

Regulations Update

OH&ESD

#21—Respiratory Protection

Published: March, 1998

Revised: January, 2004

OSHA Regulation: 29 CFR 1910.134

On January 8, 1998, The Occupational Safety and Health Administration (OSHA) issued a final rule for respiratory protection. The standard was published in the *Federal Register*, 63 *Fed. Reg.* 1151 and will be codified as 29 CFR 1910.134. The standard applies to general industry, construction, shipyard, longshoring and marine terminal workplaces. The previous 29 CFR 1910.134 will be recodified as 29 CFR 1910.139 and applies only to respiratory protection against *M. tuberculosis* (TB) and applies in lieu of 1910.134.* The new 1910.134 applies to biohazards except for TB. This summary of the respiratory protection standard was prepared by 3M OH&ESD and focuses primarily on the more significant changes to the standard. It does not represent an official, legal nor complete interpretation of the standard. If specific questions arise, the standard itself should be reviewed and relied on, rather than this summary. A copy of the new 1910.134 can be viewed or copied from our website; www.3M.com/occsafety.

Summary

This final rule replaces the previous 29 CFR 1910.134 that was adopted by OSHA in 1971. The new standard requires employers to establish and maintain a respiratory protection program to protect their employees who wear respirators.

The major changes to the respiratory protection standard include:

- definitions important to the standard;
- requirement for a program administrator;
- requirements when respirator use is not required, but permitted;
- establishment of a cartridge change schedule when gas and/or vapor respirators that do not have end-of-service-life indicators are used;
- restrictions for non-high efficiency particulate air filters approved under 30 CFR 11 to particle size distributions of contaminants with an MMAD (mass median aerodynamic diameter) > 2 µm;
- mandatory medical evaluation questionnaire;
- requirements for fit testing all tight-fitting respirators with a repeat frequency of at least every 12 months; and
- specific qualitative and quantitative fit testing protocols.

The final standard also modifies some of the respirator requirements in other OSHA health standards that duplicate those in the final standard and revises some other respirator-related provisions to make them consistent with 1910.134. For example, the substance specific standards' fit testing requirements have been replaced with those of 1910.134 and numerous standards that referred to 30 CFR 11 have been updated to 42 CFR 84.

Dates

The final rule becomes effective April 8, 1998 except as follows:

- The determination that respirator use is required [paragraph (a)] shall be completed no later than September 8, 1998.
- Compliance with all other provisions of this section shall be completed no later than October 5, 1998.

Major Changes to 1910.134

The following discussion summarizes the paragraphs of the new 1910.134 and discusses some of the major changes in more detail.

* Author's Note: Since the promulgation of the rule, OSHA has withdrawn 29 CFR 1910.139 and use of respirators against *M. tuberculosis* is now regulated under 1910.134. The revocation was published in the *Federal Register*, 68 *Fed. Reg.* 75776 on December 31, 2003.

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Definitions

The final standard includes definitions of important terms used in the regulatory text. Some of the more important definitions are:

- **Filtering Facepiece (dust mask):**

A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

- **High Efficiency Particulate Air (HEPA) Filter:**

A filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.

- **Physician or other Licensed Healthcare Professional (PLHCP):**

An individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by paragraph (e) of 1910.134.

- **User Seal Check:** An action conducted by the respirator user to determine if the respirator is properly seated to the face.

Respiratory Protection Program

This paragraph of the new 1910.134 requires the employer to develop and implement a written respiratory protection program with required worksite-specific procedures and elements for required respirator use. A suitably trained program administrator must administer the program. In addition, certain program

elements may be required for voluntary use to prevent potential hazards associated with the use of the respirator.

