

Nuclear Regulatory Commission Standards: 10 CFR 20

On October 7, 1999 the Nuclear Regulatory Commission (NRC) amended its regulations regarding the use of respiratory protection and other controls to help reduce worker exposures to radioactive material. These amendments were published in the *Federal Register*, 64 *Fed. Reg.* 54543. They are codified in 10 CFR 20. The NRC also revised Regulatory Guide 8.15. 3M OH&ESD prepared this summary of the amendments to 10 CFR 20. It does not represent an official, legal, nor complete interpretation of the standard. If specific questions arise, the standard itself and Regulatory Guide 8.15 should be reviewed, rather than this summary. A copy of the amendments and Regulatory Guide 8.15 can be viewed or copied from our web site.

Summary

According to the NRC, the amendments to 10 CFR 20 make these regulations

- more consistent with the philosophy of controlling the sum of internal and external radiation exposure,
- reflect current guidance on respiratory protection from the American National Standards Institute (ANSI),
- consistent with recent (1998) revisions to the Occupational Safety and Health Administration's (OSHA's) respiratory protection rule,
- less prescriptive while reducing unnecessary regulatory burden without reducing worker protection.

The amendments provide greater assurance that recent technological advances in respiratory protection equipment and procedures are reflected in NRC regulations and clearly approved for use by licensees.

In addition to the amendments to 10 CFR 20, the NRC has revised Regulatory Guide 8.15, Acceptable Programs for Respiratory Protection. Regulatory Guides provide descriptions of acceptable programs, are for guidance only and cannot be enforced unless a licensee commits to use specific regulatory guides in its license. Regulatory Guide 8.15 provides useful guidance for implementing an acceptable respiratory protection program.

Effective Date: This final rule becomes effective February 4, 2000.

NRC vs. OSHA Jurisdiction

In 1988 the NRC and OSHA signed a Memorandum of Understanding clarifying jurisdictional responsibilities at NRC licensed facilities. The NRC regulates three areas:

- Radiation risk produced by radioactive materials.
- Chemical risk produced by radioactive materials.
- Plant conditions that affect the safety of radioactive materials and thus present an increased radiation risk to workers.

If an NRC licensee is using respiratory protection to help protect workers against non-radiological hazards, OSHA requirements apply. NRC states that: "This final rule would not require a licensee to maintain two distinct programs, and only minor differences exist between the OSHA requirements and this final rule."

Standard

The NRC's respiratory protection regulations are set up differently than OSHA's. Regulations for protection against radiation are in Title 10 of the Code of Federal Regulations (CFR) Part 20. The respiratory protection regulations are located in Subpart H of Part 20. They are located in several sections of Subpart H such as 20.1701, 20.1702, 20.703 etc. With OSHA, the entire respiratory protection standard is in one section, 1910.134 in Subpart I of OSHA's General Industry standards, 29 CFR Part 1910. Thus while the OSHA Respiratory Protection Standard is referred to with one number, several numbers are needed to reference NRC's requirements. For this reason, when talking about NRC's requirements in general terms, referral is made to Subpart H instead of the various section numbers. Definitions for respiratory protection terms are found in a separate section, 20.1003. They are located in Part 20, but not Subpart H.

Definitions

The NRC added several terms to the "Definitions" section dealing with respiratory protection. Prior to these amendments the only term that appeared was "respiratory protective device". In 20.1003, respiratory protective device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

Control Methods

Sections 20.1701 and 20.1702 state NRC's hierarchy of controls. It is similar to OSHA's in that engineering controls are preferred. Only when it is not practical to apply process or engineering controls is respiratory protection allowed as a means to control worker exposures to radioactive material in the air.

Use of Respirators (20.1703)

The majority of the requirements for use of respiratory protection are found in section 20.1703. The NRC considers a respiratory protective device for reducing intake of airborne radioactive material unless the device is clearly and exclusively used for protection against nonradiological hazards. This section applies whenever respiratory protection is used.

NIOSH Approved Respirators

Generally, respirators approved by the National Institute for Occupational Safety and Health (NIOSH) are required to be used. An exception is made for respirators that have not been approved, are not listed in Appendix A, or for which there are no test schedules. In these situations the licensee can apply to NRC for authorization to use this equipment.

Respiratory Protection Program

The NRC requires that a respiratory protection program be implemented. This program must include:

- Air sampling;
- Surveys and bioassays;
- Testing of respirators for operability immediately prior to use;
- Written procedures;
- Medical fitness determination by a physician; and
- Fit testing.

Written procedures must be developed regarding:

- Monitoring, including air sampling and bioassays;
- Supervision and training of respirator users;
- Fit testing;
- Respirator selection;
- Breathing air quality;
- Inventory and control;
- Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protective equipment;
- Recordkeeping; and
- Limitations on periods of respirator use and relief from respirator use.

