June 30, 1999

MEMORANDUM TO: Joseph A. Murphy, Chairman
Committee To Review Generic Requirements

FROM: Roy P. Zimmerman, Deputy Director "Original Signed by RZimmerman"
Office of Nuclear Reactor Regulation

SUBJECT: REQUEST FOR REVIEW AND ENDORSEMENT OF A FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20," AND REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION" (WITS-9700194)

Enclosed for CRGR review and endorsement is a Commission paper and supporting documents for the subject final rule and regulatory guide revision. The support documents include a Federal Register Notice of final rulemaking, a regulatory analysis, an environmental assessment, congressional letters and a public notice, as well as a copy of a revision of Regulatory Guide 8.15. This final rule accomplishes the following:

- Incorporates consensus national standards on respiratory protection published as ANSI Z-88.2(1992).
- Brings NRC regulations on radiological respiratory protection into conformance with recently published OSHA regulations on generic respiratory protection.
- Removes numerous requirements, including two reports/records, that are redundant, no longer correct or no longer needed.
- Provides a reduction in unnecessary regulatory burden to the nuclear industry, estimated to be 1.5 million dollars per year.

The staff has previously provided copies of all public comments received on the rulemaking, and copies of all office concurrence memos. Section II of the Federal Register Notice provides a discussion of how the staff resolved public comments.

In accordance with the March 26, 1999, E-mail from Raji Tripathi to multiple addressees, "Reg Analysis v. Responses to the CRGR Charter Questions," we are not providing a CRGR Charter Review Package and request the CRGR to rely on the regulatory analysis provided as Attachment 3 of the attached Commission paper.

Attachment: Commission paper

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A. Roecklein, NRR
415-3883

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*See previous concurrence

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#1
6/28

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20," AND REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION."

PURPOSE:

To obtain the Commission's approval to publish a final rule in the Federal Register that amends 10 CFR Part 20. The amendments recognize new respiratory protection devices and procedures that have been proven effective, adopt new recommendations from the American National Standards Institute, reduce licensee burden significantly without reducing worker safety, and are consistent with the Commissions intent to promulgate performance-based rules.

BACKGROUND:

On May 21, 1991 (56 FR 23360), the Nuclear Regulatory Commission (NRC), published a major revision of 10 CFR Part 20 that included a new requirement to maintain the sum of internal and external dose as low as is reasonably achievable (ALARA). This resulted in a significant reduction in the use of respiratory protection. Other than this change, the NRC has not made substantive changes to its regulation for the use of respiratory protection by licensees in several decades. Although, 10 CFR Part 20 was comprehensively revised in 1991, major changes in respiratory protection were not proposed because important consensus standards development was underway by the American National Standards Institute (ANSI) on respiratory protection equipment and procedures. The new guidance, ANSI standard Z88.2-1992, "American National Standard Practice for Respiratory Protection," became available and

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NOTE: To be made publically available when the final SRM is made available

provided the primary technical base for the proposed rulemaking published for public comment in July of 1998.

Eighteen letters of public comment were received on the proposed rule and eight letters of comment on the draft revision of Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." Section II of the attached Federal Register Notice discusses how the public comments were resolved by the NRC staff.

DISCUSSION:

These changes reaffirm the Commission's intent to apply ALARA principles to the sum of external and internal doses and to reduce the use of respirators when their use may cause more risk. The use of process or engineering controls, decontamination of work areas, access control, and other procedures are stressed. The automatic use of respiratory protection devices, which tends to increase worker external dose and stress, would be reduced correspondingly.

The final rule also recognizes new respiratory protection devices that have been proven effective, adopts new Assigned Protection Factors (APFs) based on ANSI determinations, and revises requirements for respiratory protection procedures, such as fit testing, to reflect current industry good practice. The changes are believed by the staff to be a burden reduction that may save NRC licensees an estimated 1.5 million dollars per year. The rule is considerably less prescriptive with no reduction in worker health or safety.

The amendments are described in detail in the attached Federal Register notice (Attachment 1). A summary is provided here.

1. The rule clarifies that a respiratory protection program is required if a licensee issues respiratory protection equipment to limit the intake of radioactive material. Some licensees have misunderstood the intent of the existing rule and believe that a respiratory protection program is needed only if the licensee "takes credit" for the use of respirators in estimating dose.

2. The rule makes extensive changes to Appendix A to 10 CFR Part 20. Appendix A lists the respirator types considered acceptable by the NRC and lists the Assigned Protection Factors (APFs) (i.e., approved measures of respirator effectiveness). The current list is out of date. Some new and effective devices are not recognized in the Appendix and many of the APFs are no longer correct. The major changes to Appendix A, discussed in more detail in the Federal Register notice, are listed here.

   - Several footnotes that contain general programmatic requirements are moved to the body of the rule. Several are deleted because they are considered to be redundant with the NIOSH certification requirement.

   - Several devices, such as single-use disposable and air-supplied suits, are now recognized as being useful in respiratory protection and are listed with no APFs to provide licensees with greater flexibility in selecting respirators when limiting the intake of radioactive material is not the primary concern.

- Several Assigned Protection Factors (APFs) are revised to be consistent with the new ANSI guidance.

3. The rule specifies the "fit factors" that licensees need to achieve in fit tests in order to apply the "assigned protection factors" specified for different types of devices pursuant to ANSI guidance. The rule also specifies the frequency of fit testing. The NRC staff is retaining a requirement for a retest frequency not to exceed 1 year. The proposed rule had specified a retest frequency not to exceed 3 years. Several public commenters had objected to this proposal and recent OSHA regulations retained the one year retest frequency. The NRC staff decided not to change the currently required annual retest.

4. The rule deletes the current requirement for licensees to issue a written policy statement on respiratory protection because the staff believes that all of the essential elements addressed by a policy statement are already addressed in required written licensee procedures. This change results in some burden reduction.

5. The rule deletes a requirement that a licensee notify in writing the director of the NRC Regional Office 30 days before the date that respiratory protection is first used. The only purpose of this notification was to alert inspectors of the need to look at a licensee's respiratory protection program. This requirement contributes little to worker safety. This change results in a minor burden reduction.

The NRC staff believes that the changes to the regulations for the use of respiratory protection constitute an overall burden reduction, result in a set of requirements and guidance documents that are clearer and better organized and thus easier to implement, and when implemented, will make worker protection more effective.

A copy of Revision 1 to Regulatory Guide 8.15, "Acceptable Program for Respiratory Protection" is provided as Attachment 2.

A Regulatory Analysis (Attachment 3) was prepared to evaluate the cost/benefit of the proposed rulemaking. This analysis concludes that a cost reduction for all affected licensees on the order of 1.5 million dollars per year will result from the rule changes. The cost savings are found to result from permitting the use of low-cost disposable masks rather than more expensive half-masks, deleting a requirement to issue a policy statement, and deleting the report to the region on startup of a respiratory program.

An environmental assessment (Attachment 4) was performed and concluded that the amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. This finding is based on the observation that the amendments are focused on technical and procedural improvements in the use of respiratory protection devices and that all of the impacts occur on site with no effect on any places or entities off the licensed site.

Although the net effect of the rule amendments is a reduction in burden, changes in licensee procedures would be required, constituting a backfit. However, because the rule amendments

incorporate national consensus standard (ANSI) recommendations that are worker safety related, the NRC staff believes that this rulemaking is justified as a cost-beneficial safety enhancement.

RESOURCES:

Resources to complete this rulemaking are included in the current budget. No additional resources are required for implementation; in fact, minimal NRC resource savings are expected (<0.5 FTE per fiscal year).

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed this proposed rule for information technology and information management implications and concurs in it. The Office of Information Resources Management has determined that the proposed reduction in information collection requirements is insignificant (250 hours annually) when compared to the overall requirements of the 10 CFR Part 20 (210, 200 hours annually) and that the requirements of the Paperwork Reduction Act are not triggered.

RECOMMENDATION:

That the Commission:

3. Approve the notice of final rulemaking for publication (Attachment 1).

4. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

5. NOTE:

   a. The rulemaking would be published in the Federal Register to become effective 120 days after publication;

   b. A Regulatory Analysis will be available in the Public Document Room (Attachment 3);

   c. An Environmental Assessment and a finding of no significant impact have been prepared (Attachment 4);

   d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act;

   e. The appropriate Congressional committees will be informed (Attachment 5);

f. A press release will be issued (Attachment 6); and

g. Copies of the Federal Register notice of final rulemaking and the Regulatory Guide revision will be distributed to all Commission licensees likely to use respiratory protection and each Agreement State. The notice will be sent to other interested parties upon request.

William D. Travers
Executive Director
for Operations

Attachments:
1. Federal Register Notice
2. Regulatory Guide 8.15
3. Regulatory Analysis
4. Environmental Assessment
5. Congressional Letters
6. SBREFA Letter to GAO
7. Press Release

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f. A press release will be issued (Attachment 6); and

g. Copies of the Federal Register notice of final rulemaking and the Regulatory Guide revision will be distributed to all Commission licensees likely to use respiratory protection and each Agreement State. The notice will be sent to other interested parties upon request.

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Executive Director
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1. Federal Register Notice
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[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-AF81

Respiratory Protection and Controls to Restrict Internal Exposures

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the use of respiratory protection and other controls to restrict intake of radioactive material. The amendments 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), are consistent with recently effective revisions to OSHA's respiratory protection rule, and make NRC requirements for radiological protection less prescriptive without reducing worker protection. The amendments provide greater assurance that worker dose will be maintained as low as is reasonably achievable (ALARA) and that recent technological advances in respiratory protection equipment and procedures are reflected in NRC regulations and clearly approved for use by licensees.

EFFECTIVE DATE: (Insert date 120 days from date of publication in FR).

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-3883; email AKR@nrc.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

The NRC published a major revision of 10 CFR Part 20, "Standards for Protection Against Radiation," on May 21, 1991 (56 FR 23360). Although the NRC was aware that certain provisions of Subpart H and Appendix A to Part 20 were out of date and did not reflect new technology in respiratory devices and procedures, the NRC made minimal changes in the May 21, 1991 final rule. The NRC was aware that an ANSI standard was being prepared that was expected to provide state-of-the-art guidance on acceptable respiratory protection devices and procedures. Therefore, the NRC decided to address further revisions to Subpart H and Appendix A to Part 20 when the ANSI guidance was complete.

In response to public comments on the proposed 10 CFR Part 20, the NRC made several changes to Subpart H in the May 21, 1991, final rule to make it consistent with the new philosophy and science underlying the new Part 20. The new Subpart H required that the practice of ALARA apply to the sum of internal and external dose; addressed correction of both high and low initial intake estimates if subsequent, more accurate measurements gave different results; and clarified that a respiratory protection program consistent with Subpart H is required whenever respirators are used to limit intakes of radioactive material.

After 10 CFR Part 20 was revised, the American National Standards Institute approved publication of ANSI Z88.2-1992, "American National Standard for Respiratory Protection". This

document provides an authoritative consensus on major elements of an acceptable respiratory protection program, including guidance on respirator selection, training, fit testing, and assigned protection factors (APF). The NRC is amending Subpart H of Part 20 to make the regulations less prescriptive without reducing worker protection. This rule is consistent with the 1992 ANSI guidance and is consistent with new regulations on respiratory protection published by the Occupational Safety and Health Administration (OSHA).

## II. Analysis of Public Comments and Staff Response

The proposed rule was published for public comment in the Federal Register July 17, 1998 (63 FR 38511). By mid-November seventeen letters had been received from the public providing comments on the rule. One letter was received from an Agreement State and eight letters provided comments on the draft revision to Regulatory Guide 8.15.

This section discusses the comments received, how the NRC staff was able to incorporate many of the comments into the final rule, and if not, why a comment was not accepted. Numerous suggestions for changes were acceptable to the NRC staff consistent with maintaining a comprehensive set of regulations for the use of respiratory protection against airborne radioactive materials, adequate to assure health and safety of workers at NRC-licensed facilities. Every effort was made to retain the burden reduction provided by the amendments in the proposed rule and to comply with the Commission's intent that regulations be risk informed and performance based. Because many commenters addressed the same issues, this analysis will address all comments but specific commenters will not be identified.

Several commenters suggested endorsing the regulations on respirator use published recently by the Department of Labor, Occupational Safety and Health Administration (OSHA),

29 CFR Parts 1910 and 1926. The proposed NRC regulations were in most respects consistent with those adopted by OSHA. Because OSHA's, as well as NRC's, regulations on respirator use may be applicable to facilities that have both radiological and non-radiological hazards, additional changes have been made to the NRC rule to make it even more consistent with OSHA requirements. However, the suggestion to rely entirely on the published OSHA rules is not possible for the following reasons.

The Atomic Energy Act (AEA) gives the NRC the statutory responsibility to protect public health and safety, which includes worker radiological health and safety, in the use of source, byproduct, and special nuclear materials. The Occupational Safety and Health Act (OSH) Act provides that for working conditions where another Federal agency exercises statutory authority to protect worker health and safety, the OSH Act is inapplicable. Therefore in implementing its statutory authority, the NRC preempts the application of the OSH Act for those working conditions involving radioactive materials.

In 1988, the NRC and OSHA signed a Memorandum of Understanding (MOU) to make jurisdictional responsibilities at NRC licensed facilities clear. Three areas of interest are intended to be regulated by the NRC. These are:

- 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.

The NRC cannot meet its responsibility to protect worker and public radiological safety in these areas without a comprehensive body of regulations to guide inspection and enforcement of essential safety issues specifically addressing radiological hazards.

In addition, the NRC regulation includes the Assigned Protection Factors (APFs) recommended by the American National Standards Institute (ANSI) with some modifications.

Because, in radiological applications, using APFs to generate an estimate of intake of radioactive materials is an acceptable method to demonstrate compliance with NRC dose limits, APFs must be included in the regulation. However, OSHA rules do not specify APFs because this section of the OSHA rules is still under development.

The NRC regulations include dose limitation for radiation exposure with the unique concept of keeping total dose As Low As Is Reasonably Achievable, (ALARA). OSHA does not address radiation hazards and does not include the ALARA concept.

Finally NRC requirements do make it clear that if an NRC licensee is using respiratory protection to protect workers against non-radiological hazards, the OSHA requirements apply. If the NRC has jurisdiction and is responsible for inspection, the MOU specifies that NRC will inform the licensee and OSHA if the NRC observes an unsafe condition relative to non-radiological hazards. For all of these reasons, NRC believes it must have respiratory protection regulations in place, rather than rely on OSHA regulations.

Several commenters suggested endorsing ANSI guidance in the regulations such as ANSI Z88.2-1992, "American National Standard for Respiratory Protection." The ANSI standards are viewed by the NRC staff as comprehensive guidelines that if implemented would contribute to an acceptable program. The NRC staff participated in development of the standards. However, the ANSI standard does not specifically address radiological protection. In addition, the ANSI recommendations for general respirator usage are too prescriptive to be incorporated as regulatory requirements given the Commission's intent to promulgate risk-informed and performance-based rules.

With changes to the proposed rule discussed here, 10 CFR Part 20, Subpart H will be consistent in almost all respects with ANSI guidance. The final Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection", will endorse, with exceptions, ANSI Z88.2, 1992, as providing useful guidance for implementing an acceptable respiratory protection

program. This is considered by the NRC to be consistent with the National Technology Transfer and Advancement Act of 1995.

Several commenters objected to the NRC proposed change that fit tests could be performed every three years, instead of annually, with supervisory attention to any physiological changes that might suggest more frequent tests. The commenters observed that the NRC proposal was inconsistent with ANSI guidance and the OSHA requirement for annual fit testing. The OSHA requirement for annual fit testing is based on several research studies that showed significant numbers of workers failing to maintain an acceptable level of fit after only 1 year. The NRC staff agrees and has retained the requirement for annual fit testing in the final rule.

Several commenters suggested that disposable respirators (filtering facepieces or dust masks) without elastomeric sealing surfaces and adjustable straps, should have an APF equal to 10 listed in Appendix A to be consistent with ANSI. The final rule does not assign an APF to "filtering facepieces" that are not equipped with elastomeric face seals and at least two adjustable straps, unless the licensee can demonstrate a fit factor of at least 100 by use of a quantitative or qualitative, and validated or evaluated fit testing protocol. If the device can be fit tested to demonstrate a fit factor of at least 100 then an APF of 10 may be used. Although stated differently, this is essentially the condition that ANSI would require of disposables. The NRC rule has the benefit of calling attention to the possibility that some devices, such as dust masks, may not retain good fit under conditions of use in the work place. This provision also permits the use of dust masks and other disposables, if requested by a worker, without the requirement to perform medical exams or fit tests. Fit testing is only required if an APF is assigned, or if credit is taken for use of the device in estimating intake or dose, suggesting that the intent is to limit intake of radioactive material.

Three respirator types operating in demand or in demand, recirculating mode were given APFs of 5 in the proposed rule. This was in an effort to discourage their use by mistake

in high concentration areas. ANSI gives these devices APFs equal to 100. Consistent with ANSI and in response to public comment, the NRC staff has changed these APFs to 100. There is little practical difference between a 5 and a 100, and, because a higher fit factor will then be required for their use, workers will not be put at greater risk.

It was suggested that Appendix A could be put into Regulatory Guide 8.15 so that changes could be made more easily as ANSI revised APFs. This suggestion is not accepted by the NRC staff because APFs may be used to generate estimates of dose of record from the intake of radioactive material and as such should be regulatory requirements. Regulatory Guides provide descriptions of acceptable programs, are guidance only, and cannot be enforced. The relative effort required to revise Appendix A as part of 10 CFR Part 20, as compared to revising a Regulatory Guide, is not considered significant by the NRC staff.

Several commenters suggested that the NRC terms and definitions should be consistent with those used by OSHA. The NRC staff agrees. Several OSHA terms and definitions have been added to 10 CFR Part 20 in this final rule and several proposed NRC definitions have been amended to be more consistent with OSHA terms.

A commenter observed that § 20.1703(c)(3) requires that respirators be tested for operability prior to each use but that such tests (user seal checks) are not quantitative and there is no requirement to document the check. It was suggested that this requirement be deleted. The NRC staff does not intend that user seal checks (fit checks) be quantitative nor that they be documented. User seal checks have been required by the NRC since 1979 and are well known to the industry. Licensee training programs describe the procedures and the procedures are subject to periodic licensee and NRC audits. The need to perform a user seal check (fit check) prior to each use is considered an essential safety procedure, consistent with industry practice and ANSI guidance. This requirement is retained.

A commenter stated that § 20.1703(c)(2) requires the use of bioassays during respirator use in order to evaluate actual intakes and that for certain radionuclides, such as W-and Y-class forms of thorium and Y-class forms of uranium, bioassay techniques are relatively insensitive. The NRC staff observes that § 20.1204, "Determination of internal exposure," permits the use of air sampling, bioassays or combinations of these measurements to assess dose from the intake of radioactive materials. The final § 20.1703(c)(2) states that a licensee shall implement and maintain a respiratory protection program that includes surveys and bioassays, as necessary, to evaluate actual intakes. The intent of this provision is to identify elements required to be addressed in the program description. This section does not replace § 20.1204 which permits methods other than bioassay to be used to determine dose from intake.

A commenter observed that under the proposed rule, if a licensee determined that a work situation did not require the use of respirators but a worker requested one, then a respiratory protection program would be required to be in effect. This is true for any respirator that has been assigned an APF in Appendix A. However, the rule now recognizes the use of disposable filtering facepieces (dust masks) without an APF. If no credit is to be taken for their use then program elements such as a medical exam and fit test are not required. Other program elements such as minimal training on the limitations of these devices and correct methods of use would be considered essential.

A comment was made that the final rule should establish the extent to which emergency planning efforts must incorporate the programmatic requirement of 10 CFR 20.1703. 10 CFR Part 20 does not directly address emergency situations but provides programmatic requirements for normal operations. However, § 20.1001 notes that "...nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety." This suggests that in the event of an emergency, such as a major release or spill of radioactive material, conditions would need to be assessed and the need for respiratory protection

determined. Licensees should determine whether or not an emergency situation could reasonably be expected to arise that would require the establishment of a respiratory protection program, and how extensive that program would need to be. For nuclear power plants, § 50.47 (b)(8) requires "adequate ... equipment to support the emergency response." This includes respiratory protection equipment that would be needed in an emergency and a program for its use.

