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DRAFT REGULATORY GUIDE DG-8022
(Proposed Revision 1 to Regulatory Guide 8.15)

ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION

A. INTRODUCTION

The proposed revision of Subpart H, "Respiratory Protection and Controls To Restrict Internal Exposure in Restricted Areas," of 10 CFR Part 20, "Standards for Protection Against Radiation," would specify the conditions under which respiratory protection equipment may be used and list the procedural requirements that must be met by a licensee when using respirators to limit intakes of radioactive material and to take credit for the protection assigned to a respirator in limiting and estimating exposures of individuals to airborne radioactive materials. If an ALARA (as low as reasonably achievable) evaluation shows that further exposure reduction is appropriate, and no other practicable means are available to reduce exposure to airborne radioactive materials, respiratory protective equipment may be assigned or its use may be permitted consistent with the intent of the guidance provided in this regulatory guide. This guide describes the elements of a respiratory protection program that is acceptable to the NRC.

Licensees are encouraged to limit the use of respirators to those situations when their use is shown to keep total effective dose equivalent (TEDE) ALARA. Other methods of respiratory protection, such as the use of process or other engineering controls, limitation of exposure times, decontamination and so on, should be considered before the assignment of respirators.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC.

Comments will be most helpful if received by **September 30, 1998**.

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The information collections contained in this draft regulatory guide are covered by the requirements of 10 CFR Part 20, which were approved by the Office of Management and Budget, Approval No. 3150-0014. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

Summary of Regulatory Requirements

It is widely recognized among safety professionals that the use of respiratory protection devices in the workplace can impose physiological and psychological stresses on workers, obstruct their vision, hinder their movements, and make effective communications difficult. These factors increase the risk of physical injury to respirator wearers that, in many cases, far exceeds any potential risk associated with the inhalation of a small quantity of airborne radioactive material. Therefore, in Section 20.1703 the NRC proposes to require a minimum respirator program to control the risks associated with respirator use, even if the licensee does not intend to take credit for the protection provided by the respirators.

In Section 20.1701, process or engineering controls would be required to be used to the extent practicable to control the concentration of radioactive material in air. This suggests that the use of respiratory protection devices should be considered only after other measures to limit intake are exhausted.

Further, Section 20.1702 builds on Section 20.1701 by stating that if process or other engineering controls are judged not practicable, the licensee must increase monitoring and limit intakes by using access controls, limiting exposure times, or using respiratory protection or other (unspecified) controls to keep TEDE ALARA. Guidance for performing ALARA evaluations (that is, determining whether the use of respirators optimizes the sum of internal and external dose) is provided in this regulatory guide.

Licensees who use respiratory protection equipment to limit intakes of radioactive material must follow Section 20.1703. If a respiratory protection device is assigned or permitted to be used, the device is considered by the NRC as being used to limit intakes of airborne radioactive materials unless the device is clearly and exclusively used for protection against nonradiological hazards. Whether or not credit is taken for use of the device to reduce intake and dose, Section 20.1703 would apply whenever respiratory protection devices are used. (See NUREG/CR-6204, "Questions and Answers Based on Revised 10 CFR Part 20"¹ (USNRC, May 1994), page 44, Question 9.) The minimum respiratory protection program expected of any licensee who assigns or permits respirator use is outlined in Section 20.1703.

While the NRC does not regulate the use of respiratory protection devices against nonradiological hazards (except, for example, when fire or a toxic gas release could affect plant conditions), licensees are reminded that the respiratory protection requirements of OSHA apply to most industrial situations and that these requirements are similar in many respects to NRC requirements (see Appendix R to 10 CFR Part 50). The memorandum of understanding (MOU) between NRC and OSHA requires that NRC-identified violations of OSHA regulations that are significant safety concerns must be reported to OSHA.

Section 20.1703 also contains requirements that must be met before a licensee may use an assigned protection factor (APF) to take credit for the use of any respiratory protection device to reduce intake and dose.

According to the proposed Section 20.1704, the NRC may place additional restrictions on licensees' respiratory protection programs that limit exposures to airborne radioactive materials consistent with keeping TEDE ALARA and limiting the use of respiratory protection equipment instead of process and engineering controls.

The proposed Section 20.1705 would specify that a licensee must obtain authorization from the NRC before using assigned protection factors in excess of those specified in Appendix A to 10 CFR Part 20. The required application must describe the need for the higher APF and demonstrate that the proposed equipment provides the higher APF.

¹Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

Additional Information

When a licensee permits or assigns the use of respiratory protection devices, use of such devices should be in accordance with the manufacturer's instructions and should be consistent with the intent of the guidance provided in this regulatory guide, which describes the elements of a respiratory protection program that is acceptable to the NRC. More detailed advice and technical information can be found in NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials,"² which is currently being revised; Revision 1 will be available soon.

C. REGULATORY POSITION

1. ANSI STANDARD Z88.2-1992

The American National Standards Institute standard, ANSI Z88.2-1992, "For Respiratory Protection,"³ contains information that may be used by licensees in respiratory protection programs, with the exceptions noted in this regulatory guide

2. ALARA REQUIREMENT

Section 20.1101(b) states that licensees must use, to the extent practicable, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses that are ALARA.

Section 20.1702 provides that licensees limit intakes by means of engineering controls or procedures, including the use of respirators, consistent with maintaining the total effective dose equivalent ALARA.