Program Elements

The elements of the respiratory protection program are essentially the same as in the previous 1910.134, however, they have been organized differently. The employer is required to provide respirators, training, and medical evaluations at no cost to the employee. The term “standard operating procedures” has been replaced with “worksite-specific procedures”. The standard states:

In any workplace where respirators are necessary to protect the health of the employee or whenever respirators are required by the employer, the employer shall establish and implement a written respiratory protection program with worksite-specific procedures. The program shall be updated as necessary to reflect those changes in workplace conditions that affect respirator use. The employer shall include in the program the following provisions of this section, as applicable:

1. Procedures for selecting respirators for use in the workplace;
2. Medical evaluations of employees required to use respirators;
3. Fit testing procedures for tight-fitting respirators;
4. Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
5. Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;

6. Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;
7. Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations;
8. Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use, and their maintenance; and
9. Procedures for regularly evaluating the effectiveness of the program.

Program Administrator

The employer shall designate a program administrator who is qualified by appropriate training or experience that is commensurate with the complexity of the program to administer or oversee the respiratory protection program and conduct the required evaluations of program effectiveness.

Voluntary Use

For those situations where respirator use is not required by OSHA or the employer, but is permitted by employers upon request by employees, the employer may allow voluntary use if the respirator use will not in itself create a hazard. If voluntary respirator use is permissible, the employer must provide the basic advisory information on respirators, as presented in Appendix D of 1910.134, in any written or oral format. In addition, those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the

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respirator is cleaned, stored, and maintained so that its use does not present a health hazard to the user must be implemented.

Exception: Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces (dust masks).

3M recommends that whenever respirators of any type are used that a complete respiratory protection program covering the elements in 1910.134 be implemented.

Selection of Respirators

This paragraph requires the employer to evaluate respiratory hazard(s) in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. The respiratory hazard evaluation includes “a reasonable estimate of employee exposures to respiratory hazard(s)”. Where the employer cannot identify or reasonably estimate the employee exposure, OSHA requires the employer to consider the atmosphere as IDLH. The paragraph also specifies appropriately protective respirators for use in IDLH atmospheres, and limits the selection and use of air-purifying respirators.

OSHA requires that the employer “select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.” This new wording now applies to the substance specific standards as well.

Table II of 1910.134

Altitude (ft.)	Oxygen Deficient Atmospheres (% O ₂) for Which the Employer May Rely on Atmosphere-Supplying Respirators
Less than 3001	16.0–19.5
3,001–4,000	16.4–19.5
4,001–5,000	17.1–19.5
5,001–6,000	17.8–19.5
6,001–7,000	18.5–19.5
7,001–8,000 ¹	19.3–19.5

¹ Above 8,000 feet the exception does not apply. Oxygen-enriched breathing air must be supplied above 14,000 feet.

Respirators for IDLH Atmospheres

OSHA still requires all oxygen-deficient (<19.5%) atmospheres to be considered IDLH.

Exception: If the employer demonstrates that, under **all foreseeable** (3M’s emphasis) conditions, the oxygen concentration can be maintained within the ranges specified in Table II of 1910.134 (i.e., for the altitudes set out in the table), then any atmosphere-supplying respirator may be used.

Assigned Protection Factors

The new 1910.134 does not contain assigned protection factors (APFs). OSHA intends to promulgate APFs in the future. In the interim, OSHA expects employers to take the best available information into account in selecting respirators. 3M believes this to be the APFs established by the American National Standards Institute (ANSI) Z88.2-1992 compared to the National Institute for Occupational Safety and Health (NIOSH) recommended APFs for several reasons:

- They are based on more recent information;

- They are based largely on WPF studies instead of fit testing performed in the middle 1970s;
- They used data on NIOSH approved respirators instead of US BM approved respirators; and
- They provided more complete documentation as to how the APFs were established.

OSHA, however, may attempt to enforce the APFs from the NIOSH Respirator Decision Logic (RDL).

Respirators for Atmospheres that are not IDLH

For protection against gases and vapors, the new standard requires the use of an atmosphere-supplying respirator, or an air-purifying respirator, provided that:

- The respirator is equipped with an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant; or
- If there is no ESLI appropriate for conditions in the employer’s workplace, the employer implements a change schedule for canisters and cartridges that is based on objective information or data that will ensure that canisters and cartridges are changed before

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the end of their service life. The employer shall describe in the respirator program the information and data relied upon and the basis for the canister and cartridge change schedule and the basis for reliance on the data.