Program Administration

Program administration is not addressed specifically by 10 CFR 20. The NRC recognizes the importance of program administration. Regulatory Guide 8.15 states that a program should be established that identifies the individuals who have supervisory and technical responsibilities in the respiratory protection program, including the respirator program administrator. It is acceptable to the NRC that the radiological and nonradiological respiratory protection programs may have different administrators. However, adequate communication and coordination must exist between the programs.

Respirator Maintenance

10 CFR 20 requires that written procedures be developed for storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protective equipment. The requirements do not specify what needs to be done. OSHA standard 1910.134 provides more detail. Guidance is provided on respirator maintenance, storage, control, issuance and recordkeeping in Regulatory Guide 8.15.

Medical Evaluation

A physician selected by the licensee should determine which screening methods and tests are appropriate, should set the acceptance criteria for those methods and tests, and should periodically review the implementation of the program. While the physician is responsible for the fitness determination, the physician need not administer each test personally. The physician may designate a certified, medically trained individual who in the judgment of the physician has adequate experience, education, training, and judgment to administer the screening program.

The fitness determination must be performed prior to the initial fit test for tight fitting respirators and prior to the first field use of loose-fitting devices. The worker must be re-evaluated every 12 months thereafter or at some frequency established by the licensee's physician. Both NIOSH and ANSI Z88.6-1984 have suggested re-evaluation periods that a physician may use. The ANSI Z88.6-1984 document is no longer available from ANSI, but the NIOSH recommendations are very similar. The OSHA questionnaire is acceptable for medical screening, but the physician establishes the precise screening method.

Fit Testing

All tight-fitting respirators must be fit tested. Fit testing must be performed before the first respirator use and annually thereafter. Qualitative fit testing (QLFT) or quantitative fit testing (QNFT) must be performed in the negative pressure mode, regardless of the respirator mode of operation that will be used in the field. The minimum acceptable fit factor for negative pressure respirators is 10 times the APF. For positive pressure respirators the minimum acceptable fit factor is 500. This requirement is different than the OSHA requirement. For OSHA, either QLFT or QNFT is acceptable and positive pressure respirators can be used up to its assigned protection factor. Present QLFT methods are designed to ensure a fit factor of 100. Therefore, QLFT is only appropriate for devices with an APF of 10 or respirators with an APF greater than 10 where the licensee only takes credit for a protection factor of 10. In order to take credit for an APF greater than 10 for those devices listed in Appendix A to Subpart H quantitative fit testing must be performed. Fit testing performed in accordance with the OSHA protocols will comply with NRC's requirements.

User Seal Checks

Each respirator wearer must perform at least one type of user seal check each time a face-sealing respirator is used. Acceptable user seal checks include the positive-pressure check and the negative-pressure check. The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive- or negative-pressure check procedures, provided that the employer demonstrates that the manufacturer's procedures are effective. The user seal checks recommended by 3M on disposable half facepiece respirators have been demonstrated to be effective. (see *Appl. Occup. Environ. Hyg.* 10(11):934-942;1995) The NRC also outlines seal checks using irritant and odorous test agents.

Respirator Relief

The standard requires that the licensee must advise each respirator user that they may leave the area at any time for relief from respirator use. Conditions that may require relief from use include equipment malfunction, physical or psychological distress, procedural or communication failure, and significant deterioration of operating conditions.

Limitation Considerations

The licensees are required to consider limitations of the respirator type and mode of use. The licensees must provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment when necessary.

Breathing Air Quality

Atmosphere-supplying respirators must be supplied with respirable air of Grade D quality or better as defined by the Compressed Gas Association publication, G7.1. Moisture content in breathing air cylinders is not specified in 10 CFR 20, but Regulatory Guide 8.15 states that the NRC requires compliance with the OSHA requirement (dewpoint $\leq -50^{\circ}$ F). They suggest, if practical, compliance with the moisture requirement of Grade L (dewpoint $\leq -65^{\circ}$ F).

Face-to-Facepiece Seal Integrity

Anything in the face-to-facepiece seal area of a tight-fitting respirator is prohibited by 10 CFR 20.1703(h). This includes facial hair, hair from the head, cosmetics, spectacle temple bars, and protective clothing and equipment that projects into the seal area. The Regulatory Guide 8.15

states the worker must be clean shaven, but that a respirator wearer should not be required to shave more than once during a 12-hour period.

Appendix A of Subpart H

Appendix A lists respirator types and their assigned protection factors established by the NRC. The APFs are from ANSI Z88.2-1992. Several footnotes are attached with this table. They explain the use of this table where NRC differs with the APF or respirator classification of ANSI Z88.2-1992. The more significant differences involve quarter facepiece respirators, half facepiece respirators, disposable filtering facepiece respirators, and the effect of filter selection on APF.