The NRC views the TEDE-ALARA requirement as a subset of the general ALARA requirement of 10 CFR 20.1101. That is, the focus should be on programmatic controls. The NRC does not expect or require that each action taken by the licensee be ALARA, nor does the

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³Copies may be obtained from the American National Standards Institute, Inc., 11 West 42nd Street, New York, NY 10036.

NRC require that all doses be ALARA, or that the licensee use all possible ways and means to reduce the TEDE. The NRC does not expect the worker TEDE to be ALARA in all cases. However, each licensee must have an ALARA program that is integrated into the site radiation protection program. Each licensee must track doses and take reasonable measures to maintain worker doses ALARA. The NRC recognizes that, when evaluations are needed to comply with Section 1702, those evaluations (and the factors needed to make them) are not exact science. Assumptions for worker efficiency, stay time hours, estimated intakes, etc., are by their very nature not precisely known. Therefore, when the evaluation results do not show a clear, obvious direction (to use or not use respirators), the NRC expects the licensee to use professional judgment as to whether or not to assign respirators.

2.1 ALARA Evaluation

Licensees who perform analyses to determine whether or not the use of respirators will optimize the sum of internal and external dose and who record these ALARA evaluations in accordance with the following guidance will be considered to be in compliance with the requirements for such evaluations.

2.1.1 The licensee should establish a reasonable threshold value for prospective external deep dose equivalent (DDE) (in rem) for an individual from a task or job *below* which a record of such an evaluation is not needed, and

2.1.2 The licensee should establish a reasonable threshold value for prospective collective external DDE (person-rem) for a task or job *below* which the record of such an evaluation is not needed.

When the licensee plans to use respiratory protection equipment, the licensee does *not* need to record ALARA evaluations for situations in which the projected external DDE dose to any individual or group of individuals is below the thresholds established for both the projected individual external dose (2.1.1 above) and projected collective external dose (2.1.2 above).

The licensee does not need to record ALARA evaluations when the intake is below the threshold if the licensee has established a threshold value for possible intake of radioactive material (as a fraction of ALI or as some number of DAC-hours) for an individual or group of individuals from a task/job *below* which a record of the evaluation is not needed.

Regardless of the magnitude of the projected external dose, the licensee does *not* need to perform or record such evaluations before requiring the use of respiratory protection equipment as a precautionary measure when there is a large uncertainty about the magnitude of the projected concentrations of airborne radioactive material to which the workers will be exposed (e.g., a new job with significant airborne contamination potential, but with no history of previous similar jobs). (See NUREG/CR-6204,¹ Question 60.)

2.2 Findings of ALARA Evaluation

When a specific ALARA evaluation is performed to justify the use or nonuse of respirators, the evaluation should consider the following:

- 2.2.1 Use of process and engineering controls, filtered ventilation systems, and decontamination instead of respiratory protection devices,
- 2.2.2 Control of access, limitation of exposure time, or the use of other types of exposure controls instead of respiratory protection devices, and
- 2.2.3 The estimated benefit. The evaluation should show that the TEDE for the job will be ALARA; that is, the internal dose avoided by using the respiratory protection equipment is likely to be greater than any additional external dose that may result from the use of these devices from respirator-induced inefficiency and other factors.

In performing an ALARA evaluation, when deciding which respirator is to be considered for assignment during a specific task, the licensee should divide the average ambient concentration of radioactive material in work place air (or the estimated average) by the appropriate DAC value for the contaminants present. The number obtained may be considered initially as an ideal minimum APF for the selected device. If the ALARA evaluation determines that use of a respiratory protection device might be justified, a device with this APF or greater should be considered. If selection of a respirator with this APF is inconsistent with ALARA, however, the licensee may select a device with a lower APF. Worker safety factors other than radiological factors should also be taken into account when performing such an ALARA evaluation.

The extent and level of detail addressed in TEDE ALARA evaluations should be commensurate with the potential radiological and physical risks involved in the activity. Consideration should be given to the potential consequences of performing the work or of not performing the work. The following factors should be considered in a respirator-TEDE ALARA evaluation.

- Environmental conditions,
- Protective equipment and clothing, including the respirator, to be required for the activity being evaluated, and their effects on worker efficiency,
- Comfort level of the workers regarding the use of respirators,
- Experience and skill level of the individual with respect to the task,
- Process and engineering controls to be used,
- Specific details of the task to be performed (e.g., dose rates, estimated average airborne concentrations),
- Potential post-activity negative impacts (e.g., personnel decontamination and skin dose assessments, portal monitor alarms).

Such evaluations should be documented in accordance with implementing procedures, but they may either be job-specific or be performed for general job types. Additional details on TEDE ALARA evaluations will be included in NUREG-0041. ALARA evaluations performed for general job types should be reviewed periodically to ensure that none of the assumptions or parameters upon which the evaluation is based have changed. The licensee, however, should be able to support the decision to use or not to use respirators in each circumstance. Supporting information could include the results of surveys, measurements and calculations, previous history with this or similar jobs, or other reasonable methods. The judgment of individuals with extensive knowledge and experience in the field may also be sufficient in circumstances that are not amenable to quantitative analysis.

For ALARA evaluations, a respirator-induced worker inefficiency factor of up to 15% may be used without further justification. Larger worker inefficiency factors may be used, but the licensee should have test data to support them.