In NUREG-6204, Question and Answers Based on Revised 10 CFR Part 20, a question was posed as to whether the requirements of 10 CFR 20.1703 apply to respiratory protection equipment that is to be used only in emergencies. The NRC staff position is that if the equipment is to be used to limit intakes of radioactive material, this requirement applies. Also, footnote i to the new Appendix A makes it clear that full facepiece, Self-Contained-Breathing-Apparatus (SCBA) operating in pressure demand, or positive pressure recirculating mode may be used as an emergency device in unknown concentrations for protection against inhalation hazards. If a licensee determined that there was sufficient likelihood of an emergency situation, including significant airborne radioactive material, to justify the maintenance of emergency use SCBA, then a program would be necessary to assure the safe use of the equipment should it be needed. The NRC staff believes that any respiratory protection program that meets Part 20 requirements should provide a good basis for respirator use in emergency situations. Further guidance is provided in Regulatory Guide 8.15.

A commenter stated that § 20.1703(b) requires application to the Commission for approval to use respiratory devices not tested or certified by NIOSH. It was suggested that this application would not be necessary if the respirator were used in a situation where no protection factor was needed. The program elements described in § 20.1703 come into effect "...if the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material." The NRC clarified the statement of considerations to help define "limit

intake." In effect, if a licensee determines that respiratory protection is not required to limit intake of radioactive material and a respirator is used for some other reason, then the § 20.1703 conditions are not applicable. However, in this case, other regulations would govern the use of respirators. For example, if a worker requests a respirator, or if the respirator is not used to limit intakes of radioactive material, then OSHA or State requirements would come into play. For example, OSHA requirements for the voluntary use of disposable filtering facepieces (dust masks) would be little more than brief instruction on the limitations of the device and correct methods of use. NRC, as well as OSHA requirements for the use of tight-fitting, half or full-facepiece respirators are more extensive, including medical evaluation.

A suggestion was made that § 20.1703(d) should include instructing a worker that a respirator could be removed in any situation where the user judges that his or her health is at risk due to physical or psychological stress caused by use of the respirator. The NRC staff believes the present language in this section and guidance in Reg. Guide 8.15, is adequate to assure that a worker knows when and how to secure relief from respirator-induced stress.

A commenter requested that provisions be added to allow the use of combination full facepiece, pressure demand, supplied air respirators with auxiliary self-contained air supply for use during emergency entry into an unassessed environment. The NRC staff intends that Appendix A Section III, Combination Respirators, include any devices or combinations of devices as approved by NIOSH in 42 CFR Part 84.70. Regulatory Guide 8.15 provides further guidance on the use of combination respirators. The NRC staff does not believe that any change is needed in the regulation to permit (and continue to allow) the use of these approved devices.

A commenter questioned the statement in footnote d of Appendix A that "...no distinction is made ... between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the face piece (e.g., disposable or reusable

disposable)." The commenter observed that there is no assurance that a filtering facepiece would provide the same degree of protection as a respirator equipped with an elastomeric facepiece. The NRC staff agrees with this statement and has assigned a protection factor of 10 only to devices having elastomeric face sealing properties and two or more adjustable straps. Filtering facepieces not having these design features are the first entry in Appendix A and are not given an APF.

A commenter observed that proposed footnote e would permit the use of filtering facepiece respirators (dust masks) without medical screening or fit testing. The footnote also provides that if a licensee can demonstrate a fit factor of at least 100 using an acceptable fit test protocol, then an APF of 10 can be used. At question is whether the medical screening becomes necessary if the device qualifies for an APF. The waiver of medical screening in the new footnote d is based on the fact that these devices do not impose physiological stress because they are light weight, do not have a tight seal, and do not contribute significantly to breathing resistance. The use of these devices, such as dust masks, is likely to occur in response to a worker's request for a respirator when the licensee has determined that a respirator is not needed. Under these circumstances, the least burdensome design available should be used. If a filtering facepiece device passes a fit test, and is to be used to limit intake, and an APF greater than 1 is used to estimate intake, then a full program is required including medical screening. This requirement is consistent with the recent OSHA regulations.

A suggestion was made that Appendix A could be clearer with more explanatory text in the table, fewer footnotes, and terminology that tracks OSHA. The NRC staff has revised Appendix A to some extent, by spelling out modes of operation and adopting OSHA terminology whenever possible.

A suggestion was made that Appendix A would be less complicated if there was only one column of APF values. The NRC staff agrees and the APF column for air purifying

respirators is now labeled Particulate, and the columns of APFs for atmosphere supplying respirators and combination respirators are now labeled Particulate, Gases, and Vapors.

A commenter observed that footnote a should reference OSHA regulations in addition to 29 CFR 1910. The NRC staff agrees and footnote a in the final rule references Department of Labor regulations. The revised Regulatory Guide 8.15 discusses OSHA regulations and guidance in more detail.

A commenter observed that the NRC-proposed filter efficiency requirements specified in proposed footnote c do not take into account the observation that filter performance is far better in the field than under NIOSH certification testing conditions. The NIOSH tests are conducted at extreme conditions such as high flow rates, the challenge aerosol is selected to be the most penetrating particle size, and long test durations are used. Under field conditions most filters perform at nearly 100 percent efficiency.

Also it is not necessarily most protective to select a high efficiency filter because that results in a higher pressure drop across the filter which could increase breathing resistance and lead to a greater possibility of leakage around the seal as well as increased worker stress. The NRC staff agrees with this comment and final footnote b is changed to specify 95 percent efficiency filters for APFs less than 100, 99 percent efficiency filters for APFs equal to 100, and 99.97 percent efficiency for APFs greater than 100.

A commenter suggested that some language in proposed footnote d be clarified and that the last sentence could be covered in the text of the rule. The NRC staff has revised the first sentence in final footnote f to read, "The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard." The last sentence in proposed footnote d made it clear that some sorbent cartridges have been proven to be effective against airborne gases and vapors and, after NRC staff review and approval on a case-by-case basis, the NRC will continue to permit their use. This

provision clearly modifies information in Appendix A. The NRC staff believes it should remain in the footnotes. With the restructuring of Appendix A, this information is found in new footnotes c and f. More detailed discussion of the criteria for approval of sorbent cartridges against gases and vapors has been added to Regulatory Guide 8.15.

A commentor suggested deleting proposed footnote e because the initial statement to the effect that filtering facepieces may be used without medical screening or fit testing applies to all tight fitting respirators. That is not the case. Fit testing and medical screening are required for any respirator that is assigned a protection factor (APF). Only disposable, filtering facepieces without elastomeric sealing surface and adjustable straps that do not have an APF can be used without medical screening. If the devices are fit tested in order to use an APF, then medical screening would also be required.

This commentor suggested that the caution in the proposed footnote e to the effect that it is difficult to perform positive or negative pressure user seal checks on filtering facepiece respirators is not based on technical information. The statement is based on cumulative experience in the industry and inspection by the NRC staff of a large number of filtering facepiece respirators that do not have elastomeric sealing surfaces and adjustable straps. In most cases, it was very difficult for highly experienced respirator users to effectively perform a user seal check in the negative or positive pressure mode.

A commentor proposed deleting the last sentence in the final footnote i that warns against using SCBA in pressure demand or recirculating positive pressure modes if any outward leakage of breathing gas is perceived. This is an important warning for use of these devices in emergencies or unassessed situations because leakage could significantly reduce the expected duration of the air supply and thus stay time. Premature exhaustion of the air supply could result in serious injury or death of a worker in an IDLH area. This warning appropriately modifies the assigned protection factor for this type of device.

A commentor suggested several revisions to the NRC proposed definitions. Based on several comments the NRC staff has decided to use OSHA definitions for consistency and the OSHA definitions are consistent with the suggestions made by this commentor.

A commentor questioned the use of the words "as necessary" in § 20.1703 (c)(2). The intent of the words "as necessary" is that surveys or bioassays should be included in the program only if a licensee believes that these methods would be needed to determine intake. For example, if air sampling during all procedures indicates that no radioactive material is ever released into the air, then evaluation of actual intakes using bioassay would not be necessary. Section 20.1204, Determination of internal exposure, states that for purposes of determining dose the licensee shall measure concentrations, do bioassay, whole body count, or combinations of these measurements. The purpose of § 20.1703(c)(2) is to identify elements of an acceptable program that may need to be included in the program, not to require performance of bioassay if it is not needed.

A commentor observed that the proposed § 20.1701 stated that "The licensee shall use, to the extent practicable, process or other engineering controls (e.g. containment, decontamination, or ventilation) to control the concentration of radioactive material in air. The word "practicable" is used in place of "practical" as found in the current regulations. The NRC staff agrees with this comment to the effect that "practicable" would require any action that was "possible," whereas "practical" specifies action that would be "useful". The word "practical" is consistent with "reasonable" as found in ALARA, As Low as Is Reasonably Achievable, and the final rule has been changed to retain the word "practical."

A commentor observed that the proposed definition of "fit factor" is a quantitative measure of the fit of a respirator to an individual. The proposed definition of "fit test" is a test, quantitative or qualitative to evaluate the fit of a respirator and to determine the fit factor. The commentor states that a qualitative fit test cannot yield a quantitative fit factor. In fact,

approved qualitative fit test protocols are considered by NIOSH, OSHA, and ANSI to imply minimum quantitative fit factors, usually limited to 100.

However, because the NRC has decided to adopt the OSHA definitions, the final rule defines fit factor as "...a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of substance in ambient air to its concentration inside the respirator when worn." This definition permits use of a challenge medium whose concentration at ambient temperature and pressure can be estimated ($C_1$) and if not detected by the test subject, a maximum concentration inside the mask can be assumed, ($C_2$). The estimated fit factor would then be the ratio $C_1/C_2$. These qualitative fit factors are permitted to be used to determine fit factor, and Reg. Guide 8.15 will provide more detailed guidance on the use of approved protocols.

A commentor suggested that the listing of irritant smoke (hydrogen chloride) as an acceptable challenge agent in a user seal check (fit check), be removed. There is evidence of health risks associated with exposure to this chemical agent, not only to the worker but also to the person performing the test. The NRC staff has decided to keep this option as one of the acceptable user seal checks along with positive and negative pressure check and isoamyl acetate, because both OSHA and ANSI list it. However, the final version of Reg. Guide 8.15 will include a caution regarding excessive exposure to this agent as well as some suggestions for performing user seal checks with irritant smoke so as to minimize exposure.

This commentor pointed out that deleting the words "...or had certification extended" from § 20.1703(a) and § 20.1703(b), is appropriate but that users should be advised that any particulate respirators certified under 30 CFR Part 11 remain certified. The new certification regulations are at 42 CFR Part 84. The NRC staff agrees, and the statement of considerations includes a note to this effect, and Reg. Guide 8.15 discusses certification in more detail.

The commentor questioned the wording in § 20.1703(c)(3) that would exempt respirators with no APFs from user seal checks for tight fitting respirators and functional or operability checks for others such as atmosphere supplied suits. The NRC staff agrees that if a device is capable of being fit checked or operability checked then these checks should be performed each time the device is used whether or not a APF is used. The words "...with APFs..." are removed from § 20.1703(c)(3).

It was observed that § 20.1703(c)(6) does not specify that fit testing measures face seal rather than equipment operation and therefore must always be performed with the facepiece operating in the negative pressure mode. This provision has been changed to be consistent with ANSI. Also, the proposed requirement to fit test any tight-fitting, positive pressure, continuous flow and pressure demand devices to a fit factor $\geq$ 100 is inconsistent with the OSHA specification of 500. This difference could result in workers using different masks depending on whether the respirator was used for protection against radiological or non-radiological hazards. It was further stated that a fit factor of 100 may be too low for full-face tight- fitting masks because it in fact would represent a relatively poor fit. The NRC staff believes that the OSHA recommended fit factor of 500 is not difficult to achieve and provides an additional increment of safety. The final rule reflects this change.

A commentor observed that Appendix A lists a positive pressure (PP) operational mode for some air purifying respirator types. This designation refers to "powered air purifying respirators (PAPR) and should be so designated. The NRC staff agrees and has made this change.

A commentor suggested the use of "intake" or "dose from internal radioactive material," instead of "internal exposures," because there is some confusion regarding the meaning of that term. The NRC staff has reviewed the final rule and, whenever appropriate, more precise terminology has been used as suggested.

A commenter references question number 91 in NUREG/CR-6204, Questions and Answers Based on Revised 10 CFR Part 20, in which the NRC staff stated that the requirements in 10 CFR 20.1703(a) must be met to use respiratory protection whether or not credit is taken for the device. This statement was made before the NRC staff recognized the utility of permitting the use of disposable filtering facepieces (dust-masks) not equipped with elastomeric sealing surfaces and adjustable straps. The NRC continues to require compliance with § 20.1703(a) if respiratory protection is used. However, dust masks and other similar devices can be used, probably on request of a worker, without fit testing or medical screening. These half-face, light-weight devices do not present any significant physiological stresses and are to be used in situations that do not require limiting intake. Therefore, these devices can be removed at any time they become stressful without any harm to the user. Minimal training on the limitations and proper use of the devices would be required.

The commentor observed that the proposed rule would require fit factors that are ten times the APF for the specific negative-pressure air-purifying device, but that the rule does not specify how this fit testing can be accomplished. The NRC staff notes that guidance on fit testing, both quantitative and qualitative protocols, is found in Reg. Guide 8.15.

A commentor states that the term "adequate communication" in § 20.1703(e) may be difficult to demonstrate due to the limited communications options available with some respiratory devices and that "adequate" is subject to interpretation. The NRC staff agrees and intends that this requirement be determined by licensee judgement. Adequate, or "sufficient for a specific requirement," is discussed in Reg. Guide 8.15, and guidance as to what constitutes adequate communication is provided. This is not a new requirement and the NRC staff is not aware of licensees having difficulty with its implementation.

The commentor questioned the requirement in § 20.1703(f) for "direct" communication between the standby rescue person and the worker because it might be necessary for the

standby person to be in a high radiation area or otherwise be exposed to radiation or physiological stress. The NRC staff agrees and has changed this section to require the standby rescue person to "maintain continuous communication" with the workers. Acceptable communication methods are identified as, visual, voice, signal line, telephone, radio, or other suitable means.

The commentor stated that proposed § 20.1703(h) regarding materials or substances that might interfere with the seal of a respirator did not adequately reflect the discussion in the statement of considerations, and that, because the fit test proves the ability to properly maintain a seal, this restriction is not needed. The NRC staff observes that a fit test is not performed every time that a worker uses a respirator. A user seal check might work with some obstruction in the seal area but then break down in the work situation. To better reflect the scope and intent of this provision and to be consistent with OSHA, the NRC staff has added the underlined words as follows: (h) No objects, materials, or substances, such as facial hair, or any other conditions that interfere with the face - facepiece seal or valve function, the presence or absence of which is under the control of the respirator wearer, may be present....

A commentor suggested elimination of the planned revision of NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Material," because the document contains information that is found elsewhere and is redundant. The NRC staff agrees that it would not be useful to repeat information that is found elsewhere and one reason for updating and revising the NUREG is to eliminate and avoid redundancy. The document will be a technical source for NRC licensees setting up or operating respiratory protection programs that will include many references to ANSI, NIOSH, and other documents that describe acceptable programs. Only procedures unique to protection against airborne radioactive material will be addressed in detail if no other sources are available.

The commentor observed that waiving the medical screening requirement for the use of single-use disposable respirators is inconsistent with OSHA. In fact, OSHA waives the medical screening requirement for any voluntary use of filtering facepiece respirators. The assumption is that if a licensee determines that a respirator is not needed (meets ALARA considerations) but a worker requests one, then the least intrusive device should be used, such as a disposable, filtering facepiece with no APF that would be unlikely to expose the worker to physiological stress. The NRC position is consistent with that of OSHA.

Several commentors questioned the use of 15 percent loss of worker efficiency when using a respirator as a recommended, upper bound default value if a licensee is not able to justify a higher value. An EPRI study, for example, showed that loss of worker efficiency did not exceed 7 percent. Other measurements resulted in findings of 25 percent loss of efficiency under conditions requiring respiratory protection. With this range, a recommended default value of not more than 15 percent, as specified in Reg. Guide 8.15 seems reasonable. The guide provides suggestions for determining an efficiency loss factor that would be job and site specific.

A commentor questioned the need to apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine). The commentor stated that the NRC should specify the same APF listed for particulate filters for radioactive gases or vapors with good warning properties. The NRC staff is aware that radionuclides (e.g., airborne radioiodines) have poor to no warning properties. For this reason, the NRC staff intends to continue requiring a specific case approval process with some demonstration of effectiveness before approval for use.

A commentor suggested permitting "a licensed health care professional," in addition to a physician, to determine that a person is medically fit to use a respirator, as is done by OSHA. The established NRC position, as described further in Reg. Guide 8.15, continues to be that a

licensed health care professional can administer a medical exam, but the program must be designed by, and be under the supervision of a physician. The NRC staff is aware that serious injury and death can occur if a person with certain medical conditions is permitted to use a respirator, and is not convinced that the importance of the medical evaluation should be reduced.

A commentor observed that ANSI Z88.2-1992, does not include APFs for SCBA used in the pressure-demand or positive pressure recirculating modes, because some workplace simulation tests showed that up to 5 percent of workers don't achieve protection factors that high. ANSI instead suggests that APFs up to 10,000 should be used only for emergency planning purposes. Footnote a to Appendix A in the NRC regulation makes it clear that the APFs apply only to airborne radiological hazards and not when chemical or other respiratory hazards exist.

A commentor suggested deletion of irritant smoke and isoamyl acetate as example of a user seal check because these are not checks that a user can perform without assistance. The NRC staff agrees but does not preclude the use of assistance in performing a user seal check. It is common for a technician to perform user seal checks on a work crew preparing for entry to a job site requiring respirators. If no assistance is available then clearly positive or negative pressure checks would be the available options.

It was suggested that more guidance be provided on functional check or testing for operability. The NRC staff agrees and Reg. Guide 8.15 will be expanded to provide more guidance on accepted techniques.

It was suggested that more specificity regarding actual procedures be put in the rule or the Reg. Guide and that requirements for addressing non-routine and emergency use of respirators should be added. The NRC staff does not agree because respiratory programs should be site and work specific and the intent of revising the rule was to make it more

performance based. Considerable guidance on acceptable methods exists and is referenced in Reg. Guide 8.15 or NUREG-0041.

A commentor said that NRC should require use of the OSHA medical check questionnaire, or its equivalent. The NRC staff agrees that the OSHA questionnaire is an acceptable way, along with appropriate medical oversight, to medically screen workers to use respirators safely, but that other methods are also acceptable. In the interest of maintaining a performance-based rule, the NRC will rely on review of a licensee's/physician's judgement regarding the best way to qualify workers. The OSHA questionnaire is referenced in Reg. Guide 8.15 for guidance.

It was suggested that provisions for vision, communication, and low temperature protection be made at no cost to the employee. The NRC staff believes that this issue is outside the scope of 10 CFR Part 20 and should be addressed between workers and licensee management.

A commentor suggested adding a definition for "Immediately Dangerous to Life or Health," IDLH. Subpart H of 10 CFR Part 20 provides program requirements for respiratory protection against airborne radioactive material. It would be extremely rare for airborne concentrations of radioactive material to reach IDLH levels. IDLH refers to industrial and toxic chemical hazards that NRC licensees must be alert to in compliance with OSHA regulations. It would be inappropriate for NRC to suggest that airborne radiological condition would require a definition of IDLH. OSHA defines IDLH as "...an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individuals' ability to escape from a dangerous atmosphere."

It was suggested that § 20.1703(f) state that a sufficient number of standby rescue persons must be available to provide effective emergency rescue. The NRC staff agrees and these words have been added.

A commentor observed that the APFs specified by NRC in Appendix A are not in complete agreement with those recommended by ANSI. The difference for disposable filtering facepieces (dust masks) has been discussed. Other differences are minor, do not impose a burden on licensees, and are based on field experiences. The few changes made by the NRC staff are reductions to the APF assigned by ANSI and result in APFs still high enough to accommodate radiological conditions usually encountered. The reduced APFs are more conservative, are based on work place experience, and would result in estimates of intake that could be modified according to § 20.1703(i) by more precise measurements of intake.

Eight comment letters were received regarding the draft Reg. Guide 8.15. All of the suggested changes derived from comments made on proposed Subpart H of 10 CFR Part 20. Reg. Guide 8.15 has been revised based on this analysis of comments submitted on the proposed rule and the changes that have been made to the rule as discussed in this section.

## III. Summary of Changes

This final rule amends § 20.1003, "Definitions", §§ 20.1701 through 20.1704, adds § 20.1705, and amends Appendix A to Part 20.

In § 20.1003, the NRC is adding definitions for Air-purifying respirator, Assigned protection factor (APF), Atmosphere-supplying respirator, Demand respirator, Disposable respirator, Filtering facepiece (dust mask), Fit factor, Fit test, Helmet, Hood, Loose-fitting facepiece, Negative pressure respirator, Positive pressure respirator, Powered air-purifying respirator (PAPR), Pressure demand respirator, Qualitative fit test (QLFT), Quantitative fit test (QNFT), Self-contained breathing apparatus (SCBA), Supplied-air respirator (SAR) or airline respirator, Tight-fitting facepiece and User seal check. These added definitions clarify the new regulations at §§ 20.1701 through 20.1705.

