximum filter penetration) because the test conditions are the most severe that are likely to be encountered in a work environment. These conditions are:

- Air flow that simulates a high work rate (85 \pm 4 liters per minute for single filters, 42.5 \pm 2 liters per minute through each filter for paired filters)
- The most penetrating aerosol size (approximately 0.3 micrometer)
- Charge-neutralized particles
- The most filter-degrading test aerosol for R- and P-series filters
- Measurement of instantaneous (not average) penetration
- High total filter loading (up to 200 mg for N- and R-series filters, and continued loading until there is no further decrease in efficiency for P filters)

The degradation categories (N-, R-, and P-series) will be determined by using either sodium chloride (NaCl) or dioctyl phthalate (DOP) as the test aerosol. NaCl is only slightly degrading to filter efficiency, whereas DOP is very degrading. Respirators tested with NaCl (i.e., N-series filters) are not resistant to efficiency degradation by oils and should be used only in workplaces free of oil aerosols. Filters passing DOP oil tests (i.e., R- and P-series filters) are resistant to efficiency degradation and can be used for protection against any aerosols (including oil-based particulates) in the workplace.

D. Use Limitations

The service life of all three categories of filters efficiency degradation (i.e., N-, R-, and P-series) is limited by considerations of hygiene, damage, and breathing resistance. All filters should be replaced whenever they are damaged, soiled, or causing noticeably increased breathing resistance (e.g., causing discomfort to the wearer).

R- or P-series filters can be used for protection against oil or non-oil aerosols. N-series filters should be used only for non-oil aerosols. Use and reuse of the P-series filters would be subject only to considerations of hygiene, damage, and increased breathing resistance. Generally, the use and reuse of N-series filters would also be subject only to considerations of hygiene, damage, and increased breathing resistance. However, for dirty workplaces that could result in high filter loading (i.e., 200 mg), service time for N-series filters should be extended beyond 8 hours of use (continuous or intermittent) by performing an evaluation in specific workplace settings that: (a) demonstrates extended use will not degrade the filter efficiency below the efficiency level specified in Part 84, or (b) demonstrates the total mass loading of the filter(s) is less than 200 mg. The R-series filters should be used only for a single shift (or for 8 hours of continuous or intermittent use) when oil is present. However, service time for the R-series filters can be extended using the same two methods described above for N-series filters. These determinations would need to be repeated whenever conditions change or modifications are made to processes that could change the type of particulate generated in the user's facility.

E. Particulate Respirator Selection

To select the correct respirator for protection against particulates, the following conditions must be known:

- The identity and concentration of the particulates in the workplace air
- The OSHA or MSHA permissible exposure limit (PEL), the NIOSH recommended exposure limit (REL), or other occupational exposure limit for the contaminant
- The hazard ratio (HR) (i.e., the airborne particulate concentration divided by the exposure limit)
- The APF^s for the class of respirator (the APF should be greater than the HR)
- The immediately dangerous to life or health (IDLH) concentration, including oxygen deficiency [NIOSH 1994]
- Any service life information available for combination cartridges or canisters

Multiplying the occupational exposure limit by the APF for a respirator gives the maximum workplace concentration in which that respirator can be used. For example, if the commonly accepted APF for a half-mask respirator is 10 and the PEL is 5 mg/m³, then 50 mg/m³ is the highest workplace concentration in which a half-mask respirator can be used against that contaminant. If the workplace concentration is greater than 50 mg/m³, a more protective respirator (with a higher APF) should be used. In no case should an air-purifying respirator be used in IDLH concentrations.

[Appendix B](#) presents a simplified guideline that can be used to identify an appropriate Part 84 particulate respirator when a properly selected Part 11 respirator is already in use.

[Appendix C](#) presents a flow chart that can be used to select the appropriate Part 84 particulate filters.

[Appendix D](#) presents some substance-specific examples of Part 84 respirator selection.

[Appendix E](#) answers questions commonly asked about Part 84 respirators.

Note Concerning Part 11 Particulate Filters

Because research shows that particles sized 2 micrometers or smaller can penetrate some DM and DFM filters, these Part 11 filters should be used only when the mass median aerodynamic diameter (MMAD) is known to be greater than 2 micrometers [NIOSH 1995]. If this diameter is less than 2 micrometers or is unknown, a Part 11 HEPA filter or *any* Part 84 filter should be used.

Note on Respirator Fit

OSHA requires that all respirators be properly **fit-tested** using a quantitative or qualitative fit test when initially assigned to a user and periodically thereafter. In addition to fit-testing, your respirator manufacturer has recommended **fit-checking** procedures that should be followed by the user each time the respirator is worn.

F. Respiratory Protection for Tuberculosis

The only respirators certified by NIOSH under Part 11 that meet CDC filtration efficiency performance criteria for protection against tuberculosis (TB) are those with HEPA filters. All nine classes of nonpowered, air-purifying, particulate-filter respirators certified under Part 84 meet or exceed the CDC filtration efficiency performance criteria [CDC 1994]. Several of the Part 84 particulate-filter respirators will be less expensive and more comfortable than Part 11 HEPA-filter respirators, and they are likely to be more readily accepted by health care facilities and workers.

Health care delivery settings are generally free of oil aerosols that would be degrading to filter efficiency. Therefore, N-, R-, or P-series respirators are appropriate for protection against TB in health care settings and other workplaces in which oil aerosols are absent; these respirators are subject to replacement as necessary by considerations of hygiene, damage, and breathing resistance.