2.3 Exceptions to Respirator-ALARA Requirement

The ALARA principle must be applied in a reasonable fashion when making respirator use decisions. The NRC staff recognizes that there may be situations when the dose evaluation clearly indicates that respirators not be used, but the licensee makes a professional decision to use respirators in spite of the evaluation for reasons that are valid but may not be quantifiable (or vice versa). The following paragraphs provide some additional examples of reasonable exceptions to the respirator-ALARA requirement.

When the use or non-use of respirators has no clear impact on TEDE, the licensee should opt to not use respirators in most circumstances. There could be some reasonable exceptions to this, however. For example, respirator use could be considered if a nonradioactive nuisance dust exists in the work area. In these cases, the respirators should be selected to have the least possible impact on worker stress, vision, and ability to communicate.

Other valid exceptions would be certain respiratory protection devices used to reduce heat stress on workers or used as contamination-control devices in high contamination but relatively low airborne radioactivity areas (e.g., the use of airline-supplied hoods for steam generator entries).

Also, a reduction in TEDE for a worker would not be *reasonable* if an attendant increase in the worker's industrial health and safety risk (from a vision limitation or other respirator-related problem) would exceed the benefit to be obtained by reducing the risk associated with the reduction in the TEDE. (See NUREG/CR-6204,¹ Question 387.) This determination is likely to be based on judgment rather than any quantitative comparison.

The NRC is aware of existing State OSHA regulations that *require* an employer to provide a worker with a respirator upon request. Compliance with such State regulations is acceptable to the NRC. (See NUREG/CR-6204,¹ Question 386.)

3. PROCEDURES AND PROGRAMS

3.1 Applicability

Pursuant to the proposed Subpart H of 10 CFR Part 20, a licensee may assign or permit the use of, and take credit for the use of, respiratory protective equipment to limit intakes of airborne radioactive material. Unless the licensee can clearly show otherwise, any use of respirators is considered to be for the purpose of limiting intake of radioactive material.

Therefore, if respirators are assigned or permitted, the licensee's respiratory protection program must include all the requirements contained in Section 20.1703 as a minimum.

3.2 Written Procedures

Section 20.1703 requires that written procedures be in place. These procedures are to address and implement the following respiratory protection program elements:

- Monitoring, including air sampling and bioassays,
- Training of respirator users, including the requirement for each user to inspect and fit check a respirator each time it is donned,
- Fit testing,
- Selecting respirators,
- Breathing air quality,
- Inventory and control of respiratory protection equipment,
- Storage and issuance of respiratory protection equipment,
- Maintenance, repair, testing, and quality assurance of respiratory protection equipment,
- Recordkeeping,
- Limitations on periods of respirator use and relief from respirator use.

Written procedures should also be in place for:

- Performing and documenting the required medical evaluation,
- Supervision of the program, including program audits,
- Training and minimum qualifications of respirator program supervisors and implementing personnel,
- Maintaining TEDE ALARA and performing ALARA evaluations with regard to respiratory protection.

Written procedures should also include a description of the following applications of respirators:

- Routine respirator use (e.g., while engineering controls are being established)
- Nonroutine respirator use (e.g., nonrecurring tasks for which engineering controls are not justified); and
- Emergency respirator use (e.g., recovery of an injured person in an unassessed portion of the restricted area or an area that may become immediately dangerous to life or health (IDLH)).

3.3 Application of Assigned Protection Factors

If the APF of a respirator is greater than the multiple by which average ambient concentration of airborne radioactive material in the workplace exceeds the applicable DAC value, and the licensee's respiratory protection program meets all the requirements of Subpart H, no record of internal exposure (DAC hours) or internal dose (mrem) need be kept, calculated, or retained.

3.4 Surveys

The proposed Paragraphs 20.1703(c)(1) and (2) require a survey program that is adequate to identify potential respiratory hazards, to permit selection of the proper respiratory protection method (not necessarily the assignment of respirators), and to evaluate actual or suspected intakes. Survey programs include (but are not necessarily limited to) surveys for radiation, contamination, airborne radioactive materials, and bioassay measurements.

3.5 Supervisory Requirements

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), specifies minimum training and retraining requirements for each position, and identifies the minimum qualifications for appointment or assignment to these positions. The radiological and nonradiological respiratory protection programs may have different administrators, so long as adequate communication and coordination exist between the programs. [This is an exception to paragraph 4.5.1 of ANSI Z88.2-1992.]

3.6 Inappropriate Uses of Respirators

Using respirators for the following reasons is considered misapplication of these devices.

1. For performing routine tasks or tasks that are accomplished frequently or repetitively, unless unusual circumstances exist. Exposure to airborne contaminants during routine or repetitive tasks should normally be controlled in other ways.

2. For compensation for poor work practices (e.g., to prevent workers from rubbing or touching their faces with contaminated gloves);
3. For eye protection only;
4. For protection from surface contamination in excess of certain levels without additional justification. Consideration should also be given to other factors that would affect the potential for the contamination to become airborne.

4. EQUIPMENT

4.1 NIOSH-Approved Equipment

The National Institute for Occupational Safety and Health (NIOSH) issues approvals for respiratory protection devices. A list of the manufacturers and model numbers of such devices are available from NIOSH.⁴ The NRC requires that only NIOSH-approved equipment be used in a radiological respiratory protection program, unless a variance has been granted as described in 10 CFR 20.1703(b). In addition, the licensee must use, maintain, and store these devices in such a manner that they are not modified and are in like-new condition at the time of issue (see "NIOSH Approval Requirements for Respiratory Protection Equipment," *Radiation Protection Management*, Vol. 14, September/October 1997). A reasonable amount of wear that does not affect performance is acceptable.