Quarter Facepiece Respirators

Quarter facepiece respirators seal over the bridge of the nose, around the cheeks, and between the point of the chin and the lower lip. They are not listed in Appendix A of 10 CFR 20 and may not be used in an NRC-regulated respiratory protection program. 3M OH&ESD does not make or sell quarter facepiece respirators.

Half Facepiece Respirators

ANSI Z88.2-1992 considers all filtering facepiece respirators as half facepiece respirators. The NRC has two entries, one as filtering facepiece disposable respirators and another as half facepiece air-purifying respirators. An APF is not assigned to disposable filtering facepiece respirators. The NRC definition (explanation) of a half-facepiece air-purifying respirator **includes** [3M emphasis] a filtering facepiece respirator if it has two characteristics. In order to be considered a half-facepiece respirator it must:

1. Have seal enhancing rubber or elastomeric material applied to the **entire** face-to-facepiece seal area and
2. An **adjustable** four-point (minimum) suspension strap system (e.g. 3M 8212, 8233, 8293). [NRC emphasis]

Most of these devices have exhalation valves, but an exhalation valve is not as essential design component. Devices that meet these criteria are considered half-facepiece respirators by NRC and have an APF = 10. They are acceptable for use in an NRC-regulated program as long all program requirements (e.g. medical screening, fit-testing, training) are fulfilled.

The other filtering facepiece respirators may be used if they are fit tested to demonstrate a fit factor of at least 100. The qualitative fit test protocols for saccharin and Bitrex™ in the OSHA standard, 29 CFR 1910.134 were designed to demonstrate a fit factor of 100. Thus an APF of 10 may be used for these respirators as well. Although stated differently, this is the same as ANSI Z88.2-1992.

Other Filtering Facepiece Respirators

Other NIOSH-certified filtering facepiece respirators that do not fit NRC's description are referred to as single-use disposable respirators or dust masks in its Regulatory Guide 8.15. Voluntary use of these devices is acceptable to the NRC when no hazard exists and no APF is required. These devices do not have an APF in Appendix A. These devices are permitted for use in a radiological respiratory protection program, but no credit may be taken for their use **unless** [3M emphasis] certain criteria are met. NRC's requirements for respirators used voluntarily are different than the OSHA requirements. As long as no APF is used, licensees are relieved of the requirement to medically screen and fit test the wearers of these devices. A user seal check should be performed in accordance with the manufacturer's instructions, and all other applicable program requirements listed in 10 October 1999

CFR 20.1703 apply. According to the NRC, the devices must be NIOSH-certified and wearers trained in the proper use and limitations of the devices. The information in OSHA's Appendix D to 29 CFR 1910.134 constitutes acceptable training for users of these devices.

In Appendix A to Part 20, voluntary use appears to be viewed as the primary use for these type respirators and no APF is listed. The use of these devices for protection appears to be considered by NRC as a secondary use. This is supported by the placement of the conditions for use with an APF of 10 in the footnotes to Appendix A.

If the licensee wants to use an APF for these devices, the rule permits the use of an APF of 10 if the licensee can demonstrate a fit factor of at least 100 by using a validated or evaluated qualitative or quantitative fit test. If an APF is used for these devices, the requirement for medically screening the user is reinstated. Acceptable protocols for qualitative fit testing can be found in Sections B1-B5 of Appendix A to OSHA's 29 CFR 1910.134. **In other words, these respirators may be used like any other half-facepiece respirators as long as they are treated like all other half-facepiece respirators.**

Respirator Filters

The decision as to whether N-, R-, or P- type filters should be used is left to the licensee. P100 filters are not required to be used on half facepiece respirators, but the NRC has made the APF for air purifying respirators dependent upon the filter efficiency chosen. ANSI Z88.2-1992 APFs for negative pressure respirators are not dependent upon the filter being used. The APF takes into account filter leakage and facesal leakage (see JobHealth Highlights Vol. 16, No. 4; 1998).

For negative-pressure air-purifying respirators with an APF < 100, filters of at least 95% efficiency are required to be used (e.g. N95). For negative-pressure air-purifying respirators with an APF = 100, filters of at least 99% efficiency must be used. A negative-pressure full facepiece respirator with N95 filters has an APF of less than 100 according to the NRC. For positive-pressure air-purifying respirators with an APF > 100, filters of at least 99.97% efficiency are required to be used. Currently, powered air-purifying respirators are only certified with HEPA filters, so this should not be an issue.

The reader is encouraged to read 10 CFR 20, Subpart H and Regulatory Guide 8.15 for more details.