In § 20.1701, the word "decontamination" is added to the list of examples of process or engineering controls that licensees should consider for controlling the concentration of radioactive material in air. The NRC intends that licensees consider decontamination, consistent with maintaining total effective dose equivalent (TEDE) ALARA, to reduce resuspension of radioactive material in the work place as a means of controlling internal dose instead of using respirators.

Section 20.1702 is revised to clarify that if a licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological. A reduction in the TEDE for a worker is not reasonably achievable if, in the licensees' judgement, an attendant increase in the worker's industrial health and safety risk would exceed the benefit obtained by the reduction in the radiation risk. Regulatory Guide 8.15, "Acceptable Programs For Respiratory Protection," and NUREG–0041, "Manual of Respiratory Protection Against Airborne Radioactive Material" address how factors such as heat, discomfort, reduced vision, etc., associated with respirator use, might reduce efficiency or increase stress thereby increasing dose from external sources or health risk. The NRC expects that licensees will exercise judgment in determining how nonradiological factors apply to selecting an appropriate level of respiratory protection. In the proposed rule this amendment would have been accomplished by adding a footnote to paragraph (c). The NRC has instead restructured the section to add similar language to a new subparagraph § 20.1702(b) in the text of the rule to facilitate clarification of this important provision.

Section 20.1703 states the requirements for licensees who use respiratory protection equipment to limit intake of radioactive material. The use of a respirator is, by definition, intended to limit intakes of airborne radioactive materials, unless the device is clearly and exclusively used for protection against non-radiological airborne hazards. Whether or not credit is taken for the device in estimating doses, use of the respiratory protection device to limit

intake of radioactive material and associated physiological stresses to the user activates the requirements of § 20.1703. Thus § 20.1703 defines the minimum respiratory protection program expected of any licensee who assigns or permits the use of respirators to limit intake.

The term "limit intake of radioactive material" is not specifically defined in this rule. The licensee must determine whether the use of a respirator for protection against non-radiological airborne hazards or at the request of a worker also limits the intake of radioactive material. If so a §20.1703 program is required. An acceptable approach is for the licensee to evaluate the existing or potential airborne concentrations of radioactive material (from routine operations, likely operational occurances, and credible emergency conditions) and determine whether a Part 20, Subpart H respiratory program would have been required by the concentration of radioactive material. If the analysis shows that respiratory protection would not have been required in order to limit intake of radioactive material, then compliance with Subpart H would not be required. Respirators used for the express purpose of protection against non-radiological hazards, and that only incidentally limit the intake of radioactive materials that may be present in the air, are not considered to fall under the "limit intake" category. Such respirator use is not regulated by Subpart H provisions.

However, respiratory protection that is used to protect against non-radiological hazards or at the request of a worker invokes OSHA program requirements. The programmatic requirements prescribed by OSHA are commensurate with the degree of hazard present, ranging from a program more prescriptive than Subpart H to brief instruction on safety issues in the case of the voluntary use of "dust masks." Under a Memorandum of Understanding between the NRC and OSHA, the NRC inspection staff is obligated to notify the licensee and OSHA if industrial safety problems are observed.

In § 20.1703(a), the phrase "pursuant to § 20.1702" is removed. This language has been misinterpreted to mean that an approved respiratory protection program is not needed if

respirators are used when concentrations of radioactive material in the air are already below values that define an airborne radioactivity area. Section 20.1703 now makes it clear that, if a licensee uses respiratory protection equipment "to limit intakes," the provisions of § 20.1703 are the minimum applicable requirements.

In final § 20.1703(a), licensees are permitted to use only respirators that have been tested and certified by NIOSH. The words "or had certification extended" are removed because all existing extensions have expired and no new extensions will be granted except for classes of respirators certified under 42 CFR Part 84. (Note: The respiratory certification regulations at 42 CFR Part 84 replaced those previously at 30 CFR Part 11 for air purifying respirators. Devices formerly certified under 30 CFR Part 11 remain certified but newer devices certified under 42 CFR Part 84 have demonstrated improved performance).

In final § 20.1703(b), licensees are permitted to apply for authorization to use equipment that has not been tested or certified by NIOSH. The words "and has not had certification extended by NIOSH/MSHA" have been removed because all existing extensions have expired and no new extensions will be granted except for classes of respirators certified under 42 CFR Part 84. The words "to the NRC" are added to make it clear that applications for authorized use of respiratory equipment must be submitted to the Commission.

In new § 20.1703(c), paragraphs (c)(1) through (5) are retained as presently codified with the exception of some minor editing. Paragraph (c)(4) is reworded to improve clarity, reorder priorities, and bring together in one paragraph all of the elements of the required written procedures. Paragraph (c)(5) is revised to clarify that the worker's medical evaluation for using non-face sealing respirators occurs before first field use, not before first fitting (as required for tight fitting respirators) because fit testing is not needed for these types.

A new § 20.1703(c)(6) is added to require fit testing before first field use of tight-fitting, face sealing respirators and periodically after the first use. This change clarifies when and how

often fit testing is required. The NRC requires that the licensee specify a frequency of retest in the procedures, that may not exceed 1 year (see HPPOS-219 for NRC staff position on testing intervals). The proposed rule would have extended the retest period up to three (3) years. However, public comment and the NRC's intent to be consistent with OSHA requirements, convinced the NRC staff to retain annual fit testing. (See Analysis of Public Comment).

The new § 20.1703(c)(6) also codifies existing NRC staff guidance and ANSI recommendations regarding the test "fit factors" that must be achieved in order to use the APFs. Specifically, fit testing with "fit factors" ≥ 10 times the APF is required for tight fitting, negative pressure devices. A fit factor ≥ 500 is required for all tight fitting face pieces used with positive pressure, continuous flow, and pressure-demand devices. This provision is intended to maintain a sufficient margin of safety to accommodate the greater difficulty in maintaining a good "fit" under field and work conditions as compared to fit test environments. It is important to note that all tightfitting facepieces are to be fit tested in the negative pressure mode regardless of the mode in which they will be used.

Current § 20.1703(a)(4), which required licensees to issue a written policy statement, is removed because the NRC believes that it is not needed. All of the elements that were required to be in the policy statement are already found in Part 20 and in the requirement for licensees to have and implement written procedures (see § 20.1703(c)(4)).

The requirements of § 20.1703(a)(6) have been moved to § 20.1703(e), clarified and expanded to emphasize the existing requirements that provisions be made for vision correction, adequate communications, and low-temperature work environments. A licensee is required to account for the effects of restricted vision and communication limitations as well as the effects of adverse environmental conditions on the equipment and the wearer. The NRC considers the inability of the respirator wearer to read postings, operate equipment and/or instrumentation, or properly identify hazards to be an unacceptable degradation of personnel safety.

A requirement for licensees to consider low-temperature work environments when selecting respiratory protection devices is added in § 20.1703(e). The NRC believes that this requirement is needed because the moisture from exhaled air when temperatures are below freezing could cause the exhalation valve on negative pressure respirators to freeze in the open position. The open valve would provide a pathway for unfiltered air into the respirator inlet covering without the user being aware of the malfunction. Lens fogging that reduces vision in a full facepiece respirator is another problem that can be caused by low temperature.

The reference to skin protection in § 20.1703(a)(6) has been removed. The NRC does not consider skin protection to be an appropriate reason for the use of respirators (with the exception of air supplied suits). Limitation of skin dose is currently dealt with elsewhere in the regulations (§ 20.1201(a)(2)(ii), skin dose limit). It may be inconsistent with ALARA to use tight fitting respirators solely to prevent facial contamination. Other protective measures such as the use of faceshields instead of respirators, or decontamination should be considered.

A new § 20.1703(f) is added to include a requirement for standby rescue persons in the regulatory text. This requirement was previously contained in a footnote in Appendix A to Part 20. This provision retains a requirement for standby rescue persons to be present whenever one-piece atmosphere-supplying suits, or any other combination of supplied air respirator device and protective equipment are used that are difficult for the wearer to take off without assistance. Standby rescue persons would also need to be in continuous communication with the workers, be equipped with appropriate protective clothing and devices, and be immediately available to provide needed assistance if the air supply fails. Without continuous air supply, unconsciousness can occur within seconds to minutes.

A new § 20.1703(g) moves a requirement from a footnote in Appendix A to Part 20, into regulatory text. This paragraph specifies the minimum quality of supplied breathing air, as defined by the Compressed Gas Association (CGA) in their publication G-7.1, "Commodity

Specification for Air," 1997 (ANSI-CGA G-7.1, 1997), that must be provided whenever atmosphere-supplying respirators are used. This change which recognizes the CGA recommendations for air quality, was initiated by NIOSH and endorsed by ANSI. The quantity of air supplied, as a function of air pressure or flow rate, would be specified in the NIOSH approval certificate for each particular device and is not addressed in the rule.

A new § 20.1703(h) is added to clarify and move a requirement from the footnotes of Appendix A into regulatory text. This provision prohibits the use of respirators whenever any objects, materials, or substances such as facial hair, or any other conditions interfere with the seal of the respirator. The intent of this provision is to prevent the presence of facial hair, cosmetics, spectacle earpieces, surgeons caps, and other things from interfering with the respirator seal, exhalation valves, and/or proper operation of the respirator.

Section 20.1703(b)(1) discussed the selection of respiratory protection equipment so that protection factors are adequate to reduce intake. This paragraph permitted selection of less protective devices if that would result in optimizing TEDE. The NRC staff believes that this requirement is redundant with the requirement to be ALARA. These recommendations are removed from the regulation and are now discussed in revised Regulatory Guide 8.15.

The remainder of § 20.1703(b)(1) has been moved to § 20.1703(i) and incorporates the new ANSI terminology for "assigned protection factor". This paragraph retains the provisions for changing intake estimates if later, more accurate measurements show that intake was greater or less than initially estimated.

Section 20.1703(b)(2), specifying procedures for applying to the NRC to use higher APFs, has been moved to § 20.1705.

Section 20.1703(c) is removed because it requires licensees to use only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH, as emergency devices. Because only equipment approved by

NIOSH or NRC can be used in the respiratory protection program pursuant to § 20.1703(a) and (b), this provision is redundant. The revisions of Regulatory Guide 8.15 and NUREG-0041 discuss acceptable types of emergency and escape equipment .

Section 20.1703(d) is removed. This provision required a licensee to notify the director of the appropriate NRC Regional Office in writing at least 30 days before the date that respiratory protection equipment is first used so that the NRC staff could review the licensee program. All licensees who possess radioactive material in a form that requires a respiratory protection program are required to submit a program description during the license application, amendment, or renewal processes. Their programs would be reviewed during this process. A 30–day notification requirement imposes a needless administrative burden on licensees with no increase in worker health and safety. This change is considered to be a burden reduction.

Section 20.1704(a) is revised to clarify that the Commission will use ALARA considerations in any additional restrictions imposed by the Commission on the use of respiratory protection equipment for the purpose of limiting exposures of individuals to airborne radioactive materials.

Appendix A to Part 20 - " Assigned Protection Factors for Respirators," is modified extensively. In general, new devices are recognized, APFs are revised to be consistent with current ANSI guidance and technical knowledge, and the footnotes to Appendix A are moved, deleted, revised, or adjusted so that only those necessary to explain the table remain. Footnotes that are instructive or that facilitate implementation of the rule are being moved to Regulatory Guide 8.15. Several footnotes are considered to be redundant in that they reiterate NIOSH certification criteria to be discussed in NUREG–0041 and are removed. Generic regulatory requirements, previously contained in footnotes in Appendix A, have been moved to the text of Part 20.

The column headed "Tested and Certified Equipment" is removed from the table. The references to Titles 30 and 42 of the CFR currently found in this column apply primarily to respirator manufacturers and are not very useful to NRC licensees. Instruction on how to determine if a respirator is NIOSH approved are provided in the revision to NUREG–0041.

The column headed Gases and Vapors is deleted, and the APFs for Air Purifying respirators are designated "particulate only," while APFs for Atmosphere Supplying and Combination Respirators are designated for "particulate, gases and vapors". This change simplifies Appendix A.

Footnote a to Appendix A is removed because it is redundant with air sampling requirements and requirements for estimating possible airborne concentration addressed in § 20.1703(c)(1) and § 20.1703(i).

Footnote b, which permits the use of devices only when nothing interferes with the seal of a face piece, has been moved to the text of the rule at § 20.1703(h).

Footnote c, proposed footnote b, which defines the symbols for modes of operation, is removed as a result of public comment and operating modes are spelled out in Appendix A.

Footnote d.1 is removed because the essential information regarding the meaning and use of APF is in § 20.1703(i). Further guidance regarding the application and limitation of APFs is provided in the revisions of Regulatory Guide 8.15 and NUREG–0041.

Footnote d.2(a) stated that APFs are only applicable for trained individuals who are properly fitted and for properly maintained respirators. This footnote is redundant because adequate provisions for training, fit-testing, and equipment maintenance are found in the final rule (§ 20.1703(c)(4)).

Footnote d.2(b) stated that APFs are applicable for air-purifying respirators only when high-efficiency particulate filters are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards. This statement is revised and included

in footnote b to say that if using a respirator with an APF less than 100, a filter with a minimum efficiency of 95 percent must be used. Air purifying respirators with APF = 100 must use a filter with an efficiency rating of at least 99 percent. Respirators with APF > 100 must use filters with at least 99.97 percent efficiency. Further guidance is provided in Regulatory Guide 8.15 and NUREG-0041. The definitions of filter types and efficiencies are discussed in the revisions of Regulatory Guide 8.15 and NUREG–0041.

Footnote d.2(c) stated that APFs cannot be used for sorbents against radioactive gases and/or vapors (e.g., radioiodine). This is no longer an absolute prohibition. A provision is made in footnote c for licensees to apply to the Commission for the use of an APF greater than 1 for sorbent cartridges.

Footnote d.2(d) restated part of the NIOSH approval criteria for air quality for supplied air respirators and self-contained breathing apparatus. This requirement is changed to reflect the fact that air quality standards derive from ANSI's recognition of the Compressed Gas Association guidance, and is moved to the text of the rule (§ 20.1703(g)). Air quality is discussed further in Regulatory Guide 8.15 and NUREG-0041.

Footnote e made it clear that the APFs for atmosphere-supplying respirators and self-contained breathing apparatus are not applicable in the case of contaminants that present a skin absorption or submersion hazard. This statement is retained in footnote f in Appendix A to Part 20. However, the current exception provided for tritium oxide requires correction in that the effective protection factor cannot exceed 3, rather than 2 as previously stated. This correction is made to footnote f of Appendix A. This basis for this change is discussed further in revised NUREG-0041.

Footnote f stated that canisters and cartridges for air purifying respirators will not be used beyond service-life limitations. This observation restates a NIOSH approval criterion and

is more appropriate to guidance than to the regulations. This footnote is removed. Service life limitations are addressed in Regulatory Guide 8.15 and NUREG-0041.

Footnote g addressed four issues. The first limits the use of half-mask facepiece air purifying respirators to "under-chin" types only. This limitation is retained in footnote e to the new Appendix A to Part 20. The only type of facepiece eliminated by this requirement is the so-called "quarter-mask" which seals over the bridge of the nose, around the cheeks and between the point of the chin and the lower lip. These devices can exhibit erratic face-sealing characteristics, especially when the wearer talks or moves his/her mouth.

The second issue precluded this type of respirator if ambient airborne concentrations can reach instantaneous values greater than 10 times the pertinent values in Table 1, Column 3 of Appendix B to Part 20. Because respirator assignment is now based on TEDE, ALARA, and other considerations, this part of footnote g is removed from the new footnote e.

The third issue precluded the use of this type of respirator for protection against plutonium or other high-toxicity materials. Half-mask respirators, if properly fitted, maintained, and worn, provide adequate protection if used within the limitations stated in the NIOSH approval and in the rule. The NRC finds no technical or scientific basis for continuing this prohibition in view of current knowledge and it is removed.

Finally this footnote required that this type mask be checked for fit (user seal check) before each use. This provision is removed because § 20.1703(c)(3) requires a user to perform a user seal check (e.g., negative pressure check, positive pressure check, irritant smoke check) each time a respirator is used.

Footnote h provided several conditions on air-flow rates necessary to operate supplied air hoods effectively. Because all of these requirements are elements of the NIOSH approval criteria, they are redundant and are removed. These NIOSH requirements are discussed further in the revision to NUREG-0041.

Footnote i specified that appropriate protection factors be determined for atmosphere-supplying suits based on design and permeability to the contaminant under conditions of use. Conditions for the use of these devices are retained in footnote g to the revision of Appendix A. Guidance on the use of these devices and on determining appropriate protection factors is included in the revision to Regulatory Guide 8.15. Footnote i also required that a standby rescue person equipped with a respirator or other apparatus appropriate for the potential hazards, and communications equipment be present whenever supplied-air suits are used. This requirement is moved to the text of the rule (§ 20.1703(f)).

Footnote j stated that NIOSH approval schedules are not available for atmosphere-supplying suits. This information and criteria for use of atmosphere supplying suits is addressed in footnote g to Appendix A. Note that an APF is not listed for these devices. Licensees may apply to the Commission for the use of higher APFs in accordance with § 20.1703(b).

Footnote k permitted the full facepiece self-contained breathing apparatus (SCBA), when operating in the pressure-demand mode, to be used as an emergency device in unknown concentrations. This provision is retained in footnote i to Appendix A, and full facepiece SCBA operating in positive pressure, recirculating mode is added.

Footnote l required quantitative fit testing with a leakage less than 0.02 percent for the use of full facepiece, positive pressure, recirculating mode SCBA. This requirement is removed from the footnotes and fit test criteria consistent with ANSI guidance are inserted at § 20.1703(c)(6). Fit testing is addressed in the revision to Regulatory Guide 8.15.

Footnote l also stated that perceptible outward leakage of breathing gas from this or any positive pressure SCBA whether open circuit or closed circuit is unacceptable, because service life will be reduced substantially. This provision is retained in footnote i to Appendix A.

Footnote I also required that special training in the use of this type of apparatus be provided to the user. The NRC believes that the training requirement that would be retained at § 20.1703(c)(4) is adequate to assure the training necessary for the use of SCBA devices. This element of footnote I is removed.

Note 1 to Appendix A to Part 20 discussed conditions under which the protection factors in the appendix may be used, warned against assuming that listed devices are effective against chemical or respiratory hazards other than radiological hazards, and stated the need to take into account applicable approvals of the U.S. Bureau of Mines/NIOSH when selecting respirators for nonradiological hazards. Note 1 is retained in footnote a to Appendix A and amended to reference Department of Labor (DOL) regulations. The NRC believes that these conditions are essential to the safe use of respirators and that the DOL regulations also apply when hazards other than radiological respiratory hazards are present.

Note 2 to Appendix A warned that external dose from submersion in high concentrations of radioactive material may result in limitations on occupancy being governed by external dose limits. This note is retained as the second paragraph of footnote a to Appendix A to Part 20.

In the title of Appendix A, and throughout the rule, the term "assigned protection factor" (APF) is used to be consistent with the new ANSI Z88.2-1992 terminology.

Although ANSI suggested an APF = 10 for all half-mask filtering facepiece disposable respirators, disposables that do not have seal-enhancing elastomeric components and are not equipped with two or more adjustable suspension straps are permitted for use but do not have an APF assigned (i.e., no credit may be taken for their use). The NRC believes that without these design features it is difficult to maintain a seal in the workplace. These devices have little physiological impact on the wearer, may be useful in certain situations, and they may accommodate workers who request respiratory protection devices as is required by OSHA. Medical screening is not required for each individual prior to use because the devices impose

very little physiological stress. In addition, fit testing is not required because an APF is not specified (i.e., no credit may be taken for their use). However, all other aspects of an acceptable program specified in § 20.1703 are required including training of users in the use and limitations of the device. The NRC believes that this provision allows the flexible and effective use of these devices without imposing conditions that are burdensome.

However, for those licensees who would like to use the ANSI-recommended APF of 10 for filtering facepiece (dust masks), footnote d to Appendix A permits an APF of 10 to be used if the licensee can demonstrate a fit factor of at least 100 using a validated or evaluated, quantitative or qualitative fit test. This requirement is consistent with ANSI recommendations because fit testing is an explicit component of the ANSI respirator program. The full § 20.1703 program would then be needed including a medical evaluation.