According to Section 20.1703(e), the licensee is to provide adequate equipment or material as necessary to supplement respiratory protective equipment to reduce the likelihood that respirator use might contribute to workplace accidents or injury. Examples of such equipment would be spectacle adapters, voice amplification equipment, material or equipment to prevent or reduce fogging of respirator lenses, and body-cooling equipment in environments with high temperature and high humidity.

Other safety or protective equipment used in conjunction with respirators should not interfere with the proper fit or operation of the respirator.

⁴This list is available from Publications Dissemination, DSST, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

4.2 Non-NIOSH-Approved Equipment

If a licensee identifies a need for a respiratory protection device that would adequately provide the needed protection but the device is not NIOSH-approved, is not listed in Appendix A to 10 CFR Part 20, and no comparable NIOSH-approved device exists, the licensee may apply to the NRC to use the nonapproved device (Sections 20.1703(b) and 20.1705). NRC approval is required whether or not APF credit will be used. This application should include an explanation of why no existing NIOSH-approved device meets the licensee's need, and it should include evidence that the material quality and performance characteristics of the proposed device are capable of providing adequate respiratory protection to the wearer under the proposed conditions of use, while not subjecting the wearer to undue physical or psychological stress or undue hazard.

Such test information may be provided by the licensee, the equipment manufacturer, or by a reliable third party. The manufacturer of such a device should have previous experience with the design and manufacture of respiratory protection equipment. The licensee may use such devices under controlled test conditions to develop information for the authorization application. When an authorization for such a device has already been granted to a licensee by the NRC, subsequent applications by additional licensees may make use of test information that was submitted previously. As a minimum for devices that have not yet been authorized for use by the NRC, the licensee should be involved in at least one operational test of the device.

4.3 Inventory, Inspection, and Storage

Respirator facepieces that are routinely available for issue should be visually inspected at least every month. If such devices are stored in clear plastic bags, they should be handled and examined, but need not be removed from the bags for this inspection as long as the licensee can determine that the device is ready for issue. Respirator facepieces (face-sealing types) must be checked for leakage prior to each use (Section 20.1703(c)(3)). A fit check performed by the person being issued the respirator fulfills this requirement.

Equipment used in conjunction with facepiece respirators (e.g., belt- or mask-mounted air regulators, air-supply hoses, portable distribution manifolds, etc.) should be inventoried and functionally tested periodically.

Emergency respiratory protection equipment (SCBA) should be donned and operationally tested frequently (at least quarterly). Other respiratory protection devices designated for

emergency use (e.g., escape-only devices, air-purifying respirators specifically designated for emergency use, such as at the Emergency Operations Center at a commercial power reactor facility) should be removed from any protective bag and thoroughly examined periodically (2-3 times per year).

Repair and replacement parts for respiratory protection devices should be inventoried and inspected periodically as recommended by the manufacturer.

When in storage and not available for use, respirators and component parts of respiratory protection devices should be stored in such a way as to prevent damage to such components and devices. Devices in storage should be inspected prior to being made available for issue.

4.4 Maintenance and Repair

Respirators and component parts of respiratory protection devices should be maintained and repaired only by persons specifically trained to perform this work. Such repairs and maintenance should be accomplished in accordance with the manufacturer's instructions, but in general, training by the device manufacturer is not required. Maintenance and repair of some components of certain devices require manufacturer-certified training (e.g., SCBA regulator, SCBA low-pressure alarm function). These components are specified by the device manufacturer.

Records of all maintenance and repairs should be maintained in a manner consistent with good quality assurance practices. Records of other aspects of the program should be kept in a manner that shows compliance with the requirements of the applicable regulations.

4.5 Control and Issuance

Licensees should maintain positive control over the issuance of respiratory protection devices. Sufficient control should be established and maintained so that persons not authorized to wear such devices are effectively prevented from obtaining them.

4.6 Half-Mask Respirators (APF = 10)

A relatively new variation on the half-mask respirator is referred to variously as a "reusable," "reusable-disposable," or "maintenance-free" device. In these devices, the filter

medium is an integral part of the facepiece and is not replaceable. The four-point suspension straps are adjustable. Also, the face-sealing capabilities are enhanced by the application of plastic, rubber, or a similar elastomeric material to the entire facepiece seal area. (Note that the presence of an exhalation valve does not automatically put a device into this category.) These devices are considered half-masks (APF = 10). They are acceptable to the NRC as long as they are made of high efficiency ($\geq 99\%$) filter media, a fit check can be properly performed by the wearer upon donning, and all other requirements (e.g., fit testing, training) are fulfilled. It is important to follow manufacturer's recommendations and contamination control procedures to establish the length of time such facepieces may be used before being discarded.

The use of quarter-mask respirators (which seal over the bridge of the nose, around the cheeks, and between the point of the chin and the lower lip) is not acceptable to the NRC.

4.7 Single-Use Disposable Respirators (No APF)

Characteristics of single-use disposable respirators are

- Nonadjustable suspension straps
- Relatively thin layer of filter media
- Metal strip near the top intended to be pinch-fitted over the bridge of the wearer's nose
- Packaged 10 or more to a box or bag, rather than individually
- Efficiency of filter medium is $< 99\%$.

While a few respirators of this type may lack one or more of the characteristics listed above, an experienced respirator program administrator should be able to easily distinguish between single-use disposable respirators and those that qualify as half-mask respirators in an NRC-regulated program. [This is an exception to ANSI Z88.2-1992, Table 1. The standard does not differentiate between single-use disposables and half-masks, but allows an APF = 10 to all disposables, quarter- and half-masks.]