At a stakeholders' meeting with OSHA, OSHA stressed that existing data and experience can be used along with professional judgment for establishing cartridge change schedules.

For protection against particulate contaminants, OSHA requires that one select either:

- An atmosphere-supplying respirator; or
- An air-purifying respirator equipped with a filter certified by NIOSH under 30 CFR part 11 as a high efficiency particulate air (HEPA) filter, or an air-purifying respirator equipped with a filter certified for particulates by NIOSH under 42 CFR part 84; or
- For contaminants consisting primarily of particles with mass median aerodynamic diameters (MMAD) of at least 2 micrometers, an air-purifying respirator equipped with any filter certified for particulates by NIOSH.

3M Note—The MMAD may be established in two ways:

- From particle size sampling; or
- From past studies on similar operations published in the literature.

A review of literature indicates that for most mechanically generated aerosols, the MMAD is > 2 µm. This concern will disappear as 30

CFR 11 approved particulate filters are phased out and replaced with those approved under 42 CFR 84. The concern can be eliminated earlier by immediately switching to the new particulate filters.

Medical Evaluation

Respirator use may place a physiological burden on an employee that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the employee's ability to use a respirator. The medical evaluation must be conducted before the employee is fit tested or required to use a respirator in the workplace. Annual medical evaluations are not required.

The medical evaluations must be performed by a physician or other licensed health care professional (PLHCP) using a mandatory medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire (Sections 1 and 2, Part A of Appendix C of 1910.134). Any PLHCP (e.g., nurse practitioners, physician assistants, occupational health nurses) may evaluate the employee's medical ability to use a respirator provided that the PLHCP is authorized to do so by state license, certification, or registration. There may be some variation by states as to who is capable of performing the evaluation.

Follow-Up Medical Examination

Follow-up medical examinations may be required depending on the results of the medical evaluation or where the initial medical examination demonstrates the need for a follow-up medical examination. The follow-up medical examination shall include any medical tests, consultations, or diagnostic procedures that the PLHCP deems necessary to make a final determination. Pulmonary function tests are only required if the PLHCP deems them necessary.

Additional Medical Evaluations

At a minimum, the employer shall provide additional medical evaluations if:

- An employee reports medical signs or symptoms that are related to his/her ability to use a respirator;
- A PLHCP, supervisor, or the respirator program administrator informs the employer that an employee needs to be reevaluated;
- Information from the respiratory protection program, including observations made during fit testing and program evaluation, indicates a need for employee reevaluation; or
- A change occurs in workplace conditions (e.g., physical work effort, protective clothing, and temperature) that may result in a substantial increase in the physiological burden placed on an employee.

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Fit Testing

Before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used. OSHA specifies the kinds of fit tests allowed, the procedures for conducting them, conditions for additional fit tests, and how the results of the fit tests must be used.

Either a qualitative fit test (QLFT) or quantitative fit test (QNFT) using an OSHA-accepted QLFT or QNFT protocol must be passed. QLFT may only be used to fit test negative pressure air-purifying respirators that must achieve a fit factor of 100 or less [APF \leq 10]. If the fit factor measured during a QNFT is equal to or greater than 100 for tight-fitting half facepieces, or equal to or greater than 500 [APF \leq 50] for tight-fitting full facepieces, the QNFT has been passed with that respirator. The OSHA-accepted QLFT and QNFT protocols and procedures are contained in Appendix A of 1910.134.

Employees using tight-fitting facepiece respirators must be fit tested:

- prior to initial use of the respirator;
- whenever a different respirator facepiece (size, style, model or make) is used; and
- at least annually thereafter.

Additional fit tests must be conducted whenever conditions that could affect respirator fit develop.