The half-facepiece respirator continues to be approved with an APF = 10, but relatively new variations of this type of device are referred to in the industry as "reusable," "reusable-disposable," "filtering facepiece" or "maintenance-free" devices. In these devices, including those considered to be disposables, the filter medium may be an integral part of the facepiece, is at least 95 percent efficient, and may not be replaceable. Also, the seal area is enhanced by the application of plastic or rubber to the face-to-facepiece seal area and the 2 or more suspension straps are adjustable. These devices are acceptable to the NRC, are considered half facepieces, may be disposable, and are given an APF = 10, consistent with ANSI recommendations. Individual workers must achieve a fit factor of at least 100 to use the APF of 10.

The APF for full facepiece air purifying respirators operating in the negative pressure mode is increased from 50 to 100. This change is consistent with ANSI recommendations based on review of industry test results. Appendix A previously listed a protection factor of 50

because one design that was tested at Los Alamos in 1975 did not meet the protection factor criterion of 100. This device is no longer available.

A fit factor of 10 times the APF for tight fitting, negative-pressure air-purifying respirators, which must be obtained as a result of required fit testing under § 20.1703(c)(6), is recommended by ANSI and is required under the new rule. A person would have to achieve a minimum of 1,000 on a fit test in order to use an APF of 100 in the field. Requiring a fit factor of 10 times the APF for negative pressure devices effectively limits intake and protects against any respirator leakage that might occur during workplace activities. A fit factor ≥ 500 is required for any positive pressure, continuous flow and pressure demand device. The proposed rule had stated a fit factor of 100. However, public comment suggested this number was too low, and OSHA rules also require 500.

A new category of respirator, the loose-fitting facepiece, positive pressure (powered) air purifying type, is included in Appendix A to Part 20. An APF of 25 is assigned to this new device in accordance with ANSI Z88.2-1992.

The half facepiece and the full facepiece air-line respirators operating in demand mode were listed in the proposed rule with APFs unchanged at 5. In order to be consistent with ANSI and with public comment, the APFs for these two devices have been changed. The new APF for the half facepiece is 10, and the APF for the full facepiece is 100. The NRC believes that supplied-air respirators operating in the demand mode should be used with great care in nuclear applications. Because they are very similar in appearance to more highly effective devices (continuous flow and pressure-demand supplied air respirators), they might mistakenly be used instead of the more protective devices.

The APFs for half-and full-facepiece air-line respirators operating on continuous flow are reduced from 1,000 to 50 and from 2,000 to 1,000 respectively. The APF for a full facepiece air-line respirator operating in pressure-demand mode is reduced from 2,000 to 1,000. These

changes are based on ANSI recommendations and the results of field and laboratory experiences indicating that these devices are not as effective as originally thought. This change is expected to have little impact on licensees because typical workplace concentrations encountered are far less than 1000 times the derived air concentrations (DACs). However, licensees may apply for higher APFs if needed and justified. A half-mask air-line respirator operating in pressure-demand mode is added to Appendix A with an APF of 50 based on ANSI recommendations. The helmet/hood air-line respirator operating under continuous flow is retained with the APF listed as 1,000. Footnote h which specified NIOSH certification criteria for flow rates is removed. The criteria for air flow rates are part of the NIOSH approval and are addressed in the revision to NUREG-0041.

The new loose-fitting facepiece design is also included as an air-line respirator operating under continuous flow. This device is assigned an APF of 25 in Appendix A consistent with ANSI recommendations.

The air-line atmosphere-supplied suit is not assigned an APF. These devices have been used with no APF for many years in radiological environments, such as control rod drive removal at boiling water reactors. These devices are primarily used as contamination control devices, but they are supplied with breathing air. No worker safety problems are known to have occurred at nuclear power plants or other NRC licensees that would disallow use of these devices. The NRC is allowing the use of non-NIOSH-approved suits but wearers are required to meet all other respirator program requirements in § 20.1703 except the need for a fit test. Licensees have an option to apply to the Commission for higher APFs for these devices in accordance with § 20.1703(b). Requirements for standby rescue persons apply to operations where these devices are used (§ 20.1703(f)).

In Appendix A to Part 20, APFs for SCBA devices remain unchanged except for those operating in demand or demand recirculating modes. APFs for these two devices have been

changed from 5 to 100 to be consistent with ANSI and in response to public comment. Use of SCBA in demand open circuit and demand recirculating mode requires considerable caution. In the NRC's view, the performance level and reliability of these devices in the demand mode is questionable. The chance of facepiece leakage when operating in the negative pressure mode is considerably higher than when operating in a positive pressure mode. This is especially critical for devices that could be mistakenly used in immediately dangerous to life and health (IDLH) areas during emergency situations. Although ANSI lists relatively high APFs for these devices, they are not recommended by the NRC for use and acceptable alternative devices are readily available. Footnote h requires that controls be implemented to assure that these devices are not used in IDLH areas.

A specific statement is added in footnote f, to exclude radioactive noble gases from consideration as an inhalation hazard and advising that external (submersion) dose considerations should be the basis for protective actions. DAC values are listed for each noble gas isotope. This has led some licensees to inappropriately base respirator assignments in whole or in part on the presence of these gases. The requirement for monitoring external dose can be found in 10 CFR 20.1502.

## IV. Issue of Compatibility for Agreement States

In accordance with the Policy Statement on Adequacy and Compatibility of Agreement State Programs published September 3, 1997 (62 FR 46517) and implementing procedures, the modifications to § 20.1701 through § 20.1703 (except 20.1703(c)(4)), have health and safety significance and Agreement States should adopt the essential objectives of these rule modifications. Therefore, these provisions are assigned to the "Health and Safety (H&S)" category. The definitions (added to § 20.1003), of Air Purifying respirator, Atmosphere-

supplying respirator, Assigned Protection Factor (APF), Demand respirator, Disposable respirator, Fit factor, Fit test, Filtering facepiece (dust mask), Helmet, Hood, Loose-fitting facepiece, Negative pressure respirator, Positive pressure respirator, Powered air-purifying respirator, Pressure demand respirator, Qualitative fit test, Quantitative fit test, Self-contained breathing apparatus, Supplied-air respirator, Tight-fitting facepiece, and User seal check (fit check), because of their precise operational meanings, are designated as compatibility category B to help insure effective communication and to promote a common understanding for licensees who operate in multiple jurisdictions. Therefore, Agreement States should adopt definitions that are essentially identical to those of NRC.

§ 20.1703(c)(4) and § 20.1704, which address requirements for written procedures, and imposition of additional restrictions on the use of respiratory protection, respectively, are designated as compatibility category D.

Appendix A to 10 CFR Part 20, and § 20.1705 which permits applying for the use of higher APFs on a case by case basis, are designated as compatibility category B. Consistency is required in APFs that are established as acceptable in NRC and Agreement State regulations to reduce impacts on licensees who may operate in multiple jurisdictions.

## V. Finding of No Significant Environmental Impact: Availability

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments are not a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

The amendments make technical and procedural improvements in the use of respiratory protection devices to maintain total occupational dose as low as is reasonably achievable.

None of the impacts associated with this rulemaking have any effect on any places or entities outside of a licensed site. An effect of this rulemaking is expected to be a decrease in the use of respiratory devices and an increase in engineering and other controls to reduce airborne contaminants. It is expected that there would be no change in radiation dose to any member of the public as a result of the revised regulation.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. Therefore, in accord with its commitment to complying with Executive Order 12898 - Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994, in all its actions, the NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. The NRC uses the following working definition of "environmental justice": the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.

The NRC requested public comments and the views of the States on the environmental assessment for this rule. No comments were received that addressed changes to the environmental assessment.

The environmental assessment is available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

## VI. Paperwork Reduction Act Statement

This final rule decreases the burden on licensees by eliminating reporting requirements in § 20.1703(a)(4) and (d). The burden reduction for this information collection is estimated to be 250 hours annually. Because the burden reduction for this information collection is

insignificant, compared to the overall burden of 10 CFR Part 20, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-0014.

## VII. Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

## VIII. Regulatory Analysis

The NRC has prepared a regulatory analysis for the amendments. The analysis examines the benefits and impacts considered by the NRC. The regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC.

## IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that, this rule will not have a significant economic impact on a substantial number of small entities. The anticipated impact of the changes will not be significant because the revised regulation basically represents a continuation of current practice. The benefit of the rule is that it provides relief from certain reporting and recordkeeping requirements, incorporates several

ANSI recommendations for improved programmatic procedures, and permits the use of new, effective respiratory devices, thus increasing licensee flexibility.

## X. Backfit Analysis

Although the NRC staff has concluded that some of the changes being made constitute a reduction in burden, the implementation of these and other changes will require revisions to licensee procedures constituting a backfit under 10 CFR §§ 50.109(a)(1), 72.62(a)(2), and 76.76(a)(1). However, because the rule incorporates national consensus standard (ANSI) recommendations that are worker safety related, the NRC staff believes that this rule constitutes a substantial increase in the overall protection of public health and safety that is cost justified.

The Regulatory Analysis that was prepared for this rule concluded that the rule would result in a net benefit to industry of about $1.5 million dollars per year, including the cost of revising procedures. The largest savings result from eliminating the need for a written policy statement and permitting the use of disposable, filtering facepieces instead of more expensive respirators. For most of the other changes made in this final rule, the costs of implementing the change are equal to the estimated cost savings.

Section III in this FR Notice, Summary of Changes, summarizes the changes to Subpart H of 10 CFR Part 20. The reasons for making these changes are also provided. Many of the changes are considered by the NRC to constitute a substantial worker safety enhancement in that they reflect new consensus technical guidance published by the American National Standards Institute (ANSI) on respiratory protection developed since 10 CFR Part 20, Subpart H was published. The changes include recognizing new respirator designs and types that were not available 20 years ago, changing the assigned protection factors (APFs) based on

new data, deleting certain reporting requirements which are considered no longer needed for oversight of a mature industry, and numerous procedural improvements that have been developed and proven by respiratory practitioners.

Permitting the use of disposable, filtering facepieces, for example, accommodates workers who voluntarily use respiratory protection when it is not needed. These devices provide some respiratory protection, do not impose stress or breathing resistance on workers as do more cumbersome designs, and when credit is not being taken for their use, do not require medical screening or fit testing.

Current NRC regulations list APFs that are inconsistent with current national consensus standards. APFs are used to select types of respirators to provide needed degree of protection, and to estimate the intake and internal dose workers might receive. The new, and correct, APFs will provide a substantial increase in worker protection.

Deleting two paperwork requirements that are no longer considered useful or needed will permit resources to be redirected to more important safety matters.

Incorporation of the ANSI fit test criteria provides a needed safety margin that protects against deteriorating conditions in the workplace that effect facepiece seal.

The rule also leads to greater uniformity of practice in that the new requirements are consistent with the general respiratory protection regulations published recently by OSHA. NRC licensees are often subject to OSHA respiratory protection regulations when the intent is to protect workers against non-radiological inhalation hazards. 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.

In addition the new rules provide greater flexibility in practice in that several new devices are now approved for use. Numerous prescriptive requirements are deleted because they are redundant or no longer needed. The Assigned Protection Factors currently in Appendix A of 10 CFR Part 20 are incorrect; some are too conservative and others might underprotect the worker. This rule corrects the APFs in the NRC regulations according to the national consensus standard recommendations of ANSI.

In conclusion, the Commission believes that for quantitative and qualitative reasons, this rule change constitutes a burden reduction and a substantial increase in the overall protection of public (worker) health and safety that is cost justified.

## XI. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

## XII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule the NRC is using the following voluntary consensus standard, "American National Standard for Respiratory Protection," (ANSI Z88.2), American National Standards Institute, 1992.

List of Subjects in 10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recording requirements, Special nuclear material, Source material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 20.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (U.S.C. 5841, 5842, 5846).

2. Section 20.1003 is amended by adding the definitions Air-purifying respirator, Assigned protection factor (APF), Atmosphere-supplying respirator, Demand respirator, Disposable respirator, Filtering facepiece (dust mask), Fit factor, Fit test, Helmet, Hood, Loose-fitting facepiece, Negative pressure respirator, Positive pressure respirator, Powered air-purifying respirator (PAPR), Pressure demand respirator, Qualitative fit test (QLFT), Quantitative fit test (QNFT), Self-contained breathing apparatus (SCBA), Supplied-air respirator

(SAR) or airline respirator, Tight-fitting facepiece and User seal check (in alphabetical order) to read as follows:

§ 20.1003 Definitions.

* * * * *

*Air-purifying respirator* means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element. * * * * *

*Assigned protection factor* (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

*Atmosphere-supplying respirator* means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

* * * * *

*Demand respirator* means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

* * * * *

*Disposable respirator* means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

* * * * *

*Filtering facepiece (dust mask)* means 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, not equipped with elastomeric sealing surfaces and adjustable straps.

*Fit factor* means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

*Fit test* means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

* * * * *

*Helmet* means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

* * * * *

*Hood* means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

* * * * *

*Loose-fitting facepiece* means a respiratory inlet covering that is designed to form a partial seal with the face.

* * * * *

*Negative pressure respirator (tight fitting)* means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

* * * * *

*Positive pressure respirator* means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

*Powered air-purifying respirator (PAPR)* means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

*Pressure demand respirator* means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

* * * * *

*Qualitative fit test (QLFT)* means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

* * * * *

*Quantitative fit test (QNFT)* means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

* * * * *

*Self-contained breathing apparatus (SCBA)* means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

* * * * *

*Supplied-air respirator (SAR) or airline respirator* means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

* * * * *

*Tight-fitting facepiece* means a respiratory inlet covering that forms a complete seal with the face.

* * * * *

*User seal check (fit check)* means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

* * * * *

3. Section 20.1701 is revised to read as follows:

§ 20.1701 Use of process or other engineering controls.

The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

4. Section 20.1702, is revised to read as follows:

§ 20.1702 Use of other controls.

(a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means --

(1) Control of access;

(2) Limitation of exposure times;

(3) Use of respiratory protection equipment; or

(4) Other controls.

(b) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

5. Section 20.1703 is revised to read as follows:

§ 20.1703 Use of individual respiratory protection equipment.

If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material,

(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this part.

(b) If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the NRC for authorized use of this equipment except as provided in this part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) Surveys and bioassays, as necessary, to evaluate actual intakes;

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(4) Written procedures regarding

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician that the individual user is medically fit to use respiratory protection equipment; before

(i) The initial fitting of face sealing respirator;

(ii) Before the first field use of non-face sealing respirators, and

(iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

(6) Fit testing, with fit factor ≥ 10 times the APF for negative pressure devices, and a fit factor ≥ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(d) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(e) The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(f) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(g) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association and endorsed by ANSI, in publication G-7.1, "Commodity Specification for Air," 1997, (ANSI-CGA G-7.1, 1997).

(h) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face - facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(i) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

6. Section 20.1704 is revised to read as follows:

§ 20.1704 Further restrictions on the use of respiratory protection equipment.

The Commission may impose restrictions in addition to the provisions of §§ 20.1702, 20.1703, and Appendix A to Part 20, in order to:

(a) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(b) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

7. Section 20.1705 is added as follows:

§ 20.1705 Application for use of higher assigned protection factors.

The licensee shall obtain authorization from the Commission before using assigned protection factors in excess of those specified in Appendix A to Part 20. The Commission may authorize a licensee to use higher assigned protection factors on receipt of an application that -

(a) Describes the situation for which a need exists for higher protection factors; and

(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

8. Appendix A to Part 20 is revised to read as follows:

## APPENDIX A TO PART 20

## ASSIGNED PROTECTION FACTORS FOR RESPIRATORS[a]

| | Operating Mode | Assigned Protection Factors |
|---|---|---|
| I. AIR PURIFYING RESPIRATORS [particulate[b] only][c] | | |
| Filtering facepiece disposable[d] | Negative Pressure | (d) |
| Facepiece, half[e] | Negative Pressure | 10 |
| Facepiece, full | Negative Pressure | 100 |
| Facepiece, half | Powered air-purifying respirators | 50 |
| Facepiece, full | Powered air-purifying respirators | 1000 |
| Helmet/hood | Powered air-purifying respirators | 1000 |
| Facepiece, loose-fitting | Powered air-purifying respirators | 25 |
| II. ATMOSPHERE SUPPLYING RESPIRATORS [particulate, gases and vapors[f]] | | |
| 1. Air-line respirator | | |
| Facepiece, half | Demand | 10 |
| Facepiece, half | Continuous Flow | 50 |
| Facepiece, half | Pressure Demand | 50 |
| Facepiece, full | Demand | 100 |
| Facepiece, full | Continuous Flow | 1000 |
| Facepiece, full | Pressure Demand | 1000 |
| Helmet/hood | Continuous Flow | 1000 |
| Facepiece, loose-fitting | Continuous Flow | 25 |
| Suit | Continuous Flow | (g) |
| 2. Self-contained breathing Apparatus (SCBA) | | |
| Facepiece, full | Demand | 100[h] |
| Facepiece, full | Pressure Demand | 10,000[i] |
| Facepiece, full | Demand, Recirculating | 100[h] |
| Facepiece, full | Positive Pressure Recirculating | 10,000[i] |
| III. COMBINATION RESPIRATORS Any combination of air-purifying and atmosphere-supplying respirators | Assigned protection factor for type and mode of operation as listed above | |

a. These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to Part 20 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

b. Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs > 100 must be equipped with particulate filters that are at least 99.97 percent efficient.

c. The licensee may apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

d. Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in § 20.1703 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

e. Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.

f. The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

g. No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., § 20.1703).

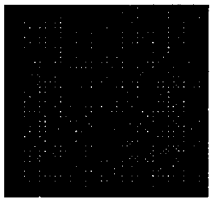
h. The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

i. This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

Dated at Rockville, Maryland this __ day of _____, 1999.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.



U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE

June 1999
Division 8
Revision 1

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# REGULATORY GUIDE 8.15

**(Draft was issued as DG-8022)**

# ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION

## A. INTRODUCTION

The 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," specifies the conditions under which respiratory protection equipment may be used and lists 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 practical 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 in this regulatory guide. This regulatory guide describes a respiratory protection program that is acceptable to the NRC staff.

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 protection against airborne radioactive material, 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.

The information collections contained in this 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 10 CFR 20.1703 the NRC requires 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 estimating intakes.

In 10 CFR 20.1701, process or engineering controls must to be used to the extent practical to control the concentration of radioactive material in air. The use of respiratory protection devices should be contemplated only after other measures to limit intake are considered.

Section 10 CFR 20.1702 builds on 10 CFR 20.1701 and states that if process or other engineering controls are judged not practical, the licensee must increase monitoring and limit intakes by using access controls, limiting exposure times, using respiratory protection devices, or by employing 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 and other risks) is provided in this regulatory guide.

If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, the requirements stated in 10 CFR 20.1703 must be followed. A 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 non-radiological hazards. Whether or not credit is taken for use of the device to reduce intake and dose, 10 CFR 20.1703 would apply whenever respiratory protection devices are used.[1] The minimum respiratory protection program expected of any licensee who assigns or permits respirator use is outlined in 10 CFR 20.1703. Part 20 and this regulatory guide describe an exception for voluntary use of one type of filtering facepiece respirator when no APF is applied.

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 are in 10 CFR 20.1703.

According to 10 CFR 20.1704, the NRC may place additional restrictions on licensees' respiratory protection programs that might further limit exposures to airborne radioactive materials consistent with keeping TEDE ALARA and limiting the use of respiratory protection equipment instead of using process and engineering controls.

Also, 10 CFR 20.1705 specifies that a licensee must obtain authorization from the NRC before using APFs 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.

## Applicability of OSHA's Respiratory Protection Rules

The Atomic Energy Act (AEA) gives the NRC the statutory responsibility to protect public health and safety, which includes worker health and safety, in the use of source, byproduct, and special nuclear materials. The Occupational Safety and Health (OSH) Act provides that for working conditions where another Federal agency exercises statutory authority to protect worker health and safety, the OSH Act is inapplicable. Therefore in implementing its statutory authority, the NRC preempts the application of the OSH Act for those working conditions involving radioactive materials.

In 1988, the NRC and OSHA signed a Memorandum of Understanding (MOU) to make jurisdictional responsibilities at NRC licensed facilities clear. NRC is responsible for three areas

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[1] See NUREG/CR-6204, "Questions and Answers Based on Revised 10 CFR Part 20," (USNRC, May 1994), page 44, Question 91. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-1800); 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.

of interest.

- 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.

The MOU makes it clear that if an NRC licensee is using respiratory protection to protect workers against non-radiological hazards, the OSHA requirements apply. If the NRC has jurisdiction and is responsible for inspection, the MOU specifies that NRC will inform the licensee and OSHA if the NRC observes an unsafe condition relative to non-radiological hazards. In general, the NRC's revised rules are such that if a licensee is in compliance with the NRC regulations in Subpart H, the licensee is considered to be in compliance with the corresponding and comparable OSHA regulations on respiratory protection.