Single-use disposable respirators are inexpensive; have little or no impact on worker vision, cardiopulmonary stress, heat stress, and ability to communicate verbally; and they create very little solid radioactive waste. These devices are now permitted for use in a radiological respiratory protection program, but no credit may be taken for their use. Licensees are also relieved of the requirement to medically screen and fit-test the wearers of such devices. Since it is very difficult to effectively perform a standard fit check on these devices prior to use, this requirement does not apply. All other applicable program requirements listed

in 10 CFR 20.1703 apply. Devices must be NIOSH-approved, and wearers must be trained in the proper use and limitations of the devices. The availability of the devices should be controlled so that untrained individuals cannot obtain these devices and so that these devices are not mistakenly substituted for a more protective device in the field.

The proposed rule would permit a licensee to use an APF of 10 for these devices if the licensee can demonstrate a fit factor of at least 100 by using a validated or evaluated, qualitative or quantitative fit test. If the licensee does use an APF of 10, all pertinent requirements in 10 CFR 20.1703 would need to be satisfied. Acceptable protocols for qualitative fit testing can be found in Sections B1 through B5 of Appendix A to OSHA's 1910.134, "Respiratory Protection."

Single-use respirators might be appropriate in situations when a respirator is not necessary but one is requested by a worker. Single-use respirators could limit intakes of nuisance dusts when use of a more protective device cannot be TEDE ALARA-justified. These devices should be discarded each time they are removed, and a new device should be used for subsequent work.

4.8 Respirator Filters

NIOSH has changed the way nonpowered air-purifying respirator filters are certified and designated. Under the old rule (30 CFR Part 11), respirator filters for protection against airborne radionuclides were required to be 99.97% efficient for the collection of 0.3 μm mass median aerodynamic diameter particles, the particles being produced by the vaporization and condensation of dioctyl phthalate (DOP). Filters that meet this criterion are commonly designated high-efficiency particulate air (HEPA) filters. Under the new rule (42 CFR Part 84), filters are divided into three categories based on their performance characteristics when used against oil-containing and non-oil-containing airborne hazards. The categories are N (non-oil-resistant), R (oil-resistant), and P (oil-proof). Within each category, three levels of efficiency are defined: 95 (95% minimum efficiency), 99 (99% minimum efficiency), and 100 (99.97% minimum efficiency). Some examples of filter designations would be N-99, P-95, R-99. The judgment as to whether N, R, or P filters should be used is left to the licensee. For air-purifying respirators operating in the negative-pressure mode, with APF \leq 100, filters of at least 99% efficiency should be used (e.g., N-99).

The National Institute for Occupational Safety and Health (NIOSH) has recently determined that, effective July 10, 1998, particulate filters and respirators approved under 30

CFR Part 11 can no longer be manufactured and shipped as NIOSH/Mine Safety and Health Administration (MSHA) approved items. NIOSH has also taken the position that (1) distributors who have purchased 30 CFR Part 11 particulate filters and respirators prior to July 10, 1998, will be able to sell them as approved until inventories of these products are depleted, and (2) end users who have purchased said particulate filters and respirators from these distributors will be able to use them until their inventories are depleted, or until the shelf life or service life of the product expires.

Filters for powered air-purifying respirators will continue to require that dust-fume-mist HEPA filters be used until NIOSH amends its recommendations.

4.9 Service Life Limitations

If the respirator equipment manufacturer specifies a service life limit on one or more components of a respiratory protection system, the licensee should take whatever action is recommended by the manufacturer. This will ensure that the device continues to operate properly and that the "like-new condition" criterion is maintained as described in Regulatory Position 4.1 of this guide.

4.10 Supplied-Air Suits

One-piece and two-piece supplied-air suits are permitted for use in nuclear industry respiratory protection programs, but no APF is assigned and no protection credit may be taken. NIOSH does not have a method of testing and certifying these suits, but the NRC believes that in certain nuclear industry applications they might be the best overall choice, taking into account respiratory protection, contamination control considerations, heat stress, and ALARA.

Users of supplied-air suits must still be medically approved and trained; the air supplied to the suit must meet the minimum quality requirements specified for other (NIOSH-approved) supplied-air devices; and the equipment must be stored, maintained, and tested (as applicable) in accordance with the manufacturer's recommendations and the licensee's respirator maintenance and quality assurance program.

When selecting such devices for use in a respiratory protection program, the licensee should determine that the material quality and performance characteristics of the proposed device are capable of providing adequate respiratory protection to the wearer under the

proposed conditions of use, while not subjecting the wearer to undue physical or psychological stress or undue hazard.

Such material and performance information may be provided by the licensee, the equipment manufacturer, or by a reliable third party. The manufacturer of such a device should have previous experience with the design and manufacture of respiratory protection equipment. The licensee or applicant may use such devices under controlled circumstances to develop information for the exemption application. When an exemption for such a device has already been granted to a licensee by the NRC, subsequent applications by additional licensees may make use of test information previously submitted. At a minimum, for devices that have not yet been granted an exemption by the NRC, the applicant should be involved in at least one operational test of the device.

4.11 Combination Devices

Some devices are available that combine two respirator types in one unit (e.g., a combination negative-pressure air-purifying and continuous flow airline respirator). When taking credit for use of such a combination device, the licensee must ensure that the proper APF is applied to the exposure time and airborne concentration that exists while the respirator is functioning in each mode of operation.