Positive Pressure Respirators

Fit testing of tight-fitting atmosphere-supplying respirators and tight-fitting powered air-purifying respirators shall be accomplished by performing **quantitative or qualitative** (3M emphasis) fit tests in the negative pressure mode, regardless of the mode of operation (negative or positive pressure) that is used for respiratory protection.

Use of Respirators

OSHA requires employers to establish and implement procedures for the proper use of respirators. These requirements include prohibiting conditions that may result in facepiece seal leakage (e.g., facial hair), preventing employees from removing respirators in hazardous environments, taking actions to ensure continued effective respirator operation throughout the work shift, and establishing procedures for the use of respirators in IDLH atmospheres or in interior structural firefighting situations.

User Seal Checks

Fit checks are now called user seal checks. For all tight-fitting respirators, a user seal check must be performed each time the respirator is put on. The procedures in Appendix B-1 or ones recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 must be used. [The following article demonstrates the effectiveness of 3M recommended user seal checks. Myers, W. R., M. Jaraiedi, and

L. Hendricks: Effectiveness of Fit Check Methods on Half Mask Respirators. *Appl. Occup. Environ. Hyg.* 10(11):934-942. 1995]

Maintenance and Care of Respirators

This paragraph of 1910.134 requires the employer to provide for the cleaning and disinfecting, storage, inspection, and repair of respirators used by employees.

Cleaning and Disinfecting

The employer shall provide each respirator user with a respirator that is clean, sanitary, and in good working order. The respirators must be cleaned and disinfected by either using:

- the procedures in Appendix B-2 of 1910.134; or
- the procedures recommended by the respirator manufacturer, provided that such procedures are of equivalent effectiveness.

Equivalent effectiveness simply means that the procedures used must ensure that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm to the user.

Intervals for cleaning and disinfecting respirators are the same in the new 1910.134 as in the previous standard. An additional requirement has been added to the new 1910.134 that requires respirators used in fit testing and training to be cleaned and disinfected after each use.

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Breathing Air Quality

This paragraph requires the employer to provide employees using atmosphere-supplying respirators (supplied-air and SCBA) with breathing gases of high purity, which is essentially unchanged from the previous standard. The standard states that “Compressed breathing air shall meet at least the requirements for Type 1-Grade D breathing air described in ANSI/Compressed Gas Association Commodity Specification for Air, G 7.1-1989 (G 7.1-1989 does not use Type 1 designation. It only includes gaseous air.).

New requirements for cylinders of air include:

- Cylinders of purchased breathing air have a certificate of analysis from the supplier that the breathing air meets the requirements for Grade D breathing air; and
- The moisture content in the cylinder does not exceed a dew point of -50°F (-45.6°C) at 1 atmosphere pressure.

For compressors used to supply breathing air to respirators the new requirements include:

- Minimize moisture content so that the dew point at 1 atmosphere pressure is 10 degrees F (5.56°C) below the ambient temperature;
- Maintain and replace or refurbish sorbent beds and filters periodically following the manufacturer’s instructions;
- Have a tag containing the most recent change date and the signature of the person authorized by the

employer to perform the change.

The tag shall be maintained at the compressor;

- For compressors that are not oil-lubricated, ensure that carbon monoxide levels in the breathing air do not exceed 10 ppm;
- For oil-lubricated compressors, use a high-temperature or carbon monoxide alarm, or both, to monitor carbon monoxide levels. If only high-temperature alarms are used, the air supply shall be monitored at intervals sufficient to prevent carbon monoxide in the breathing air from exceeding 10 ppm.

Identification of Filters, Cartridges and Canisters

The employer shall ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible.

Training and Information

This paragraph requires the employer to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in Appendix D of 1910.134 to employees who wear respirators when not required to do so by this standard or by the employer (voluntary use).

Program Evaluation

This section requires the employer to conduct evaluations of the workplace to ensure that the written respiratory protection program is being properly implemented, and to consult employees to ensure that they are using the respirators properly.

Recordkeeping

This section requires the employer to establish and retain written information regarding medical evaluations, fit testing, and the respirator program.