**Additional Information**

When a licensee permits or assigns the use of respiratory protection devices, such devices should be used in accordance with the manufacturer's instructions. Respiratory protection devices should also be used consistent with the intent of the guidance 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]

[2] 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.

## REGULATORY POSITION
## INDEX

## C. REGULATORY POSITION

### 1. ANSI STANDARD Z88.2-1992 AND EXCEPTIONS

The American National Standards Institute has published ANSI Z88.2-1992, "American National Standard For Respiratory Protection." Information contained in this standard may be used by licensees in respiratory protection program[3] with the following exceptions.

#### 1.1 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 Subpart H of 10 CFR Part 20 program is different from the person who administers the industrial respiratory protection program.

#### 1.2 Table 1 — Assigned Protection Factors

In ANSI Z88.2-1992, Table 1, "Assigned Protection Factors," permits the use of quarter-facepiece 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 APFs for air-purifying respirators and for atmosphere-supplying respirators. With the minor exception of those filtering facepiece respirators that do not qualify as half facepieces in NRC's view, the APFs listed in Appendix A to 10 CFR Part 20 now match the ANSI-recommended APFs.

Licensees are cautioned regarding the use of supplied air respirators and SCBA that operate in the demand mode. Since these devices operate in a negative-pressure 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 two types of SCBA: demand-only and those that have a so-called "donning switch."

For the first category, ANSI specifically prohibits the use of demand SCBA in emergency situations such as fire fighting. NRC concurs with this prohibition.

A SCBA with a donning switch operates as a pressure-demand unit when the switch is in the proper position. The purpose of the donning switch is to permit the wearer to switch the mode of regulator operation from pressure-demand to demand while donning the device, or immediately prior to removing the facepiece in a safe area. The donning mode prevents the rapid loss of air from the SCBA cylinder when the facepiece is not sealed to the wearer's face. There are two potential problems with this type of device. The wearer will not have the benefit of a highly protective pressure-demand device if (1) the switch is mistakenly left in the donning position when the wearer enters a hazardous area or (2) the switch is inadvertently changed to the donning position while the worker is in a hazardous area. Licensees who have demand-only SCBAs or SCBAs with donning switches, especially those who might need to use them in a fire fighting application, should be aware that these devices do not meet the current National Fire Protection Association (NFPA) standards[4] and the devices should either be modified to bring them up to the new standard or be replaced.

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

[4] National Fire Protection Association. "Open Circuit Self-Contained Breathing Apparatus for Fire Fighters," ANSI/NFPA 1981, 1997 edition.

### 1.3 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 individuals who achieve a fit factor >500 with a full facepiece negative-pressure facepiece but who are unable to achieve a fit factor 10 times the APF, NRC suggests that consideration should be given to a positive pressure face-sealing device or to a device for which a face seal is not necessary.

### 1.4 Paragraph 10.2

Paragraph 10.2 requires that each respirator stored for emergency use or rescue be inspected at least monthly, and that this inspection is to include the proper function of regulators, alarms, and other warning systems. NRC suggests that a monthly visual inspection of SCBAs is sufficient, and that an operational test (i.e., pressurizing the regulator, testing the low-pressure alarm) need only be done quarterly. Other devices stored for emergency use should be visually inspected monthly, but only need to be thoroughly examined 2 or 3 times per year.

## 2. ALARA REQUIREMENT

As stated in 10 CFR 20.1101(b), licensees must use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses that are ALARA.

According to 10 CFR 20.1702, licensees are to 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 all actions taken by the licensee be ALARA, nor does the NRC require that all doses be ALARA. The NRC does not expect that the licensee will 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 should have an ALARA program that is integrated into the site radiation protection program. Each licensee is required to track doses and take measures to maintain worker doses ALARA. The NRC recognizes that, when evaluations are needed to comply with 10 CFR 20.1702, 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 or 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 The 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, and the use of other types of exposure controls instead of respiratory protection devices, and

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 an evaluation of whether respirator use is ALARA.

- 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 Revision 1 of 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 pertinent data. 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 Estimated ALARA 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.

## 2.4 Exceptions to Respirator-ALARA Requirement

The ALARA principle must be applied in a reasonable fashion when making decisions on respirator use. The NRC staff recognizes that there may be situations when the dose evaluation clearly indicates that respirators need 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.

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 non-radioactive 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 (e.g., 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 (i.e., voluntary respirator use). Compliance with such State regulations is acceptable to the NRC. (See NUREG/CR-6204,[1] Question 386, and

Regulatory Position 4.7 of this guide.) Also, voluntary use of filtering facepieces (dust masks) is permitted in Appendix A to Part 20 without fit testing or medical screening.

## 3. PROCEDURES AND PROGRAMS

### 3.1 Applicability

Pursuant to Subpart H of 10 CFR Part 20, a licensee may assign 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 routinely or periodically, the licensee's respiratory protection program must include all the requirements contained in 10 CFR 20.1703 as a minimum.

If a licensee does not use respirators routinely or periodically, but has determined that there is sufficient likelihood of an emergency situation to justify the maintenance of emergency-use self-contained breathing apparatus (SCBA) or other types of respirators staged for an emergency, a program is necessary to ensure the safe use of that equipment should it be needed.

Part 20 (footnote d to Appendix A) and this regulatory guide (Regulatory Position 4.8) describe an exception for voluntary use of certain types of filtering facepiece respirators when no APF is applied.

### 3.2 Written Procedures

According to 10 CFR 20.1703, written procedures must be in place. These procedures must address and implement the following respiratory protection program elements:

- Monitoring, including air sampling and bioassays,
- Supervision of the program, including program audits,
- Training and minimum qualifications of respirator program supervisors and implementing personnel,
- Training of respirator users, including the requirement for each user to inspect and perform a user seal check (face-sealing devices) or an operational check (non face-sealing devices) on 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,
- 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)
- Non-routine respirator use (e.g., nonrecurring tasks for which engineering controls are not justified); and

- Emergency respirator use (e.g., recovery of an injured person from a portion of the restricted area where the breathing quality of the ambient air has not been assessed, or an area that may become immediately dangerous to life or health (IDLH) because of the presence of non-radiological hazards).

## 3.3 Application of Assigned Protection Factors

3.3.1 The assigned protection factors (APFs) listed in Appendix A to 10 CFR 20 are an indication of the predicted level of protection that a respirator user can expect to get from a given type of respirator. Use of the APF presumes that:

- The respirator user has been trained to properly don the device;
- The user has been satisfactorily fit tested (face-sealing devices only);
- The user properly performs either a user seal check on face-sealing devices to ensure that there is no gross seal leakage, or an operational check on non-face-sealing devices to ensure that the equipment is operating properly; and
- The respirator performs properly.

3.3.2 APFs are intended to be used as follows:

- In the selection of a type or types of respirators to be purchased by a licensee to address the expected range of potential airborne contamination levels at the facility, and credible emergency situations;
- In the selection of a specific type of respirator from among those available at the facility, to be used in the performance of a specific task, to keep the TEDE of exposed workers ALARA; and
- To estimate intake when bioassay and other evaluation methods are either not available or are not the method of choice.

3.3.3 For those personnel who participate in an internal dose-monitoring program in accordance with 10 CFR 20.1502, any intake must be recorded as specified in 10 CFR 20.1204.

3.3.4 If respirator wearers are not required to be monitored for intake of radioactive material because they do not meet the requirements of 10 CFR 20.1502 program, no record of internal exposure (DAC hours) or internal dose (mrem) need be kept, calculated, or retained if:

- The APF of the 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 10 CFR 20 Subpart H.

3.3.5 If the APF of the respirator being used is smaller than the multiple of the DAC measured in the air of the work place, the excess multiple of DAC, in combination with the exposure time, can be used to estimate and assign dose.

Example: Two fully qualified respirator users wearing half-facepiece negative-pressure respirators (APF = 10) perform work for four hours in an airborne contamination area. Four 1-hour air samples taken during the course of a task indicate that actual airborne contamination concentrations were 11.2, 15.4, 24.8, and 12.6 times the DAC respectively. Taking credit for the APF = 10, actual worker exposure can be assumed to be 1.1 DAC-h + 1.5 DAC-h + 2.5 DAC-h + 1.3 DAC-h = 6.4 DAC-h. Since 1 DAC-h = 2.5 mrem, the worker doses may be recorded as

If the licensee desires, an appropriate bioassay measurement may be performed, and the

$$\frac{6.4 \text{ DAC-h}}{1} \times \frac{2.5 \text{ mrem}}{\text{DAC-h}} = 16 \text{ mrem}$$

recorded dose adjusted in accordance with 10 CFR 1703(b)(1).

3.3.6 If an employee who does not meet the conditions for internal dose monitoring in 10 CFR 20.1502 (e.g., an adult radiation worker not likely to receive 10% of an ALI in a year) uses a respirator, and the APF of the respirator is less than the multiple by which average ambient concentration of airborne radioactive material in the workplace exceeds the applicable DAC value, the licensee should consider including this individual in the internal dose monitoring program.

### 3.4 Surveys

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 is required by 10 CFR 20.1703(c)(1) and (c)(2). Survey programs include (but are not necessarily limited to) surveys for radiation, contamination, airborne radioactive materials, and bioassay measurements. Other regulatory guides, some of which are listed below, describe such methods and programs which are acceptable to NRC.

| Number | Title | Rev. |
|---|---|---|
| 8.9 | Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program | 07/93 |
| 8.11 | Applications of Bioassay for Uranium | 06/74 |
| 8.20 | Applications for Bioassay for I-125 and I-131 Rev 1 | 09/79 |
| 8.21 | Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants Rev 1 | 10/79 |
| 8.22 | Bioassay at Uranium Mills Rev 1 | 08/88 |
| 8.23 | Radiation Safety Surveys at Medical Institutions Rev 1 | 01/81 |
| 8.24 | Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication Rev 1 | 10/79 |
| 8.25 | Air Sampling in the Workplace Rev 1 | 06/92 |
| 8.26 | Applications of Bioassay for Fission and Activation Products | 09/80 |
| 8.30 | Health Physics Surveys in Uranium Mills | 06/83 |
| 8.32 | Criteria for Establishing a Tritium Bioassay Program | 07/88 |
| 8.34 | Monitoring Criteria and Methods to Calculate Occupational Radiation Doses | 07/92 |
| 8.36 | Radiation Dose to the Embryo/Fetus | 07/92 |

### 3.5 Supervisory Positions and Responsibilities

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);
- States the responsibilities of each position;
- 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 as long as adequate communication and coordination exist between the programs.

### 3.6 Inappropriate Uses of Respirators

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

- 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 be limited by using engineering controls or limiting exposure time.

- For compensation for poor work practices (e.g., to prevent workers from rubbing or touching their faces with contaminated gloves);

- For eye protection only;

- 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-Certified 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 approved devices is available from NIOSH.[5] The NRC requires that only NIOSH-certified 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, these devices must be used, maintained, and stored in such a manner that they are not modified and are in like-new condition at the time of issue.[6] A reasonable amount of wear that does not affect performance is acceptable.

According to 10 CFR 20.1703(e), the licensee is to provide adequate equipment or material, as necessary, to supplement respiratory protective equipment in order 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 or high humidity.

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[5] This 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.

[6] See "NIOSH Approval Requirements for Respiratory Protection Equipment," *Radiation Protection Management,* Vol. 14, September/October 1997.

Other safety or protective equipment used in conjunction with respirators should not interfere with the proper fit or operation of the respirator. Manufacturer-supplied equipment (e.g., welder's shields, communications devices) specified on the approved subassemblies list for the respirator may be used in accordance with the manufacturer's instructions. Equipment or devices supplied by a company other than the respirator manufacturer may be used as long as they do not alter the form, fit or function of the respirator. Any such device that attaches to or requires penetration of the respiratory inlet covering is likely to void the NIOSH approval for the device and should not be used.

### 4.2 Non-NIOSH-Certified 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-certified, is not listed in Appendix A to 10 CFR Part 20, and no comparable NIOSH-certified device exists, the licensee may apply to the NRC to use the noncertified device (see 10 CFR 20.1703(b)). NRC approval is required whether or not APF credit will be used, except that supplied-air suits may be used without such approval as long as no APF is used (see Regulatory Position 4.10.1). The application to use a noncertified device should:

- Explain why no existing NIOSH-certified device meets the licensee's need,
- Present 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, and
- Show that using the device as proposed will not subject 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 the NRC has granted authorization to use such a device to one licensee, subsequent applications by additional licensees may make use of test information in that original submittal. As a minimum for devices that have not yet been authorized for use by 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 or in accordance with manufacturer's instructions. 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 (see 10 CFR 20.1703(c)(3)). A user seal check performed by the person being issued the respirator, either at the point of issue or immediately prior to entering an airborne contamination area, fulfills this requirement.

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

Self-contained breathing apparatus (SCBA), when provided as emergency respiratory protection equipment, should be visually inspected monthly and donned and operationally tested at least quarterly. Escape-only devices should be visually inspected monthly.

Some other respiratory protection devices, such as air-purifying respirators specifically designated for emergency use should be visually inspected monthly and should be removed from any protective container and thoroughly examined periodically (e.g., 2 to 3 times per

year). Such devices might be stored at the Emergency Operations Facility at a commercial power reactor, or at comparable locations at a materials licensee's facility.

Repair and replacement parts for respiratory protection devices should be inventoried and inspected periodically. The goal is to ensure that there are sufficient functional parts available to support the respiratory protection program when it is operating at full capacity.

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 before they are made available for issue. Equipment stored for periods of a year or more should be inspected annually to ensure that they are in good condition in case they are needed unexpectedly.

Breathing air cylinders, including SCBA cylinders, must be tested as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR 173 and 178).

Each breathing air cylinder should be permanently and legibly marked "Breathing Air" or "Compressed Breathing Air."

### 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). The device manufacturer identifies the components that require manufacturer-certified training.

### 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.

Personnel who issue respirators must ensure that each person issued a respirator has been medically screened, trained, and (for face-sealing devices) fit tested within the period prescribed. Persons may only be issued face-sealing respirators for which they have been fit tested (i.e., same make, model, style, and size).

### 4.6 Recordkeeping

Records of all the required activities in a respirator program should be kept in a manner that shows compliance with the requirements of the applicable regulations.

### 4.7 Half-Facepiece Respirators (APF = 10)

Half-facepiece respirators seal over the bridge of the nose, around the cheeks, and under the chin. Traditionally, half-facepiece respirators are made of rubber or an elastomeric material (e.g., silicone rubber), have at least two adjustable elastic head straps (4-point suspension), and use replaceable filter cartridges.

Two relatively new variations on the half-facepiece respirator are now on the market. They are sometimes referred to as "reusable," "reusable-disposable," or "maintenance-free" devices, and they are designed to be worn several times or for some period of time by the user. These devices are not intended for only a single use, and they can be divided into two general categories:

- Respirators that have a standard rubber or elastomeric facepiece with filters attached,

but the filters are not replaceable. These devices are considered to be half-facepiece respirators.

- "Filtering facepiece" respirators in which the filter medium is an integral part of the facepiece structure and is not replaceable.

In order for a device in the second category to be considered a half-facepiece respirator in an NRC program, it must contain both of two design characteristics:

- Seal-enhancing rubber or elastomeric material applied to the entire face-to-facepiece seal area, and
- An adjustable four-point (minimum) suspension strap system.

Most of the devices that qualify as half-facepiece respirators also have exhalation valves, but an exhalation valve, while desirable, is not an essential design component. Devices that meet these criteria are considered half-facepiece respirators (APF = 10). They are acceptable for use in an NRC-regulated program as long as the user can properly perform a seal check upon donning, and all other program requirements (e.g., medical screening, fit testing, training) are fulfilled. It is important to follow the manufacturer's recommendations and in-house contamination control procedures to establish the length of time such facepieces may be used before being discarded.

The use of quarter-facepiece 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 in an NRC-regulated program because it has been observed that the fit becomes unstable while the wearer moves around in the work place, especially when the wearer talks. These devices have never been permitted in an NRC-regulated respirator program, and good alternatives such as half-facepiece respirators are readily available.

### 4.8 Other Filtering Facepieces or Dust Masks (No APF)

Other NIOSH-certified filtering facepiece respirators are available that do not fit NRC's description of a half-facepiece respirator in Regulatory Position 4.7. These are generally considered to be single-use disposable respirators and are referred to in this regulatory guide as dust masks. An experienced respirator program administrator should be able to distinguish between these single-use, filtering facepiece dust masks and those that qualify as half-facepiece respirators in an NRC-regulated program. (This division of filtering facepiece respirators into two groups is an exception to ANSI Z88.2-1992, Table 1. The Standard does not differentiate between single-use disposable filtering facepieces and half-facepieces, but allows an APF = 10 to all disposables, quarter- and half-facepieces.)

Dust masks are relatively 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 permitted for use in a radiological respiratory protection program, but no credit may be taken for their use except as described below. Licensees are relieved of the requirement to medically screen and fit-test the wearers of such devices. A user seal check must be performed upon donning in accordance with the manufacturer's instructions, and all other applicable program requirements listed in 10 CFR 20.1703 apply. Devices must be NIOSH-certified, and wearers must be trained in the proper use and limitations of the devices. The information contained in OSHA's 29 CFR 1910.134 Appendix D constitutes adequate training. The availability of the devices should be controlled so untrained individuals cannot obtain them, and so that these devices are not mistakenly substituted for a more protective device in the field.

If a licensee wants to apply an assigned protection factor to these devices, the rule (at footnote d to Appendix A) 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 through B5 of Appendix A to OSHA's 29 CFR 1910.134, "Respiratory Protection."

Single-use respirators might be appropriate in situations when a respirator is not necessary but is requested by a worker (i.e., voluntary respirator use). This type of respirator can limit intakes of nuisance dusts when use of a more protective device cannot be TEDE ALARA-justified. These devices should be discarded after each use, and a new device should be used for subsequent work.

### 4.9 Respirator Filters

NIOSH has changed the way non-powered air-purifying respirator filters are certified and designated. Under NIOSH's old rule (30 CFR Part 11), respirator filters for protection against airborne radionuclides were required to be at least 99.97% efficient for the collection of 0.3$\mu$m mass median aerodynamic diameter (MMAD) particles, the particles being produced by the vaporization and condensation of dioctyl phthalate (DOP). Filters that meet this criterion are commonly referred to as 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 there are three levels of efficiency: 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-100. The decision as to whether N-, R-, or P-type filters should be used is left to the licensee. For air-purifying respirators operating in the negative-pressure mode and APF $<100$ (i.e., half-facepiece respirators), filters of at least 95% efficiency are to be used (e.g., N-95).

For air-purifying respirators operating in the negative-pressure mode and APF = 100 (i.e., full-facepiece respirators), filters of at least 99% efficiency must be used. For air-purifying respirators operating in the positive-pressure mode and APF $>100$ (i.e., full-facepiece powered air-purifying respirators), filters of at least 99.97% efficiency are to be used.

NIOSH has determined that, effective July 10, 1998, particulate filters and respirators certified under 30 CFR Part 11 can no longer be manufactured and shipped as NIOSH-certified items. NIOSH has also taken the position that (1) distributors who purchased 30 CFR Part 11 particulate filters and respirators prior to July 10, 1998, will be able to sell them as "certified" until inventories of these products are depleted, and (2) end users who purchase 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 for the products expires.

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

Respirator filters can be re-used by the same person on the same day without being re-tested, as long as contamination control is adequate and the filters do not appear to be damaged. If the licensee's procedures allow for filter re-use beyond one day by the same person, or by other persons, such filters should be re-tested before re-use occurs. Such re-testing should include a penetration test using any appropriate aerosol and a pressure-drop test. Filters to be reused should not have any apparent damage and should meet the licensee's criteria for residual contamination.

### 4.10 Service Life Limitations

If the respirator equipment manufacturer specifies a shelf life or service life limit on one or more components of a respiratory protection system, the licensee should comply with the recommendations of 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.

For example, some chin-style gas mask canisters for organic vapors are stamped with a "Use Before" date, which is 5 years from date of manufacture. Such canisters should not be used after that date has passed. Also, the date that these canisters are first unsealed should be written on the canister label, and the canisters discarded one year from the unsealing date.

## 4.11 Supplied-Air Suits

### 4.11.1 Supplied Air Suits Used With No APF

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 certification procedures do not currently include a method for testing and certifying these suits. NRC believes, however, that in certain nuclear industry applications (e.g., control-rod drive removal at boiling water reactors) 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 be medically approved and trained; the air supplied to the suit must meet the minimum quality requirements specified in CGA 7.1-1997 "Commodity Specification for Air[7]" for other (NIOSH-certified) 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.