4.12 Emergency and Escape Equipment

The equipment preferred for emergency entry into an unassessed environment is the open-circuit self-contained breathing apparatus (SCBA) operated in the pressure-demand mode. Also acceptable is the positive-pressure, closed-circuit (recirculating) SCBA.

Other equipment designated for emergency use (e.g., air-purifying devices stored at the Emergency Operations Center at a commercial power reactor facility) must be NIOSH-approved for use against the contaminants that might be encountered during an emergency. Some short-duration SCBAs are approved for escape only, and these may be used for escapes.

5. RESPIRATOR USERS

5.1 Medical Evaluation

According to Section 20.1703(c)(5), the initial medical evaluation to determine a worker's fitness to use respirators must be accomplished prior to respirator fit testing for tight-fitting facepieces, and prior to the first field use for loose-fitting devices. Re-evaluation must be performed either every 12 months thereafter, or at some other frequency established by the determining physician. ANSI Z88.6-1984, "Respirator Use -- Physical Qualifications for Personnel,"² provides guidance that is acceptable to the NRC staff for the physician in determining medical fitness. The screening method may include a medical history questionnaire and spirometry testing. The frequency of re-evaluation may range from every 5 years for workers below age 35, to annually for workers over age 45. A re-screening "grace period" of up to 90 days is considered to be reasonable.

A "hands on" physical examination by a physician is not required. A physician (the "determining physician") should determine which screening tests are appropriate, should set the acceptance criteria for those tests, and should periodically review the implementation of the program. This screening process should be sufficient to identify any persons who should not use respiratory devices for medical reasons.

The medical evaluation program should be carried out by certified, medically trained individuals such as registered nurses (RNs), licensed practical nurses (LPNs), emergency medical technicians (EMTs), or others who, in the judgment of the determining physician, have adequate experience, education, training, and judgment to carry out this program. Potential respirator users who fall outside the range of established acceptance criteria may be examined by the determining physician, who can then make a medical judgment about which types of respirators the individual may or may not wear.

Medical evaluations performed by a physician other than the determining physician may be acceptable as long as comparable screening tests and acceptance criteria are used for individuals screened in this way. The acceptability of these medical evaluations and of the physician performing them will be decided by the determining physician.

The determining physician should be licensed to practice medicine in the United States. The licensee should choose a determining physician with an appropriate specialty (e.g., internal medicine, industrial medicine, family practice).

5.2 Training

A training program, including hands-on training, must be established and implemented for respirator users (Section 20.1703(c)(4)). When face-sealing respirators will be used, this training should take place prior to fit testing. As a minimum, each trainee should:

1. Be informed of the hazard to which the respirator wearer may be exposed, the effects of those contaminants on the wearer if the respirator is not worn properly, and the capabilities and limitations of each device that will be used.
2. Be shown how spectacle adapters, communications equipment, and other equipment that will be used directly in conjunction with the respirator are to be attached and operated properly.
3. Demonstrate competency in donning, using, and removing each type of respiratory protective device that may be used,
4. Be instructed in how to inspect each type of respiratory protective device that may be used, and be instructed to perform such an inspection prior to donning any device,
5. For face-sealing devices, be instructed in how to perform a fit check, and be instructed to perform this fit check each time this type of device is donned,
6. Be informed that each respirator user may leave the work area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communications failure, significant deterioration of operating conditions, or any other condition that might necessitate such relief.

5.3 Fit Testing

A fit testing program is to be implemented for all face-sealing respirators (Section 20.1703(c)(6)), even if they will be used in a positive pressure mode in the field. Quantitative fit-testing (QNFT) is acceptable for testing all such devices. Qualitative fit-testing (QLFT) is acceptable if (1) it is capable of verifying a fit factor of 10 times the APF for facepieces that in the field will operate in the negative pressure mode or (2) it is capable of verifying a fit factor of ≥ 100 (not 100 times the APF) for facepieces that in the field will operate in a positive pressure mode (devices labeled CF, PD, PP, or RP in Appendix A to 10 CFR Part 20). Protocols that can be used for developing QLFT and QNFT procedures may be found in Sections B1 through B5

and in Sections C1 through C3 of Appendix A to OSHA's 29 CFR 1910.134, "Respiratory Protection."

The factor of 10 greater than the APF is considered to be an adequate safety factor. If, for example, a particular QLFT is only sensitive enough to show a fit factor of 500 on a negative-pressure device with APF = 100, a licensee could still allow that device to be used with an APF = 50. Fit-testing should be performed in accordance with an established protocol.⁵ Each time fit-testing is required, only a single satisfactory fit test need be performed.

Retesting does not need to be more frequent than annually, but should be at least every three years. This is an exception to the recommendations found in paragraph 9.1.4 of ANSI Z88.2-1992. A retest "grace period" of up to 90 days is considered reasonable. Many years of fit-test experience in the nuclear industry have convinced the NRC staff that face-fit characteristics do not change dramatically over a 3-year period, except as noted in the next paragraph.

Retesting should be performed before the next respirator use when a potential respirator wearer, since the last fit test, has:

1. A weight change of 10% or more,
2. Significant facial injury or scarring in the area of the facepiece seal,
3. Significant dental changes (e.g., multiple extractions without prosthesis, acquisition of dentures),
4. Reconstructive or cosmetic surgery in the area of the facepiece seal,
5. Any other condition that might change the fit of a face-sealing respirator.