- Medical Evaluation: Records of medical evaluations required by this section must be retained and made available in accordance with 29 CFR 1910.1020.
 - Fit Testing: The employer shall establish a record of the qualitative and quantitative fit tests administered to an employee including:
 - The name or identification of the employee tested;
 - Type of fit test performed;
 - Specific make, model, style, and size of respirator tested;
 - Date of test; and
 - The pass/fail results for QLFTs or the fit factor and strip chart recording or other recording of the test results for QNFTs.
- Fit test records shall be retained for respirator users until the next fit test is administered.
- Written program: The employer shall retain a written copy of the current respirator program.

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Appendices

Compliance with Appendix A, Appendix B-1, Appendix B-2, and Appendix C of 1910.134 is mandatory. Appendix D of this section is non-mandatory and is not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

Appendix A to § 1910.134: Fit Testing Procedures (Mandatory)

Qualitative Fit Test (QLFT) Protocols

There are four OSHA accepted protocols for qualitative fit testing:

- 1. Isoamyl Acetate:** The respirator must be equipped with cartridges designed to remove organic vapors.
- 2. Saccharin:** The respirator must be equipped with a particulate filter of any class.
- 3. Bitrex™:** The respirator must be equipped with a particulate filter of any class.
- 4. Irritant Smoke:** The respirator must be equipped with level 100 particulate filters.

The exercise protocol for QLFT uses seven exercises performed for 1 minute each. The exercises are: normal breathing, deep breathing, moving head side-to-side, moving head up and down, bending over (jogging in place shall be substituted for this exercise in fit testing units that do not permit bending over at the waist), talking and normal breathing. To accomplish the talking exercise, the test subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Quantitative Fit Test (QNFT) Protocols

There are three OSHA accepted protocols for quantitative fit testing:

- 1. Generated Aerosol:** Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator;
- 2. Portacount™:** Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit;
- 3. Controlled Negative Pressure:** Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

The exercise protocol for QNFT requires the same seven exercises for QLFT plus a grimace exercise. Grimace is performed by smiling and frowning. It is performed for 15 seconds. The grimace exercise is not used in the calculation of the fit factor.

Appendix B-1 to § 1910.134: User Seal Check Procedures (Mandatory)

The individual who uses a tight-fitting respirator is to perform a user seal check to ensure that an adequate seal is achieved each time the respirator is put on. Either the positive and negative pressure checks listed in this appendix, or the respirator manufacturer's

recommended user seal check method shall be used. User seal checks are not substitutes for qualitative or quantitative fit tests.

Substance Specific Standards

The OSHA substance specific standards, such as asbestos, benzene, formaldehyde and lead, now refer to the new 1910.134. The fit testing protocols published in the substance specific standards have been withdrawn. All of the substance specific standards require fit testing to be performed as described in 1910.134. This means 1910.134 determines the number of sizes and models of respirators, frequency of fit tests, protocols for performing fit tests, and when one can use qualitative or quantitative fit.

Compliance with the medical evaluation requirements of 1910.134 is not mentioned for substance specific standards. This is because these standards have their own medical *surveillance* requirements (which may or may not be useful in determining a worker's ability to use a respirator).

The requirement for an end-of-service-life indicator or cartridge change schedule has not been included in those standards that already had a similar requirement (e.g., acrylonitrile, 1,3-butadiene, benzene, formaldehyde, and vinyl chloride).

The respirator selection tables in these standards have NOT changed. The assigned protection factors and respirator terminology is the same as before January 8, 1998. OSHA stated that "these tables will remain unchanged until resolution of the reserved portions (APFs) of this final standard."

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More To Come

Several areas have been pointed out in this Regulations Update where 1910.134 is unclear. It is expected that OSHA will be publishing corrections to the rule in the near future. OSHA has also indicated that they may publish a compliance directive regarding 1910.134. It may explain what OSHA expects to be done to comply with the ambiguous areas. If something helpful is published, we expect to communicate this information as well.



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