No submittal needs to be made to the NRC staff and no permission prior to use needs to be obtained prior to using these devices.

### 4.11.2 Supplied Air Suits Used With an APF

If a licensee needs to apply an APF to supplied-air suit, a written application is to be made to the NRC in accordance with the requirements of 10 CFR 20.1705. Proposed conditions of use would include the anticipated length of air supply hose (minimum and maximum), and breathing air supply pressure (minimum and maximum). The NIOSH approval criteria for supplied-air hoods (42 CFR 84) may be useful to licensees who anticipate applying for use of an APF for supplied-air suits.

## 4.12 Combination Devices

Some devices are available that combine two respirator types in one unit (e.g., a combination of 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. For example, when using the combination device described above, an APF of 100 applies during the time the wearer is in the airborne contamination area and not connected to an air supply hose. Once the worker reaches the work site and connects the device to a supply of breathing air, the APF increases to 1,000.

Another type of combination device of interest to nuclear reactor licensees is the

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

combination particulate/organic vapor respirator canister, commonly referred to as a "radioiodine canister." When used in conjunction with the appropriate facepiece, this canister is not specifically certified for protection against airborne radioiodine because iodine does not have good user-warning properties and the canister is not equipped with an end-of-service-life indicator (ESLI). It is certified, however, for protection against airborne particulates (P-100) and for organic vapors. Therefore, an APF of 100 may be used for airborne particulates. Licensees who wish to use an APF for radioiodine for this device must apply to NRC for authorization. Alternatively they may use representative air sample data to estimate and control worker doses, then perform post-exposure bioassay to correct the estimated doses to workers. Otherwise, licensees must use representative air sample data from the workplace to assign doses to exposed workers. Requirements for determining internal doses are contained in 10 CFR 20.1204.

## 4.13 Emergency and Escape Equipment

4.13.1 Equipment for Emergency Entry

The equipment preferred for emergency entry into an unassessed environment, or into an area with high concentrations of a chemical hazard, is the open-circuit self-contained breathing apparatus (SCBA) operated in the pressure-demand mode, with a minimum rated service life of 30 minutes. Also acceptable are a combination full-facepiece pressure demand supplied air respirator with an auxiliary self-contained air supply of at least 5 minutes duration and a positive-pressure, closed-circuit (recirculating) SCBA with a minimum rated service life of 30 minutes.

4.13.2 Other Emergency Equipment

Other equipment may be designated for emergency use against airborne radioactive material. An example would be air-purifying respirators stored at the Emergency Operations Center at a commercial power reactor facility. At nuclear power plants, where emergency responders might receive a radiation dose from airborne radioiodine in a credible accident scenario, organic-vapor cartridges or canisters may be used for whatever protection they provide and radioiodine doses should be controlled and accounted for as stated in 10 CFR Part 20.

4.13.3 Escape Equipment

Some short-duration SCBAs are certified for escape only. Other escape-only devices are available that are hazard-specific (e.g., mouthpiece and bit respirators for escape from chlorine environments). These devices must be NIOSH certified for escape from the atmosphere in which they will be used. They may be used for escape from, but never for entry into, contaminated areas.

## 4.14 Decontamination and Disinfection of Facepieces; Contamination Control

Licensees should decontaminate and disinfect respirators and associated equipment in accordance with manufacturer's instructions, paying particular attention to the cleaning or sanitizing agent used, and to the maximum temperature of the water used for cleaning. Radiological limits for reuse of respirators after they have been cleaned and sanitized should be consistent with other contamination limits used at the facility.

## 5. RESPIRATOR USERS

### 5.1 Medical Evaluation

5.1.1 The Licensee's Physician

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. This screening process should be sufficient (in the opinion of the licensee's physician) to identify any persons who should not use respiratory devices for medical reasons. NRC does not require a "hands-on" physical examination by a physician.

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

5.1.2 Establishing and Performing the Evaluation

ANSI Z88.6-1984, "Respirator Use -- Physical Qualifications for Personnel,"[3] provides guidance that is acceptable to the NRC staff for the physician to use in determining medical fitness. The screening method may include a medical history questionnaire (the OSHA Respirator Medical Evaluation Questionnaire in Appendix C to 29 CFR 1910.134 is acceptable) and spirometry testing. The licensee's physician, however, establishes the precise screening method.

The medical evaluation program should be carried out by a certified, medically trained individual such as a registered nurse (RN), licensed practical nurse (LPN), emergency medical technician (EMT), or someone who, in the judgment of the licensee's physician, has adequate experience, education, training, and judgment to carry out this program.

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

5.1.3 Timing of Medical Evaluations

According to 10 CFR 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 since no fit test is required.

Re-evaluation must be performed every 12 months thereafter or at some other frequency established by the licensee's physician. ANSI Z88.6-1984 suggests a range for reevaluation from every 5 years for workers below age 35, to annually for workers over age 45.

If necessary, a re-evaluation "grace period" of up to 90 days is considered to be reasonable.[8] In unusual circumstances, an otherwise fully qualified respirator user whose medical screening has expired within the past 90 days may be issued a respirator with the concurrence of the Respirator Program Administrator. Licensees should not interpret this grace period to mean that re-screening can be accomplished every 15 months. The Health Physics Position referred to above specifies that three consecutive examinations not exceed 39 months.

5.1.4 Failure To Meet the Acceptance Criteria

Individuals whose screening results fall outside the range of the criteria established by the licensee's physician may have their cases evaluated by the licensee's physician. This evaluation might consist only of a review of the written record, or it might involve a hands-on

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[8] From Health Physics Position 219.

examination. In these situations the licensee's physician might permit the individual to use one or more types of respirators judged to impose less stress, and prohibit the use of other more stressful devices. The licensee's physician may confirm the outcome of the screening by prohibiting the individual from using any respirator.

5.1.5 Privacy of Medical Records

Medical records and the results of medical screening tests should be kept private. The only information that should be transmitted from the medical department to the respirator department is whether or not an individual may use respirators, or which devices may be used and which may not be. A simple medical-approval form is adequate.

## 5.2 Training

A training program, including hands-on training, must be established and implemented for respirator users (see 10 CFR 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:

- 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.
- 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.
- Be able to demonstrate competency in donning, using, and removing each type of respiratory protective device that may be used,
- 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,
- Be instructed in how to perform a user seal check on face-sealing devices and be instructed to perform this user seal check each time this type of device is donned,
- 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.
- Be advised that in case of respirator malfunction or wearer distress, the respirator may be removed as the respirator user exits the airborne contamination area.

## 5.3 Fit Testing

A fit testing program is to be implemented for all face-sealing respirators (see 10 CFR 20.1703(c)(6)), even if they will be used in a positive pressure mode in the field. The employee must be fit tested with the same make, model, style, and size of respirator that will be used in the field.

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

Qualitative fit testing (QLFT) and quantitative fit testing (QNFT) 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. QLFT can usually be accomplished with unmodified respirators. For QNFT, some respirator manufacturers provide a fit-test adapter to accomplish this. Otherwise, respirators used for fit testing will need to be modified. While this modification voids the NIOSH certification for the test device, certification is not required since occupational exposures are not involved during fit testing.

Filters used during fit-testing should be at least 99.97% efficient, even if less efficient

filters will be used in the work place. The fit test is intended to measure only face-to-facepiece leakage, so filter efficiency on the test respirator should be as high as possible.

The size of the particles that make up the challenge aerosol during fit testing is unimportant. The following challenge aerosols have been used successfully.

Corn oil (QNFT)
Sodium chloride (QNFT)
Ambient dust particles (QNFT)
Sodium saccharine (QLFT)
Bitrex (denatonium benzoate) (QLFT)
Amyl acetate (or isoamyl acetate or isopentyl acetate)[9], commonly called "banana oil" (QLFT) Stannic chloride (irritant smoke) (QLFT)

All these are acceptable challenge agents so long as the sensitivity of the detection system (QNFT) or the ability of the test subject to sense the challenge agent (QLFT) meets the test protocol requirements.

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. Such leakage will quickly deplete the available breathing gas and if used in an emergency could easily place the wearer in jeopardy.

5.3.1 Quantitative Fit-Testing (QNFT)

QNFT is acceptable for testing all face-sealing devices. If QNFT is used to test facepieces that will be operated in the negative pressure mode in the field, an overall fit factor of at least 10 times the APF (given in Appendix A to 10 CFR Part 20) should be demonstrated. Requiring that the overall fit factor meet the acceptance criterion means that the fit factor for one or more of the individual test exercises might be less than the acceptance criterion, but a satisfactory overall fit test can still be achieved.

If QNFT is used to test facepieces that in the field will be operated only in a positive pressure mode, an overall fit factor of at least 500 (not 500 times the APF) should be demonstrated with the facepiece operating in the negative pressure mode. Face-sealing devices that operate in a positive pressure mode are powered air-purifying respirators (PAPR), continuous flow supplied-air respirators, pressure-demand supplied air respirators and SCBA, and positive-pressure recirculating SCBA.

For combination devices (e.g., a combination of 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, or 500, whichever is greater.

During all quantitative fit tests, the sample point inside the facepiece should be midway between the mouth and the nose of the test subject.

5.3.2 Qualitative Fit-Testing (QLFT)

While no numerical measure of facepiece leakage is directly obtained from QLFT protocols, they are designed and validated quantitatively. Each validated protocol first tests the subject's ability to detect (i.e., smell or taste) a small concentration of the challenge aerosol ($C_2$). After donning the device to be tested, the seal area is then exposed to a higher concentration of the challenge aerosol ($C_1$) and the subject performs a sequence of head, neck, and body movements while the concentration of challenge aerosol is maintained. If the challenge concentration is 100 times the wearer's detection threshold, and the wearer isn't able to detect the challenge aerosol, the test has in essence measured a fit factor of at least 100 (i.e., $C_1/C_2 \geq 100$).

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[9] A fit test using amyl or isoamyl or isopentyl acetate requires that an organic vapor respirator cartridge be used in the test respirators.

QLFT is acceptable if the method used is capable of:

- Verifying a fit factor 10 times the APF for facepieces that in the field will operate in the negative pressure mode; or
- Verifying a fit factor of 500 (not 500 times the APF) for facepieces that in the field will operate in a positive pressure mode. Devices that operate in a positive pressure mode are listed in Regulatory Position 5.3.1 above.

Currently available QLFT methods are only capable of verifying a fit factor of 100. Therefore present QLFT methods are only appropriate for devices with an APF of 10 or less, unless and until new QLFT methods that can confirm higher fit factors are developed and validated. Licensees may use QLFT to test respirators with APF greater than 10, but may only take credit for an APF of 10 even though the listed APF is higher for the device in Appendix A to 10 CFR 20.

5.3.3 Irritant Smoke

The currently used irritant smoke QLFT protocol has never been validated. However, it will evoke an involuntary response in virtually anyone who smells it, and it is therefore less subjective than the other QLFT protocols. NRC considers that this protocol has been sufficiently evaluated to permit its use in nuclear industry respirator programs for half-facepiece respirators that will be used in the negative pressure mode of operation.

When stannic chloride hydrolyzes with moisture in the air it forms hydrochloric acid (HCl) and stannic oxychloride. Licensees should ensure that only stannic chloride smoke tubes are used. Similar tubes which generate smoke of a different chemical composition may not be sufficiently irritating to the test subject to be sensed at low concentrations. Smoke tubes which utilize chemicals other than stannic chloride are not acceptable.

If irritant smoke is used as the challenge aerosol during QLFT, 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, providing the test area with a ventilation or air filtration system, assigning a respiratory protection device to the person performing the fit testing, or other measures. The fit-test protocol should also be designed to limit the test subject's exposure, especially when performing the sensitivity screening checks that determine whether the test subject can detect the irritant smoke.

Because of the personnel exposures involved, NIOSH does not recommend the use of irritant smoke for respirator fit-testing.

5.3.4 Fit-Test Protocols and Procedures

Fit-testing should be performed in accordance with an established protocol.[10] Each time fit-testing is required, only a single satisfactory fit test need be performed.

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." Fit-testing performed in accordance with these protocols will comply with NRC's requirements.

5.3.5 Retesting

Retesting must be done annually. If necessary, a retest "grace period" of up to 90 days is considered to be reasonable.[11] In unusual circumstances, an otherwise fully qualified respirator user whose fit test has expired within the past 90 days may be issued a respirator

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

[11] Based on Health Physics Position 219.

with the concurrence of the Respirator Program Administrator. Licensees should not interpret this grace period to mean that fit testing can be accomplished every 15 months. Three consecutive fit test periods should not exceed 39 months.

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

- A weight change of 10% or more,
- Significant facial injury or scarring in the area of the facepiece seal,
- Significant dental changes (e.g., multiple extractions without prosthesis or acquisition of new dentures),
- Reconstructive or cosmetic surgery in the area of the facepiece seal,
- 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 retest criteria. Adding or revising some questions on a medical screening questionnaire (if used) might be considered.

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.

### 5.4 User Seal Checks

Each respirator wearer must perform at least one type of user seal check each time a face-sealing respirator is donned. A user seal 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 also perform such a user seal 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. In this case, the respirator user must perform another user seal check after donning the facepiece at the work site.

A user seal check is no substitute for a fit test. Acceptable user seal checks are described below.

*Positive pressure check*. Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

*Negative pressure check*. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. The design of the inlet opening of some cartridges cannot be effectively covered with the palm of the hand. The test can be performed by covering the inlet opening of the cartridge with a thin latex or nitrile glove. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

*Manufacturer's recommended seal check*. The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and/or negative pressure check procedures provided that the employer demonstrates that the manufacturer's procedures are equally effective.

Also acceptable as a seal check is the use of an irritant or odorous test agent, such as

stannic chloride (irritant smoke) or amyl acetate (or isoamyl or isopentyl acetate).[12] While seal checks that use these agents are more involved than other methods, require a test substance, and might require the assistance of others to properly administer, they are still permitted to be used by licensees.

### 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. For example, once an individual has donned a supplied-air hood, the air should be allowed to flow for a period of time (e.g., one minute) before the wearer enters the contaminated area. During this time support personnel should verify that the air pressure at the distribution manifold is within the proper range specified by the manufacturer and that the wearer feels that the airflow is adequate.

### 5.6 Communications

Respiratory protection devices limit the wearer's ability to communicate. NRC requires that respirator users be able to communicate well enough to be able to work safely and be able to keep radiation doses ALARA. How these goals can best be met is left to the judgment of the Respirator Program Administrator. In many situations, adequate communication can be maintained by training the respirator wearers to speak slowly and distinctly. In other situations, especially where ambient noise levels are high or where respirator wearers must communicate across long distances, voice-amplification devices or other types of systems might have to be employed.

Licensees are reminded that if these devices are attached to the respirator or require a modification of the respirator, they must be listed on the manufacturer's schedule of approved subassemblies. This ensures that the NIOSH approval for the device remains in force with the addition of the communications equipment.

After-market communications devices supplied by a company other than the respirator manufacturer may be used as long as they do not alter the form, fit, or function of the respirator. Any such after-market device that attaches to or requires penetration of the respiratory inlet covering is likely to void the NIOSH approval for the device.

### 5.7 Vision

Some types of respirators prevent the wearer from using standard spectacles or from using them properly. The ear pieces of standard spectacles pass through the seal area of full-facepiece respirators and are therefore not allowed. Half-facepiece respirators seal around the bridge of the nose and prevent standard spectacles from being worn as designed. NRC requires that respirator users be able to see well enough to be able to work safely and to be able to keep radiation doses ALARA. How these goals can best be met is left to the judgment of the Respirator Program Administrator.

Most manufacturers of full-facepiece respirators offer a spectacle adapter kit. Non-manufacturer-supplied adapters may be acceptable if they do not interfere with the facepiece seal and if it does not cause any distortion of vision, damage the lens of the facepiece, or cause any harm to the wearer during use. It is not advisable to use home-made adapters, or to simply tape the spectacles inside the facepiece.

Contact lenses are permitted for use with respirators provided the wearer has

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[12] Fit checks using amyl, isoamyl, or isopentyl acetate require that organic vapor cartridges be installed on the respirators being checked.

demonstrated successful experience in wearing such lenses. Contact lens wearers should be required to practice wearing the respirator while wearing the contact lenses, for example, during training or fit testing.

Another option is to select a respirator that does not interfere with the use of standard spectacles, such as a hood or helmet.

## 6. SAFETY

### 6.1 Standby Rescue Persons

According to 10 CFR 20.1703(f), standby rescue persons must be provided when workers wear supplied air hoods or suits, possibly in conjunction with other protective equipment, that are difficult to remove without assistance. Such standby rescue persons must be equipped with respiratory protection devices that are 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 (20.1703(f)). Standby rescue persons must be sufficiently trained or experienced to render effective assistance if needed.

### 6.2 Face-to-Facepiece Seal Integrity

Anything in the face-to-facepiece seal area of a tight-fitting respirator that is under the control of the respirator user is prohibited by 10 CFR 20.1703(h). Materials in this area might interfere with the seal of the respirator, might prevent proper exhalation valve function, or might impair the operation of a facepiece-mounted air regulator. The list of prohibited materials 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 intruding into the seal area, 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, or in response to unanticipated releases of radioactive material, the licensee must use only SCBA operated in the pressure-demand mode. The use of SCBA to circumvent the pre-exposure sampling requirement (10 CFR 20.1703(c)(1)) 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.

### 6.5 Breathing Air Quality

6.5.1 Breathing Air Systems

The breathing air supply system used by licensees may be either a dedicated system or a multi-purpose air system. While a dedicated breathing air system with non-oil-lubricated

compressors has its advantages, the only requirement 10 CFR 20.1703(g)) is that air of the minimum quality specified below be delivered to each supplied-air respirator. Licensees are cautioned, however, to avoid contaminating the internals of the system used for breathing air. This includes both radiological and non-radiological contaminants. There are two primary ways in which air systems become contaminated: allowing contaminants to be drawn into the compressor intakes, and connecting the air system to a contaminated system which then reaches a higher pressure than the air system and causes contaminated fluid to flow into the air system.

Air pressure or flow gauges used to show compliance with NIOSH certification requirements should be calibrated at regular intervals consistent with the calibration frequency of other similar gauges at the facility. Calibration annually and after gauge repair is reasonable.

Quick disconnects and other breathing air couplings should be incompatible with outlets for non-respirable air or other gas or fluid systems. Breathing air hoses may not be used for any other purpose. No asphyxiating substance may be introduced into any lines used for breathing air.

6.5.2 Air Quality Requirements

The quality of the air delivered to all atmosphere-supplying respirators must meet the requirements of Grade D air for breathing air systems as defined in CGA G-7.1-1997, "Commodity Specification for Air"[13] (See 10 CFR 20.1703(g)).

Intake points for breathing air compressors should be located and protected in such a way as to prevent airborne contaminants from being drawn in.

6.5.3 Moisture Content in Breathing Air Cylinders

OSHA requires (see 29 CFR 1910.134(i)(4)(iii)) that the moisture content in breathing air cylinders, in addition to the Grade D requirement, does not exceed a dew point of -50 °F (-45.6 °C) at one atmosphere pressure. CGA G-7.1-1997 states that air in SCBA cylinders should not exceed a dew point of −65 °F (24 ppm v/v), or 10 °F lower than the coldest temperature expected in the area where the SCBA will be used. NRC requires compliance with the OSHA requirement (29 CFR 1910.134(i)(4)(i)) for all cylinders and suggests meeting the CGA G-7.1-1997 Grade L requirement if practical.

6.5.4 Testing Frequency

The air from compressors that furnish breathing air to an in-plant header used as a breathing air supply should be tested periodically. The time interval between tests should be reasonable under the circumstances and conditions of use. Breathing air systems that are in continuous or daily use should be tested at least monthly. Breathing air systems that are only used periodically should be tested immediately prior to use, then periodically during use.

The air from compressors used to supply breathing air to cylinders should be tested periodically. This applies to cylinders filled by the licensee and to those filled by a vendor. If the air is tested and shown to meet the quality criteria at the beginning of the filling process, it is reasonable to assume that cylinders may be filled for the following 24 hours without retest. Other reasonable retest periods may be acceptable.

6.5.5 Test Methods

The test methods described in CGA 7.1-1997 are acceptable to the NRC staff. Licensees who perform weekly or more frequent air quality tests should use detector tubes filled with color-reactive chemicals sensitive to the various possible contaminants. The breathing air should be tested two to four times per year using more rigorous analytical methods (e.g., gas

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

chromatography).