Licensees should take steps to make these retest criteria known to respirator users (e.g., during training and retraining) and should work with site medical or health personnel to identify persons who meet any of the criteria. Adding or revising some questions on a medical screening questionnaire (if used) might be considered. Transient workers may need to be fit tested more often than every three years because the changes listed above are less likely to be apparent to a particular licensee.

Licensees are cautioned that Federal regulations that apply to some nonradiological hazards (e.g., 29 CFR 1910.1001 on asbestos) may require retesting at more frequent intervals, and they may require more than one satisfactory fit-test.

⁵See "Respirator Fit Testing and the Exercise Protocol," *Radiation Protection Management*, Volume 6, September/October 1989.

Fit testing must be accomplished with the facepiece operating in the negative pressure mode, regardless of the mode of operation in which it will be used in the field. Some respirators used for fit testing may need to be modified to accomplish this. While this modification voids the NIOSH approval for the testing device, approval is not required for respirators used during fit testing since occupational exposures are not involved. Filters used during fit testing should be 99.97% efficient, even if only 99%-efficient filters will be used in the work place. The fit test is intended to measure only face to facepiece leakage, so filter efficiency should be as high as possible. The size of the particles that make up the challenge aerosol during fit testing is unimportant. Corn oil, sodium chloride, and ambient dust particles are all acceptable so long as the sensitivity of the detection system meets the previously stated criteria.

If quantitative fit testing is used to test facepieces that will operate in the negative pressure mode in the field, a fit factor of at least 10 times the APF (given in Appendix A to 10 CFR Part 20) should be demonstrated before an individual is permitted to use that facepiece in the field. For combination devices (e.g., a combination negative-pressure air purifying and continuous-flow airline device), the minimum acceptable fit factor is 10 times the APF for the negative pressure mode of operation. If quantitative fit-testing is used to test facepieces that in the field will operate only in the positive pressure mode (e.g., powered air-purifying respirators), in the continuous-flow mode (e.g., air line respirators), or in the pressure demand mode (e.g., air line respirators, SCBA), a fit factor of at least 100 (not 100 times the APF) should be demonstrated with the facepiece operating in the negative pressure mode before an individual is permitted to use that facepiece in the field.

Each person being fit tested should already have been trained in how to properly don and fit-check face-sealing respirators. Therefore, during the test, no person should assist or coach fit test subjects who are not obtaining a satisfactory facepiece seal.

During training or operation, perceptible outward leakage of breathing gas from the face-to-facepiece seal area of any self-contained breathing apparatus is unacceptable, and the wearer should not be permitted to continue to use the device.

If irritant smoke is used as the challenge aerosol during qualitative fit testing, the licensee should take steps to protect the person administering the test from repeated exposures to the irritant smoke. These steps could include using a containment chamber around the head and torso of the fit test subject to contain the smoke, test area ventilation or air filtration, assignment of a respiratory protection device to the person performing the fit testing, or other measures.

5.4 Fit Checks (User Seal Checks)

With the exception of single-use disposable respirators when no credit for protection is allowed and for which the requirement is waived, each respirator wearer must perform at least one type of fit check each time a face-sealing respirator is donned. A fit check is performed immediately prior to exposure to ensure that the respirator is properly seated on the face. Some licensees may require the respirator user to perform such a fit check at the point of respirator issue to ensure that the respirator is in good working order before the worker proceeds to the job site. A fit check is no substitute for a fit test. Acceptable fit checks are a positive-pressure check, negative-pressure check, and checks performed using an irritant or odorous test agent.

5.5 Operational Checks

Non-face-sealing respirators (e.g., airline-supplied hoods) should be operationally checked to ensure proper operation a short time before the wearer enters the radiological environment for which the device is to be used for protection.

6. SAFETY

6.1 Standby Rescue Persons

Section 20.1703(f) would require that, when standby rescue persons cover workers wearing suits and other protective equipment that are difficult to remove without assistance, the standby persons must be equipped with respiratory protection devices appropriate for the potential hazards, must observe or otherwise be in direct communication with such workers, and must be immediately available to assist them in case of a failure of the air supply or any other reason that necessitates relief from distress. A sufficient number of standby rescue persons (not necessarily one-for-one) must be available to effectively assist all users of this type of equipment.

6.2 Face-to-Facepiece Seal Integrity

The prohibition in 10 CFR 20.1703(h) against anything under the control of the respirator user that might interfere with the seal of a respirator includes (but is not necessarily limited to) facial hair of any kind in the seal area (the worker must be clean-shaven), hair from the head that might interfere, cosmetics, spectacle temple bars, protective clothing, and equipment. A respirator wearer should not be required to shave more than once during each 12-hour period.

6.3 Unassessed Environments

For entry into areas where the level of hazard has not been assessed because of the existence of unusual conditions, the licensee must use only SCBA operated in the pressure-demand mode. The use of SCBA to circumvent the pre-exposure sampling requirement is not permitted for nonemergency activities.

6.4 Emergency Escape

For emergency escape from normally safe environments, where a respiratory hazard might develop suddenly, any type of device authorized for use in Appendix A may be used as long as it provides adequate short-term protection against the type of hazard that might be encountered. Single-use disposable respirators would not be appropriate for this application.