Current OSHA policy permits the use of a Part 11 HEPA filter or *any* Part 84 particulate filter for protection against TB [Miles 1995]. Pending completion of a final TB standard, respiratory protection against TB will be regulated by OSHA under the current unrevised respirator standard [29 CFR 1910.134] and compliance policy directives.

Additional information about respiratory protection for exposure to TB is found in *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities* [CDC 1994] and in *Protect Yourself Against Tuberculosis—A Guide for Health Care Workers*, [NIOSH 1996].

The APF (assigned protection factor) is the minimum anticipated level of protection provided by each type of respirator worn in accordance with an adequate respiratory protection program. For example, an APF of 10 means that the respirator should reduce the airborne concentration of a particulate by a factor of 10 (or to 10% of the workplace concentration).

OSHA currently sets APFs in some substance-specific standards. OSHA is now conducting rulemaking [29 CFR 1910.134] that will set uniform APFs for all respirator types.

Appendices

[Appendix A: Part 11 and Part 84 Labels for Various Filters](#)

[Appendix B: Substitution of Part 84 Respirators for Part 11 Respirators Already In Use](#)

[Appendix C: Flow Chart for Selecting Part 84 Particulate Filters](#)

[Appendix D: Examples of Part 84 Respirator Selection](#)

[Appendix E: Commonly Asked Questions and Answers About Part 84 Respirators](#)

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NIOSH Respirator User Notice, May 2, 1997

This notice is the first update of the NIOSH Guide to the Selection and Use of Particulate Respirators Certified under 42 CFR part 84 (NIOSH No. 96-101) published in January 1996. It modifies the NIOSH service time recommendations for P-series particulate respirators.

The Guide provided that, *"Use and reuse of the P-series filters would be subject only to considerations of hygiene, damage, and increased breathing resistance."* The Guide also stated that *"NIOSH will be conducting and encouraging other researchers to conduct studies to assure that these service time recommendations are adequate. If research indicates the need, additional service time limitations may be recommended by NIOSH for specific workplace conditions."*

Recent NIOSH laboratory studies indicate the efficiency of P-series filters may be significantly reduced with long term use in the presence of oil aerosols. Such long term oil exposure has resulted in the reduction in efficiency of P100 filters to efficiencies much less than that required of P95 filters. In some workplace situations, this reduction in filter efficiency may not always be accompanied by an increase in breathing resistance that would signal the user to replace the filter, or filter element. This reduction in filter efficiency varies significantly from model to model and NIOSH can not make a single filter change recommendation that is appropriate for all models. Therefore, NIOSH has requested each manufacturer of P-series filters to establish service time recommendations as part of their user instructions. NIOSH expects that manufacturers of P-series filters will provide such recommendations as part of their customer support programs.

These NIOSH recommendations are interim in that a full understanding of the degrading effects of workplace contaminants on filter efficiency is not yet available to NIOSH. In addition to continuing to study the degrading effects of workplace aerosols on all types of filters certified under 42 CFR part 84, NIOSH is also investigating the possible degrading effects of workplace gases and vapors on those filters.

Respirator users are also reminded that the provisions of the new 42 CFR part 84 require respirators to be far more resistant to filter degradation than did the provisions of 30 CFR part 11. That is only one of the reasons why NIOSH encourages users to discontinue the use of particulate respirators certified under 30 CFR part 11 and switch to the new particulate respirators certified under 42 CFR part 84.

Users are also reminded that NIOSH has a long standing recommendation that all 30 CFR part 11 particulate filters be replaced at least daily (once each work shift).

This User Notice does not change the NIOSH service time recommendations made in the Guide for N- and R- series respirators.

The current NIOSH service-time-limit recommendations for nonpowered particulate filter respirators are that filter elements should be replaced at the following frequencies:

All filters. The service life of all filters is limited by considerations of hygiene, damage, and breathing resistance. All filters should be replaced whenever they are damaged, soiled, or causing noticeably increased breathing resistance.

N-series filters generally should be used and reused subject only to considerations of hygiene, damage, and increased breathing resistance. However, for dirty workplaces that could result in high filter loading (i.e., 200 mg), service time for N-series filters should only be extended beyond 8 hours of use (continuous or intermittent) by performing an evaluation in specific workplace settings that demonstrates: (a) that extended use will not degrade the filter efficiency below the efficiency level specified in Part 84, or (b) that the total mass loading of the filter(s) is less than 200 mg. These determinations would need to be repeated whenever conditions change or modifications are made to processes that could change the type of particulate generated in the user's facility.

R-series filters should be used only for a single shift (or for 8 hours of continuous or intermittent use) when oil is present. However, service time for the R-series filters can be extended using the same two methods described above for N-series filters. These determinations would need to be repeated whenever conditions change or modifications are made to processes that could change the type of particulate generated in the user's facility.

P-series filters should be used and reused in accordance with the manufacturer's time-use limitation recommendations when oil aerosols are present. P-series filters should be used and reused subject only to considerations of hygiene, damage, and increased breathing resistance if oil aerosols are not present.

30 CFR part 11 filters should be replaced at least daily or more often if breathing resistance becomes excessive or if the filter suffers physical damage (tears, holes, etc.) Filter elements designed to be cleaned and reused should be cleaned at least daily in accordance with the manufacturer's instructions. Between uses, filters should be packaged to reduce exposure to conditions which cause filter degradation, such as high humidity.

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