6.5.6 Sampling Breathing Air for Radiological Contamination

When breathing air supply manifolds are permanently or temporarily located inside contaminated or airborne radioactivity areas, covers or caps should be used to protect them from contamination. Wipe samples should be taken at the air connection points prior to attaching a respirator supply hose. The breathing air should be sampled periodically for radiological contaminants.

6.5.7 Oxygen Purity Requirements

When any respiratory protection device uses an oxygen supply rather than an air supply (e.g., closed-circuit SCBA), that oxygen must meet the United States Pharmacopoeia requirements for medical or breathing oxygen.

## 6.6 Use of Higher or Lower APFs

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

Licensees may use APFs lower than the ones listed in Appendix A to 10 CFR 20 without notifying or obtaining approval from NRC.

## 6.7 OSHA Requirements

Licensees whose respiratory protection programs fulfill the requirements of Subpart H of 10 CFR 20 will meet the basic program requirements for an OSHA-regulated respiratory protection program described in 29 CFR 1910.134. This is intended to relieve licensees of the burden of developing and maintaining two parallel respiratory protection programs to comply with OSHA and NRC requirements. Radiological considerations are incorporated into the NRC-regulated program to achieve full compliance.

Minor differences between NRC and OSHA respiratory protection requirements are described below along with the resolution of or justification for the apparent conflict. The NRC requirements that are not in full agreement with OSHA rules are not likely to place any significant burden on licensees.

- OSHA's 29 CFR 1910.134(c)(2) permits individuals to provide their own respirators for voluntary use. While this is not specifically prohibited in an NRC program, contamination control issues and potential legal liability make this an unattractive option.

- OSHA exempts voluntary wearers of filtering facepieces (dust masks) from all program requirements, but such volunteers must be provided with the information contained in Appendix D to 29 CFR 1910.134. NRC differentiates between disposable filtering facepieces (no APF) and half-facepiece respirators (APF = 10), which include certain filtering facepieces. This distinction is described in Regulatory Position 4.7 and 4.8 of this guide. NRC only permits voluntary use of single-use disposable filtering facepieces and exempts such voluntary wearers from the requirements for medical screening and fit testing, but still requires that minimal training be provided, including how to don and use the facepiece effectively. This training requirement is compatible with OSHA's 29 CFR 1910.134 Appendix D.

- OSHA's 29 CFR 1910.134(d)(1)(i) requires that, if the employer cannot identify or reasonably estimate the employee exposure, the employer must consider the atmosphere to be IDLH (immediately dangerous to life or health). This leads to very specific requirements in 29 CFR 1910.134(d)(2) for the assignment of respirators. The term IDLH does not realistically apply to airborne radioactivity but could apply to certain nonradiological hazards at an NRC-licensed facility, in which case OSHA rules apply. Such non-radiological hazards include oxygen-deficient environments (e.g., inerted structures and vessels), chemical hazards (e.g., chlorine, hydrazine), and fire fighting.

- OSHA's 29 CFR 1910.134(d)(1)(iv) requires the employer to select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user. While NRC requires that respirator wearers demonstrate an adequate respirator fit, no specific requirements are placed on licensees regarding the provision of respirators in various sizes and from several different manufacturers. The NRC approach requires the exercise of the licensee's judgment with respect to how many different devices and sizes to provide. Additional information about this requirement, which is repeated in ANSI Z88.2-1992, is in Regulatory Position 7.3 of this guide.

- OSHA does not currently promulgate APFs for respirators but reserves the ability to do so (29 CFR 1910.134(d)(3)(i)(A) and Table I). The maximum APFs that may be used in an NRC-regulated program are listed in Appendix A to 10 CFR 20, and these are consistent with the APFs listed in ANSI Z88.2-1992.

- OSHA's 29 CFR 1910.134(d)(3)(iii) requires the employer to provide specific types of respirators for protection against gases and vapors. In an NRC-regulated program, exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations. Respirators do not necessarily have to be assigned for protection against airborne radioiodine vapors since personnel dose can be controlled by limiting stay times or by other methods. Airborne tritium gas and tritiated water vapor are not effectively removed by air-purifying respirators, so APFs do not apply for these devices for protection against tritium. The APF of atmosphere-supplying respirators is reduced to 3 for protection against airborne tritium since approximately one-third of the intake occurs by absorption through the skin.

- OSHA's 29 CFR 1910.134(e)(2)(i) permits a "physician or other licensed health care professional (PLHCP)" to set up, administer, and make medical decisions about the medical status of potential respirator users, and it contains a number of prescriptive requirements. In an NRC program, a physician (the licensee's physician) must set up or approve the medical screening program for respirator wearers and set the medical acceptance criteria. A licensed health care professional may carry out the screening process and medically approve as respirator users those who fall within the acceptance criteria established by the licensee's physician. However, the individuals who fall outside the established acceptance criteria must be evaluated by the licensee's physician before being designated as medically qualified to use respirators. Precisely how this additional evaluation is accomplished is a medical decision to be made by the licensee's physician and does not necessarily have to include personal contact with the person being screened.

- OSHA's 29 CFR 1910.134(e)(2)(i) requires that medical evaluations obtain all the

information requested in Sections 1 and 2 of Part A of OSHA's medical questionnaire, which is Appendix C of the OSHA rule. NRC permits, but does not require, the Appendix C questionnaire to be used in medical screening programs.

- OSHA's 29 CFR 1910.134(e)(6)(ii) requires that a powered air-purifying respirator (PAPR) be provided to a worker whose physical condition does not allow the use of a negative-pressure device. NRC places no such requirement on licensees, but the OSHA approach is an acceptable option under the NRC rules.

- OSHA's 29 CFR 1910.134(f)(7) requires a fit factor of at least 100 for tight-fitting half facepieces and at least 500 for tight-fitting full-facepiece respirators. NRC requires 10 times the APF for negative-pressure devices (i.e., 100 for half facepieces, 1000 for full facepieces), and 500 for tight-fitting respirators that will operate in a positive pressure mode in the field.

- OSHA's 29 CFR 1910.134(h)(3) requires that all respirators maintained for use in emergency situations be inspected at least monthly and in accordance with the manufacturer's recommendations, and be checked for proper function before and after each use. It also contains other specific requirements. NRC requires a monthly visual inspection of SCBAs but only requires a quarterly operational test (i.e., pressurizing the regulator, testing the low-pressure alarm). Other devices stored for emergency use must be visually inspected monthly, but under NRC guidance only need to be thoroughly examined 2 or 3 times per year.

- OSHA's 29 CFR 1910.134(i)(5)(iii) requires that suitable in-line air-purifying sorbent beds and filters be used on the intakes of breathing air compressors, and that they be maintained and replaced or refurbished periodically following the manufacturer's instructions. NRC requires only that air of Grade D quality, described in CGA G7.1, be delivered to each supplied-air respirator. How that is accomplished is left to the licensee.

- OSHA's 29 CFR 1910.134(i)(7) requires the presence of a high-temperature alarm or a carbon monoxide alarm on the discharge of oil-lubricated breathing-air compressors. As stated above, NRC requires only that breathing air of Grade D quality be provided.

Licensees are reminded that OSHA hazard-specific 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 separate from or concurrently with airborne radiological hazards. Some of these hazards to be considered are heat stress, oxygen deficiency, chemical toxicity 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 (10 CFR 20.1703(c)(4)(ix)). 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.

## D. IMPLEMENTATION

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

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in the active guide reflecting public comments will be used in the evaluation of respiratory protection programs described in a licensee's operating procedures, 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 that are in addition to those required by the NRC. They may also contain requirements for limiting or controlling hazards that 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 Enclosure ___ to SECY _____.

# REGULATORY ANALYSIS OF FINAL REVISIONS TO 10 CFR 20, SUBPART H, RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

**January 29, 1999**

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Attachment 3

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1. Statement of the Problem

With the exception of the May 1991 revision to 10 CFR Part 20 that, among other things, required licensees to maintain the sum of internal and external dose as low as is reasonably achievable (ALARA), the Nuclear Regulatory Commission (NRC) has not made substantive technical changes in its regulation on the use of respiratory protection by it's licensees in several decades. In the interim, the NRC has substantially revised regulation 10 CFR Part 20 to reflect new radiation protection recommendations with regard to primary dose limits and dosimetric models. The NRC has now prepared amendments to Subpart H ("Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas") of 10 CFR Part 20 revisions to Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." NUREG-0041 (Rev. 1), "Manual of Respiratory Protection Against Airborne Radioactive Materials" is expected to be published following the final rule. These changes reaffirm the Commission's intention to reduce the unnecessary use of respirators when their use does not optimize the sum of the Deep Dose Equivalent (DDE) and the Committed Effective Dose Equivalent (CEDE), or Total Effective Dose Equivalent (TEDE). Instead of relying on respiratory protection devices, licensees are required to consider the use of process and engineering controls, filtered ventilation systems, decontamination of work areas, control of access to radiological areas, limitation of exposure time, and use of other types of exposure controls. The new regulations and guidance generally endorse the use of ANSI standard Z88.2-1992, "American National Standard Practice for Respiratory Protection," with a few exceptions. This ANSI standard represents the most current industry guidance for the use of respiratory protection when other ALARA-based alternatives are not practicable. The new NRC standards are designed to be consistent with the new OSHA regulations at 29 CFR Parts 1910 and 1926. While licensees are required by Part 20 to use one or more of the alternative control practices discussed above (i.e., avoid use of respirators in most circumstances), respirator use would be permitted if the practice will help to optimize the TEDE. Respirators might also be used in situations where:

(1) non-radioactive nuisance dust is present in the work area, or
(2) workers and/or the health physics department are in a relatively short-term learning process or making a transition from routine use of respirators, or
(3) the use of certain respiratory protection devices reduces heat stress on workers, or
(4) they are used as contamination control devices in high contamination but relatively low airborne radioactivity areas with the potential for significant resuspension, or
(5) a worker requests a respirator when the licensee has determined that use of a respirator is not needed, or
(6) they serve as a precautionary measure in which there is a large uncertainty in the magnitude of the projected concentrations of airborne material to which workers might be exposed.

In all cases, respirators should be selected to have the least possible impact on worker function (e.g., stress from heat, breathing resistance, ability to see and communicate). These and other options are permitted by the rule change, which also revises the current table of respirator assigned protection factors (APFs) to reflect the latest information and experience available.

2. Objectives of the Rulemaking

The objective of the rulemaking is to update current NRC requirements for respiratory protection programs at licensee operations and to reduce regulatory burden while increasing flexibility. Every effort was also made to minimize any impacts of the changes on licensees.

3. Alternatives

A summary of the changes is provided in the preamble to the final rule. In most cases, the changes are made for purposes of improving operational safety, increasing operational flexibility, or for purposes of clarifying the intent of the existing rule (based on information collected since the new Part 20 was promulgated in 1991).

Retaining the current rule represents the "NO ACTION ALTERNATIVE," which the NRC found unacceptable. The NRC believes that there is a need to redefine acceptable levels of respiratory protection to be consistent with new ANSI guidance and the new OSHA regulations. The current rule is too inflexible for good health physics practice, because it does not permit the use of devices such as disposable respirators and supplied air suits and is out of date with respect to assigned protection factors. Most of the proposed changes are not expected to change the regulatory burden, and therefore have no regulatory consequences. Only those changes which carry the potential for any increase or reduction in current regulatory burden are addressed in detail in the section below and in the value/impact analysis.

4. Consequences

(1) Deletion of the current § 20.1703(a)(4) removes the requirement that licensees prepare a written policy statement on certain aspects of respirator usage. Deletion of this requirement is expected to reduce the regulatory burden. That is because, in practice, the current rule at § 20.1703(a)(3)(iv) effectively requires that licensee procedures (containing all of the elements currently required in the policy statement) be updated and reissued each time a licensee significantly changes its respiratory protection program. The potential impacts are analyzed in the value/impact analysis (Section 5).

(2) A change to the current § 20.1703(a)(6) clarifies that licensees are required to make provisions for vision correction, adequate communication, and added safety to workers using respirators at low temperatures.

The only additional requirement is that licensees are explicitly required to take into account the effects of adverse environmental conditions on the equipment and the wearer. The inability of the wearer to read postings, operate equipment and/or instrumentation, or properly identify hazards as a result of adverse conditions is considered to be an unacceptable degradation of personnel safety by NRC.

The change resolves occasional problems with freezing of respirator exhalation valves leading to possible respirator failure and inhalation of unfiltered air, and lens fogging leading to reduced vision. The amendment has the potential for some increase in regulatory burden. For example, if licensees needed special low temperature attributes not provided by NIOSH and manufacturers, the licensees would be required to apply for approval to NRC under

§ 20.1703(b). While these changes may be justified on the basis of improved personnel safety under low temperature conditions, the potential impacts are addressed in the following section.

(3) The deletion of § 20.1703(d) removes the requirement to notify the NRC region in writing 30 days before the first use of respiratory protection. Removing a requirement for duplication of reporting is expected to result in a small reduction in regulatory burden for both the NRC and some licensees, and is addressed below in the value/impact analysis.

(4) The part of Footnote g to Table 1 of Appendix A which currently precludes the use of half mask facepiece air purifying respirators for protection against plutonium or other high-toxicity materials is deleted. Half-mask respirators, if properly fitted, maintained and worn, provide adequate protection against plutonium if used within the limitations stated in the NIOSH approval and in the rule. The NRC has not identified any current technical or scientific basis for such a prohibition, and deletion may result in some reduction in regulatory burden because the change should increase operational flexibility. This is evaluated further in the value/impact analysis.

(5) The addition of single use, disposable respiratory protection devices (e.g., dust masks) to the proposed Appendix A recognizes the utility of disposables and formally permits their use with no protective credit allowed. These devices have minimal physiological impact, accommodate workers who request respirators (some States have OSHA rules which require providing respirators to workers who request them), NRC does not require fit testing or medical screening and although not quantifiable, they have been shown to provide some protection against intake. Although many of these devices cannot be tested for a measurable seal, licensees should train workers in their use and limitations. Use of such devices by persons desiring but not requiring respiratory protection (i.e., because of engineered control systems, or other factors) could result in substantial savings, and will be addressed further in the value/impact analysis.

(6) Permitting the use of "Reusable-Disposable" half-mask facepiece respirators, represents an acknowledgment of new developments in half-mask respiratory devices. This change permits increased use of these devices by licensees, and less use of more expensive respiratory protection by licensees. Reusable, reusable-disposable, or maintenance-free respiratory devices for use with radioactive material are relatively new variations on half-mask facepiece respirators. In these devices, the filter medium is an integral part of the facepiece and is not replaceable. The face-to-facepiece seal area is generally enhanced by the application of plastic or rubber. The devices have at least two adjustable suspension straps. These devices are acceptable to the NRC and are considered half masks as long as the following criteria are met: they are made of high efficiency filter media, they can be fit tested, and a fit check can be properly performed by the wearer upon donning. Since, under the proposed rule, these devices can replace more expensive respirators (primarily full facepiece respirators) their use has the potential for reducing the cost of the licensee's respiratory protection program. The use of such devices is addressed further in the value/impact analysis.

(7) The revision of Appendix A APF from 50 to 100 for air purifying, full face masks operating in negative pressure mode is consistent with ANSI Z88.2-1992 recommendations, and may result in increased flexibility (and reduced regulatory burden) for some licensees. This is addressed further in the value/impact analysis.

(8) Permitting the use of loose-fitting facepieces operated at continuous flow or positive pressure by NRC licensees (Appendix A) reflects ANSI Z88.2-1992 recognition of the limited effectiveness of these devices (APF = 25) but makes them available to NRC licensees for many uses. The change may result in some reduction in regulatory burden via increased flexibility, and is addressed further in the value/impact analysis.

(9) The reduction in the Appendix A APFs for half- and full-mask air-line respirators operating on continuous flow mode from 1,000 to 50, and from 2,000 to 1,000, respectively, reflects the current ANSI Z88 recommendations, and might result in some minimal increase in regulatory burden. The potential impacts are addressed below in the regulatory value/impact analysis.

(10) Addition of half mask air-line respirators in pressure demand mode (APF = 50) to Appendix A is expected to result in a reduction in regulatory burden due to increased flexibility in devices available to licensees, and is consistent with ANSI recommendations. This is discussed further in the value/impact analysis.

(11) Reduction of the Appendix A APF for full facepiece air-line respirators operating in pressure demand mode from 2,000 to 1,000, recommended by ANSI, is not expected to result in a significant increase in regulatory burden. Field concentration seldom presents a need for an APF of 2,000, as opposed to 1,000, and licensees may still petition NRC to use higher APFs based on measurement and documentation. The potential impacts are addressed below in the regulatory value impact analysis.

(12) Addition of the loose fitting facepiece in air-line respirators in continuous flow mode with an APF = 25 in Appendix A (as recommended by ANSI Z88.2) is expected to result in some reduction in regulatory burden due to increased flexibility in devices available to licensees. This is addressed below in the regulatory value/impact analysis.

(13) Addition of air-line suits with no APF to Appendix A merely sanctions the long term use of these suits in certain radiological environments where they are used primarily for protection against contamination (air is supplied). The addition might result in some decrease in regulatory burden (due to increased flexibility) by formally making the use of these devices acceptable to NRC. This clarifies the NRC position on the use of these devices for contamination protection, and licensees would be allowed to request higher APFs (i.e., for use as respiratory protection devices as well) by demonstration. This is addressed further in the value/impact analysis.

(14) Noble gases are excluded from respiratory protection considerations in footnote e of Appendix A by inclusion of a specific statement that noble gases are not an inhalation risk, and that external (submersion) doses are the proper basis for protective action. Some licensees have improperly assigned respirators as protection against exposure to these gases. Therefore, it is possible that some impacts may result to some licensees in order to revise their procedures. This will be addressed further in the value/impact analysis.

5. Value Impact Analysis

The value (benefit) and impact (cost) of the changes are estimated in this section. These estimates represent the best estimated incremental changes relative to the current baseline. It

is known from dosimetry reports that the existing respiratory protection rules as implemented are effective in protecting licensee's employees from inhalation exposure to airborne radioactive materials, and that these rule changes constitute a redefinition of acceptable respiratory protection. Although the changes marginally add to worker safety and health, there is no attempt to quantify added value or impact to employee health. Rather, the values and impacts of the changes are all related to potential saving or added cost in operating effective respirator programs at licensee sites. In making the estimates, the following general assumptions are made:

- There are about 250 licensees affected by the changes; 100 power reactor licensees and 150 non-power reactor licensees
- Labor cost is $145/hr for a power reactor licensee and $116/hr for other licensees
- NRC labor cost is estimated to be $70/hr
- Approximately 200,000 workers at licensee sites (primarily power reactors) are currently monitored for radiation exposure; about half of the monitored workers are exposed to a measurable dose; of those exposed to a measurable dose, about 10 percent/yr may use respirators (20,000)
- The most predominantly used respirators are the full mask negative pressure (NP) respirator, full mask positive pressure (PP) respirator or powered air-purifying respirator (PAPR), and full mask pressure demand (PD) Self Contained Breathing Apparatus (SCBA); no more than 10 percent currently use half-mask devices

These assumptions are made based on NRC data and on information obtained from industry experts on respiratory protection, licensees, and the Nuclear Energy Institute located in Washington, DC. The estimates and specific rationale used are presented below item by item following the same sequential order as the discussion in Section 4. A summary of the overall value and impact is presented at the end of this section.

(1) Elimination of Policy Statements

This change will save licensees the cost of preparing policy statements and also save NRC inspection staff from reviewing policy statements. It is assumed that about three licensees per year (one reactor licensee and two non-reactor licensees) would have prepared new policy statements in the future. Assuming that it would take 2.5 hours to prepare policy statements for a licensee, the cost saving per year would be:

($145/hr x 2.5 hr/licensee x 1 licensee) + ($116/hr x 2.5 hr/licensee x 2 licensees) ~ $1,000

Each licensee would also save the cost of an annual review of its policy statement. Assuming 0.25 hr for each review, for 250 licensees (100 reactor licensees and 150 non-reactor licensees), the annual saving would be:

($145/hr x 0.25 hr/review x 100 reviews/year) + ($116/hr x 0.25 hr/review x 150 reviews/year) = $7,975

In estimating NRC's cost saving, it is assumed that policy statements from 250 licensees would be inspected every year, at 0.1 hours per review. NRC's annual savings would be:

$70/hr x 0.1 hr/review x 250 reviews/year = $1,750/year

In addition, the three new policy statements prepared for NRC per year take NRC 0.5 hour each for review; at $70 per hour it will cost about $110/yr.