6.5 Breathing Air Quality

The quality of the air delivered to atmosphere-supplying respirators must meet the requirements of Grade D air as defined in ANSI/CGA G-7.1-1989, "Commodity Specification for Air,"⁶ as a minimum [10 CFR 20.1703(g)] in order for NIOSH certification to be applicable. The quality of the air should be tested periodically at time intervals that are reasonable under the circumstances and conditions of use. Intake points for breathing air compressors should be located and protected in such a way as to prevent airborne contaminants from being drawn in.

⁶Available from the Compressed Gas Association, Inc., 1235 Jefferson Davis Highway, Arlington, VA 22202.

6.6 Use of Higher Assigned Protection Factors

According to Section 20.1705, applications to the NRC to use higher APFs than those specified in Appendix A to 10 CFR Part 20 should describe the situation for which the higher APFs are needed and should demonstrate that the respiratory protective equipment provides these higher protection factors under the proposed conditions of use. This demonstration should be either through licensee testing or on the basis of reliable test information.

6.7 OSHA Requirements

Licensees are reminded that OSHA regulations, many of which are listed in Appendix A to this guide, may contain requirements for using respiratory protection equipment and for monitoring or controlling workplace hazards that might occur concurrently with airborne radiological hazards. Some hazards to be considered are heat stress, oxygen deficiency, and confined spaces.

6.8 Limiting Duration of Respirator Use

Licensees should establish reasonable limits on the length of time that individuals are required to work while using respirators. The NRC recognizes that such limits will vary considerably and will depend on a variety of factors such as temperature and humidity in the work area and the type of respirator being used. Limits may be based on input from medical personnel and from experienced respirator users. Additional guidance for limiting duration of respirator use will be provided in the revision to NUREG-0041.

7. ANSI Z88.2-1992, EXCEPTIONS

The American National Standards Institute has published a standard, ANSI Z88.2-1992, "For Respiratory Protection." Information contained in this standard may be used by licensees in respiratory protection programs³ with the following exceptions.

7.1 Paragraph 4.5.1

Paragraph 4.5.1 of ANSI Z88.2-1992 states "The responsibility and authority for the respiratory protection program shall be assigned by the employer to a single person." It is acceptable to the NRC staff if the individual who administers the 10 CFR Part 20 Subpart H program is different from the person who administers the industrial respiratory protection program.

7.2 Table 1 -- Assigned Protection Factors

In ANSI Z88.2-1992, Table 1, "Assigned Protection Factors," permits the use of quarter-mask respirators (which seal over the bridge of the nose, around the cheeks, and between the point of the chin and the lower lip). These are not listed in Appendix A and may not be used in an NRC-regulated respiratory protection program.

ANSI also lists various APFs for atmosphere-supplying respirators that operate in the demand mode. The NRC's position is that, since these devices operate in the demand mode, any face-to-facepiece seal leakage will permit contaminants to enter the respiratory inlet covering where they could be inhaled. Since these devices are air-supplied, individuals might perceive them to be more protective than they really are and attempt to use them in situations in which a device with a much higher APF is indicated. This is especially true of demand SCBA. The NRC, therefore, is adopting the APFs recommended by ANSI, but urges licensees to ensure that these devices are not used in areas that are immediately dangerous to life and health (IDLH).

7.3 Paragraph 9.1.4

Paragraph 9.1.4 states "A respirator fit test shall be carried out for each wearer of a tight-fitting respirator at least once every 12 months." The NRC staff's position is that the retest period in a radiological respiratory protection program may be as long as three years, with surveillance of workers as described in Regulatory Position 5.3 of this guide.

7.4 Paragraphs 9.3.1 and 9.3.2

Paragraphs 9.3.1 and 9.3.2 could be interpreted to mean that respirators from several manufacturers, or several different model respirators from the same manufacturer, are required to be available for use. The NRC staff's position is that one model respirator from one manufacturer is adequate, so long as different sizes of that facepiece are available, and adequate fit factors are obtained for greater than 99% of test subjects who are free of facial characteristics that preclude an adequate respirator fit. For those individuals who achieve a fit factor > 100 , but who are unable to achieve a fit factor 10 times the APF, consideration should be given to a positive pressure face sealing device or to a device for which a face seal is not necessary.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants regarding the NRC staff's plans for using this regulatory guide.

This draft guide has been released to encourage public participation in its development. Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, the method to be described in the active guide reflecting public comments will be used in the evaluation of applications for new licenses or license amendments and for evaluating compliance with Subpart H of 10 CFR Part 20.

APPENDIX A
OSHA Regulations

The sections of the OSHA regulations listed below, among others, may contain requirements which are in addition to those required by the NRC. They may also contain requirements for limiting or controlling hazards which are not under the jurisdiction of NRC.

29 CFR 1910.120	Hazardous Waste Operations
29 CFR 1910.134	Respiratory Protection-General Industry
29 CFR 1910.146	Permit Entry Confined Spaces
29 CFR 1910.155	Fire Protection
29 CFR 1910.401	Commercial Diving Operations
29 CFR 1910.1000	Air Contaminants (PELs)
29 CFR 1910.1001	Asbestos
29 CFR 1910.1025	Lead
29 CFR 1910.1028	Benzene
29 CFR 1910.1048	Formaldehyde
29 CFR 1926.103	Respiratory Protection-Construction Industry

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. The draft regulatory analysis, "Regulatory Analysis of Proposed Revisions to 10 CFR Part 20, Subpart H, Respiratory Protection and Controls To Restrict Internal Exposure in Restricted Areas," was prepared for the proposed amendments, and it provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the draft regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC, as Attachment 3 to SECY 98-077.

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