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NIOSH CERTIFICATION CRITERIA FOR PARTICULATE RESPIRATORS

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Background: Requirements for respiratory protection can be confusing because more than one government agency is involved in determining the standards. OSHA sets the overall respiratory program standards under 29 CFR, describing requirements for a written program, fit testing, training, recordkeeping, etc. State safety and health codes must also be at least as stringent as these. It is the National Institute for Occupational Safety and Health (NIOSH) however, that certifies respiratory protection *devices*. At one time, NIOSH shared this responsibility with the Mine Safety and Health Administration (MSHA), but as of July 1995, NIOSH has exclusive authority for testing and certifying respirators and filters under 42 CFR, except for certain mine emergencies. Respirators used in health care settings must also meet the performance criteria of the federal Centers for Disease Control (CDC). So, if you look to the written standards for clarity on this issue, there may be more than one place to look.

This article will attempt to explain the new rules regarding respiratory protection *devices*—specifically as to the testing, certification, and approval of negative pressure *air-purifying* respirators. These are the most commonly used type of respirators, which filter out undesirable *particulates* from the air. They include disposable respirator masks, as well as half-masks or full-face masks with cartridges. The new rules do not apply to *air-supplying* respirators of any kind, at least for the time being.

NIOSH is updating its entire respirator-certification program in a series of modules, divided by each respirator type, but the entire process may take years to complete. For now, nine new classes of *particulate* respirator filters will bear approval labels from NIOSH. Standards for all other respirator classes have been incorporated into the new 42 CFR without changes for the time being.

When did this change become effective?

This new respirator standard - 42 CFR 84 - became effective on July 10, 1995 and is generally referred to as PART 84. These regulations were developed by NIOSH to replace the old 30 CFR PART 11 regulations under which NIOSH and the Mine Safety and Health Administration certified respirators jointly. The standard had a three-year transition period, so that after July 10, 1998, only Part 84 - certified respirators and filters will be sold.

Why were these changes made?

The old 30 CFR Part 11 respirator certification standard was first issued in 1972. Some of the particulate filter certification testing procedures were based on very old data developed by the Bureau of Mines during the 1930s that has not been updated since. The new research, testing, and manufacturing technology of the 90's has made the particulate filter certification procedures in Part 11 obsolete.

What is the effect of this change?

The new requirements reflect 20 years of advances in respiratory protection technology, are much more demanding than the old tests, and provide much better evidence of the filter's ability to remove airborne particles. The Part 84 revision is based on tests using a worst-case penetrating aerosol (an aerosol that produces maximum filter penetration) so that the newly certified filters can be used against any size of particulate found in the workplace. This is significant because research has demonstrated that particles less than 2 micrometers in size can penetrate some dust/mist and dust/mist/fume filters that are currently certified and in use. If the diameter of particulate is less than 2 micrometers, or is unknown, a Part 11 *High Efficiency Particulate Air* (HEPA) filter, or a new Part 84 filter should be used. The new filters can be used without particle size analysis or filter penetration testing.

How can I tell which respirators or cartridges are certified under the new standard?

A new sequence of approval numbers (TC-84A-xxxx) is used for non-powered particulate respirators certified under Part 84. All air supplying respirator types will continue to use the original approval numbers under Part 11, since the certification requirements for these have not been changed yet. Respirators may be stamped with a variety of NIOSH, MSHA or DHHS (Dept. of Health and Human Services) emblems, but only the TC-84A approval number accurately indicates the new certification.

What are the filter classes?

The respirator filters are no longer classified by hazard type, such as dust, mist or fumes. Instead, filters are classified by their ability to resist degradation in the presence or absence of oil particles. Part 84 certification provides for nine *classes* of filters, based on three *levels* of filter efficiency and 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 (for oil Proof). For example, a filter marked N95 means an N series filter that is at least 95% efficient.

How can I remember these classes?

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

Will these new filters last longer?

Current OSHA standards require employers to establish a respirator cartridge change schedule and refer to NIOSH standards as a model. Note that OSHA has an excellent respiratory e-tool at OSHA.gov including 3 additional methods of determining cartridge life. The current NIOSH service-time-limit recommendations for non-powered 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.

How do I select the right respirator filters?

As in the past, each manufacturer will provide specifications for the correct filter to use, depending on the type and concentration of the atmospheric contaminant. To select the correct respirator/filters 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.

Users must also know the Immediately Dangerous to Life or Health (IDLH) concentration, including oxygen deficiency, and any service life information available for combination cartridges or canisters they plan to use. In no case should an air-purifying respirator be used in IDLH concentrations.

What is an “APF” and how do I use it?

The APF is the specific “Assigned Protection Factor,” defined as the minimum anticipated level of protection provided by a specific *type* of respirator. 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 ambient concentration - assuming that a fit test/check was passed. Multiplying the occupational exposure limit by the APF for a respirator gives the *maximum* workplace concentration in which that respirator can safely be used. For example, if the 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 this half-mask respirator can be used in the presence of that contaminant. If the ambient concentration is greater than 50 mg/m³, a more protective respirator with a higher APF must be used.

Respirator fit tests:

This requirement has not changed as a result of the standard, but employers should be aware that OSHA requires all respirator users to be properly fit-tested using a quantitative or qualitative fit test when respirators are initially assigned to a user, and periodically thereafter.

- A qualitative fit test (QLFT) is a pass/fail test that relies on the ability of the user to detect a test agent. OSHA has three testing protocols using different test agents: isoamyl acetate (banana oil), saccharin, “bitrex” solution and stannic chloride (irritant smoke).
- Quantitative (QNFT) fit testing does not depend on the wearers’ ability to detect a test agent. Instead instruments are used to measure the face seal leakage based on the difference in concentrations on the inside vs. outside of the respirator.

In addition to fit testing, whether qualitative or quantitative, respirator users *must* perform a fit check (positive and negative pressure test) each time the respirator is worn.

Part 84 changes and tuberculosis exposures in health care settings

The only respirators certified by NIOSH under Part 11 that meet CDC filtration efficiency performance criteria for protection against tuberculosis are those with HEPA filters. All nine classes of non-powered, air purifying, particulate-filter respirators certified under Part 84, however, meet or exceed the CDC performance criteria. Health care delivery settings are generally free of oil aerosols that would be degrading to filter efficiency. Therefore, any of the series N, R, or P respirators are appropriate for protection against TB in health care settings and other workplaces in which oil aerosols are absent. In addition, several of the Part 84 particulate-filter respirators are less expensive and more comfortable than the older Part 11 HEPA-filter respirators, and are thus more likely to be accepted by health care facilities and workers.

Summary:

To quote OSHA: **“Respirators should be used for protection only when engineering controls have been shown to be infeasible for the control of the hazard or during the interim period when engineering controls are being installed”**. To select a respirator, assess your exposure, account for local factors such as the job-site and worker characteristics, understand the concept of assigned protective factors and know the various kinds of respirators and their relevant characteristics.

Refer to <http://www.osha.gov/dts/osta/oshasoft/index.html> where a list of e-tools including the one on Respiratory Protection may be found. To request a free copy of “*The NIOSH Guide to the Selection and Use of Particulate Respirators Certified Under 42 CFR 84,*” call (800) 356-4674 or visit the NIOSH Home Page on the World Wide Web at <http://www.cdc.gov/niosh/homepage.html>.