Total cost savings = $10,835/year

(2) Provision for Low-Temperature Usage

If a full-mask facepiece NP respirator is to be used for a low-temperature application, revised Regulatory Guide 8.15 recommends that the facepiece should be equipped with a nose cup. Nose cups can be purchased and installed in facepieces for about $30 each. Use of NP respirators in low temperature environment is expected to be rare at the present time; though such an application may increase if more nuclear power plants are undergoing decommissioning. It is assumed that five respirators equipped with nose cups would be required per year per licensee in areas where temperatures drop below zero degrees C (assumed about 80 percent of the total). In addition to equipment cost, the affected workers need to be trained to install and use the nose cup. Assuming 0.2 hr would be needed for training, the additional annual training for 100 x 0.8 = 80 reactor licensees would cost:

$145/hr x 80 licensees/year x 0.2 hr/licensee = $2,320/year

Similarly, if an equal number of non-reactor licensees required such training, the costs would also be:

$116/hr x 80 licensees/year x 0.2 hr/licensee = $1,856/year

Therefore, the total training cost will be $4,176/year.

Annualized cost of equipment for all the reactor licensees is estimated at (assuming 5-year depreciation):

$6/nose cup x 5 nose cups/reactor-year x 80 reactors= $2,400/year

Total cost of training and equipment would be: $6,576/year.

(3) Deletion of Requirement for First Time Notification of Respirator Usage
This change could result in cost savings for a few licensees and the NRC. For most current licensees, these notifications have already been made. However, to permit potential new licensees or decontamination and decommissioning efforts that would require respirator use to begin in the future, it was assumed that two licensees per year (one reactor and one non-reactor licensee) would prepare notifications at 0.5 hour per notification, the annual cost savings would be:

($145/hr x 1 licensee/year x 0.5 hr/licensee) + ($116/hr x 1 licensee/year x 0.5 hr/licensee) = $130.5/year

For NRC, the cost of reviewing two notifications would be saved. Assuming that 0.2 hour is required for each review, the annual cost savings would be:

$70/hr x 0.2 hr/licensee x 2 licensees/year = $28/year

Because this notification was intended to trigger an NRC inspection, these costs are also avoided. Assuming 2.5 hours per inspection, the savings would be:

$70/hr x 2.5 hr/licensee x 2 licensees/year = $350/year

Total savings would be about $508/year.

(4) Removing the Prohibition of Using Half-Mask NP Respirators for Protection Against Plutonium and Other Highly Toxic Radioactive Materials

NRC licensees, and particularly reactor licensees, do not normally handle plutonium and other highly toxic radioactive materials. When plutonium is handled, it is routinely done inside airtight glove box enclosures. In either case, the likelihood of exposure to airborne plutonium is very low. Respirators may be placed in the work area for contingency use. Allowing half-mask NP respirator use under such circumstance is not expected to result in any measurable cost savings, but may increase operational flexibility, and provides additional worker protection in the event of an unexpected release from confinement. Additional savings could result from the use of reusable/disposable respirators instead of half-mask respirators, and these uses are considered in section 7 for the major users of these traditional devices (power reactors). Savings in non-reactor facilities would not be expected to increase the cost savings calculated for power reactors substantially, because relatively few respirators are used in non-reactor facilities. However, savings could be in the range of several thousand dollars per year.

(5) Acknowledging the Use of Disposable Dust Masks with no APF

This change will formally acknowledge the utility of providing disposable dust masks to employees who request such equipment in the workplace where respiratory protection against airborne radioactive material may not be needed based on ALARA considerations. This practice would be consistent with state/OSHA requirements for providing respirators to workers when they request them. Under the current rule, if an employee (e.g., maintenance or operations worker) asks for a respirator where one is not needed, a half-mask (APF = 10) or full face-piece (APF = 50) NP respirator may be the minimum available under an NRC-approved respiratory protection program.

The current rule requires a medical exam and fit testing before the use of any respirator. If a disposable respirator is provided under the proposed rule, the employee would not need a medical examination or fit test. Permitting the use of a disposable mask without all of the requirements of an approved respirator program, such as medical examinations and fit tests, could save substantial costs to licensees (especially power reactor licensees) with no reduction in worker safety.

Respirator programs currently cost about $245 per employee per year for a reactor licensee and $216 per employee per year for a non-reactor licensee (assuming 1 hour of training and fit testing plus $100 for medical examination). Because almost all respirator use among NRC licensees are for reactor operations, non-reactor licensees can be ignored in the approximation. This does not include the costs for respirators, replacement due to wear and tear, replacement of filters, or cleaning and maintenance.

Currently, it is estimated that there are about 1,000 respirator uses/reactor-year, primarily during maintenance and refueling, or about 100,000 uses per year in the U.S. This number has probably gone down considerably, but data on the change is not available. It is assumed that about 90 percent of all respirators with APFs greater than 1.0 are full-face piece respirators (APF = 50), with the remaining 10 percent, half-face mask respirators (APF = 10). It is further estimated that of all these applications, only about 10 percent require (based on ALARA considerations) use of respirators with APFs greater than one (but less than 10), while the remaining 90 percent of uses could be satisfied by a disposable respirator (no allowed protection factor). Therefore, under new rule, about 90,000 traditional respirator uses could be replaced by disposables each year. Assuming 40 percent of all half or full facepiece respirator uses would be replaced by disposable respirators (40,000 per year, averaged over several years), the new rule would replace about 40,000 traditional respirator uses each year. Assuming the current industry maintains on the order of 500 respirators at each plant (50,000 respirators) which are used about 100,000 times per year, there would be about two uses per respirator per year.

Because of radiation protection concerns about contaminating the inside of respirators when they are removed after wear in contaminated environments, and worker's fears of breathing cold bacteria, or flu or AIDS viruses from used filters (some expired air will always exit through the filters and sneezing could spray a mist on them), industry generally uses each respirator only once before it is recycled for cleaning and filter replacement.

Further, assuming full face-piece and half-mask respirators last from 5 - 10 years (7.5 years on average) before being replaced, licensees would replace 50,000 respirators/7.5 years = 6,670 respirators per year. If these respirators were replaced by traditional respirators, the cost for half-mask ($25 each) and full-face mask ($150 each) respirators would be:

$$[(\$25 \times 0.1) + (\$150 \times 0.9)] \times 6{,}670 = \$917{,}125/\text{year}$$

The cost of replacing these traditional devices by disposable masks would be:

$$0.4 \times 100{,}000 \text{ masks/yr} \times \$0.8/\text{mask} = \$32{,}000/\text{year}$$

(i.e., the net savings would be about $885,125/year)

Assuming each worker uses a respirator two times per year, about 20,000 workers x 0.4 = 8,000 workers would be using disposable masks each year for the first time under the new rule. Assuming training on use of the new disposable respirators takes 0.2 hours/worker, the training costs would be:

$$\$145/\text{worker-hr} \times 0.2 \text{ hour} \times 8{,}000 \text{ workers/year} = \$232{,}000/\text{year}$$

For traditional respirator uses, if 5 percent of the work force is replaced each year, there would be about 1,000 new workers to train each year. Under the current regulations, that training cost would be:

$145/worker x 0.2 hours 1,000 workers = $29,000/year

Maintenance costs for disposable masks would be zero. However, the maintenance costs for traditional respirators would be substantial for the 40,000 uses each year which could be avoided by using disposable masks. Assuming only 5 minutes per mask for cleaning and replacement of the filter(s) and bagging, the costs would be:

40,000 uses/year x 5/60 hr/use x $145/hr = $483,300/year

The cost of replacing the filter(s) on traditional masks would be:

40,000 uses/year x $7/use = $280,000/year

Thus, the total cost for traditional respirators would be about $1.7 million/year

New procedures would only be required if disposable masks were to be used, the cost for all operating reactors, assuming 2 hours of preparation per plant, would be:

2 hrs/plant x 100 plants x $145/hr = $29,000 **the first year only**
(or $6,000/year over a period of 5 years)

Cost Savings From Permitting Use of Disposables

| Cost of Using Traditional Masks | | Cost of Change to Disposables | |
|---|---|---|---|
| Replacing worn-out or damaged half or full-face respirators | 917K | Cost of disposables | 32K |
| Training new users of traditional masks | 29K | Training on use of new disposables | 232K |
| Respirator Maintenance | 480K | Cost of writing new procedures | 6K |
| Filter Replacement | 280K | | |
| Total | 1706K | Total | 270K |

Thus the potential savings from permitting the use of disposables is about $1,436K.

(6) Permitting the Use of "Reusable-Disposable" Half-mask Facepiece Respirators

At the present time, essentially no power reactor licensees are using half–mask respirators in the NP mode (APF = 10). Current NRC guidance discourages the use of such devices as part of licensed activities because they must be checked for fit with irritant smoke each time they are put on. Thus, licensees typically use a more expensive full facepiece respirator in the NP mode

with an APF = 50, because they are not required to perform irritant smoke tests each time those devices are donned. Under the new rule change that requirement would be removed for half-masks, and licensees would have an opportunity to replace current full facepiece respirators with half-mask disposable or reusable-disposable respirators.

One of the newest types of half-face mask devices approved by NIOSH is the "reusable-disposable" half-mask respirator. These devices are substantially less costly than current half- or full-face masks and do not require any maintenance program, since they are simply discarded when wearers have completed their work. Thus, while less costly to purchase and maintain than full face-mask devices, the costs of new reusable-disposable facepiece respirators would mount up quickly under periods of heavy use. Thus, the value must be compared with the lifetime cost per use of the respiratory devices they might replace. Because the use of these half-mask respirators would require training and procedures comparable to current respirators, there are no expected cost reductions associated with their use except the initial purchase costs relative to the cost of maintaining and replacing worn-out half and full-face respirators. Because these respiratory devices will not be useful for as long as current more expensive full-or half-mask facepiece respirators (with an accepted maintenance program), the cost of replacing some part of the currently used, more costly facepieces should also be considered in the cost analysis for the proposed rule.

It is assumed that about 10 percent of all traditional respirators in use are half-mask devices with an APF = 10; that means that about 0.1 x 50,000 = 5,000 of these devices might be used per year. If, as above, they are used about 20 times per year, cost $25 each, and last about 7.5 years on average, replacement costs are about:

$25/mask / 7.5 year x 5,000 uses/year = $16,650/year

Cleaning costs for these traditional respirators, using the same assumptions as in 6) above, would be:

5,000 uses/year x 5/60 hr/use x $145/hr = $60,417/year

Filter replacement costs at about $7 per mask would be about:

5,000 uses/year x $7/use = $35,000/year

The cost of reusable/disposable respirators is on the order of $7 (or less) each. It is assumed that they would also be used only once before disposal for each time an APF greater than one is required. Thus, annual costs of using these devices in place of traditional respirators would be:

5,000 uses/year x $7/device = $35,000/year

Cost Savings For Permitting Use of Reusable-Disposable Masks

| Cost of Using Traditional Masks | | Cost of Change to Disposables | |
|---|---|---|---|
| Replacement Cost of traditional masks | 16.6K | Cost of Disposables | 35K |
| Maintenance/cleaning | 60.4K | | |
| Filter replacement | 35K | | |
| Total | 112K | Total | 35K |

Thus the potential annual cost savings from permitting the use of reusable-disposable half-masks is about 77K.

(7) Increasing APF from 50 to 100 for Full Mask NP Respirators

With the current rule, a full face PP respirator (PAPR or airline respirator) is needed to provide a protection factor greater than 50. By crediting a full mask NP respirator with an APF of 100, in theory, the more costly PAPR can be replaced by NP full face respirator. However, the practice among licensees is that PAPRs are provided for situations where a protection factor of 50 or more is needed. In other words, a licensee already has a stock of PAPRs that will provide assigned protection factors of up to 1,000 and the PAPRs are likely to be used in preference to full mask NP respirator. As such, no material benefit is expected from this change.

(8) Permitting the Use of Loose-fitting PAPRs with APFs of 25.

ANSI created this new category of devices to accommodate this less protective type of PAPR. The APF was downgraded from 1,000 (which it remains for FF and hood-type PAPRs). Since these devices are already being used in the nuclear industry, there is no expected impact on worker safety and licensee burden, and little opportunity for significant savings. This change simply recognizes this application and formally permits licensees more choices in selecting proper respiratory equipment for exposure situations where a protection factor of no greater than 25 is needed to safely perform the work.

(9) Reducing the APF from 1,000 to 50 for Half-Mask CF Air-line Respirators and Reducing the APF from 2,000 to 1,000 for Full-Mask CF Air-line Respirators

Reducing the APF from 1,000 to 50 for a half-mask CF air-line respirator would require the use of a full-mask to achieve an APF of 1,000 (if oxygen deficiency is not a problem in the work area). Because almost all licensees already have full masks in stock, this change is not expected to increase licensee costs of operation. If oxygen deficiency is a problem, a SCBA would have to be used. Again, since licensees are likely to have SCBAs in stock, there should be little cost impact to licensees.

(10) Adding Half-Mask PD Air-line Respirators with an APF of 50

This addition will provide flexibility in selecting respirators for situations where a protection factor of no greater than 50 is needed and where oxygen deficiency (but not IDLH) is a

problem. Cost savings as a result of this additional respirator are negligible since under the current rule there is no specific air-line respirator that will provide a protection factor of up to 50. In most cases, licensees would already have air-line respirators with an APF of 1,000 in stock anyway.

(11) Reducing the APF from 2,000 to 1,000 for Full-Mask PD Air-line Respirators

This change is made pursuant to ANSI recommendations and is intended to simplify the APF System. An assigned protection factor of 2,000 is unlikely to be needed (typical concentrations of radioactivity in the field are far less than 1,000 times the DACs). A licensee can still apply for a higher APF when situations and data warrant. Because this change does not change the current practice in respiratory protection among licensees, no significant value/impact is expected.

(12) Addition of Loose-Fitting CF Air-line Respirators with an APF of 25

The addition will increase a licensee's flexibility in selecting respirators for a protection factor of no greater than 25, where oxygen deficiency (but not IDLH) is a problem. Because no currently allowed air-line respirator is specifically designed to meet this situation, a licensee would have to use an air-line respirator with an APF of 1,000 under the current rule. The addition is not likely to change licensee practice in the immediate future and no significant value/impact is expected.

(13) Addition of Air-line Suit with no APF

This addition formally sanctions the use of air-line suits with no credit for inhalation exposure reduction (i.e., for protection against contamination only). This has been in practice for years without any reported problems. Simply making the existing unsanctioned practice acceptable should add no measurable impact or value to a licensee. However, because the change also allows licensees to request approval for higher APFs where they can be demonstrated, this change may provide more operational flexibility.

(14) Exclusion of Noble Gases from Respiratory Protection Considerations

This change is intended to avoid confusion on the part of licensees as to the requirements of Subpart H related to protection against noble gases. It is assumed that perhaps 5 percent of NRC power reactor licensees will be required to modify their procedures to exclude noble gases from respiratory protection considerations (i.e., about five licensees). If the revision requires 1 hour per licensee, the cost over the remaining life of their facility (assume 10 years) would be:

$145/hr x 1 hr/licensee x 5 licensees/10 years = $73/year

A summary of the estimated annual value and impact for each major change is presented below. Total annual increase in value is estimated to be $1,829,483 while the total added cost is estimated at $311,576 for net annual savings of $1,517,907.

6. Decision Rationale

1. All of the alternatives are acceptable according to generally accepted radiation protection principles expressed by NRC, NCRP, and ICRP.

2. Compared to practice under the current Part 20, Subpart H, each proposed change either involves no change in value/impact, or represents an improvement in regulatory protection of worker health and safety without any significant added costs (i.e., all value), or presents the potential for reductions in regulatory burden and/or increased operational flexibility with net savings to licensees and the NRC.

3. Many of the proposed changes only clarify existing requirements (i.e., reduce the potential for licensee misunderstandings) or formally adopt the current ANSI standard Z88-1992 (with a few exceptions) to which most licensees already comply.

| | PROPOSED CHANGE | VALUE (per year) | IMPACT (per year) |
|---|---|---|---|
| 1. | Eliminating Policy Statement | $10,835 | $0 |
| 2. | Provision for low temperature use | 0 | 6,576 |
| 3. | Eliminating first time notification requirement | 508 | 0 |
| 4. | Allowing half-mask for plutonium use | 0 | 0 |
| 5. | Disposable mask with no APF | 1,706,000 | 270,000 |
| 6. | Reusable-Disposable mask with APF = 10 | 112,067 | 35,000 |
| 7. | Increasing APF, 50 to 100. Full mask NP | 0 | 0 |
| 8. | Loose fitting PAPR with APF = 25 | 0 | 0 |
| 9. | Reducing APF, 1,000 to 50. Half-mask Air-line CF; Reducing APF, 2,000 to 1,000. Full-mask Air-line CF | 0 | 0 |
| 10. | Half-mask Air-line PD. APF = 50 | 0 | 0 |
| 11. | Reducing APF, 2,000 to 1,000. Full mask Air-line PD | 0 | 0 |
| 12. | Loose fitting Air-line. APF = 25 | 0 | 0 |
| 13. | Air-line suits. No APF | 0 | 0 |
| 14. | Exclusion of Noble Gases from Subpart H | 73 | 0 |
| | TOTAL VALUE/IMPACT | 1,829,483 | 311,576 |

# ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT ON AMENDMENTS OF 10 CFR PART 20, SECTION 20.1003, SUBPART H - "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS," AND APPENDIX A

ALAN K. ROECKLEIN
OFFICE OF NUCLEAR REGULATORY RESEARCH
U.S. NUCLEAR REGULATORY COMMISSION

February, 1999

## I. The Action

The Nuclear Regulatory Commission is amending its regulations regarding respiratory protection to make these regulations more consistent with the philosophy of controlling the sum of internal and external radiation exposure and to incorporate current and new guidance on respiratory protection from the American National Standards Institute (ANSI). The amendment would assure that recent technological advances in respiratory protection and devices are incorporated into NRC regulations and are available for use by NRC licensees.

The amendments focus on technical and procedural improvements in the use of respiratory protection devices. The changes recognize new devices that have been proven to be useful in protecting workers and revises Assigned Protection Factors (APFs) used to estimate the degree of protection afforded workers by respirators.

## II. Need for the Rulemaking Action

A major revision of 10 CFR Part 20, "Standards for Protection Against Radiation," was published in May of 1991. ANSI Z88.2-1992, "American National Standard for Respiratory Protection" was published by the American National Standards Institute in 1992. This document provided consensus guidance on the major elements of an acceptable respiratory protection program, including guidance on respiratory selection, training, fit testing, and assigned protection factors (APFs). Consistent with the publication of ANSI Z88.2-1992 the NRC is revising Subpart H of Part 20 to incorporate some of the provisions of ANSI Z88.2 1992.

## III. Alternatives Considered

The following alternatives to rulemaking have been considered.

Alternative 1: No Action

No regulatory action would save NRC staff time and would preclude the need for a licensee to revise its respiratory protection procedures. However, no action means NRC regulations would continue to be out of date, new devices that have been proven to be effective would not be recognized, new Assigned Protection Factors would not be codified and improved respiratory protection procedures would not be incorporated by the NRC.

The no action alternative would have no impact on the environment.

Alternative 2: Revise Regulatory Guidance Only

Regulatory guides are intended to assist licensees with complying with regulatory requirements. Several elements of a respiratory protection program are significant health and

safety issues and as such need to be codified as requirements. Regulatory guides do not establish requirements.

Revision of existing regulatory guidance only would have no impact on the environment.

## IV. Environmental Impacts of the Proposed Action and the Alternatives

The environmental impacts of the action as well as the alternatives are considered negligible by the NRC staff.

The amendment is entirely focused on technical and procedural improvements in the use of respiratory protection devices to maintain total occupational dose as low as is reasonable achievable. All of the impacts associated with this rulemaking are worker related, onsite with no effect on any places or entities off a licensed site. The net effect of this rulemaking is expected to be a decrease in the use of respiratory devices and an increase in engineering and other controls to reduce airborne contaminants in the workplace. It is expected that there would be no change in radiation dose to any member of the public as a result of the revised regulation.

## V. Finding of No Significant Environmental Impact

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments are not a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

The Commission believes that these amendments would result in benefits to workers, flexibility to licensees and would continue to adequately protect public health and safety. There

will be no change in radiation exposure to the public or to the environment due to the proposed rule changes.

## VI. List of Agencies and Persons Consulted

Much of the technical information required for this rulemaking was obtained directly from technical experts both within and outside the NRC. The following individuals were contacted for technical information:

K. Paul Steinmeyer, Radiation Safety Associates, Inc.

Robert daRosa, Lawrence Livermore Laboratory, (Retired)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Joe L. Barton
Chairman, Subcommittee on Energy
Committee on Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a Press Release and a final amendment to 10 CFR Part 20 dealing with respiratory protection and other controls to restrict internal exposure of radiation workers. The amendment will be published in the Federal Register. The new rules will become effective 120 days from the date of publication.

These amendments are based on guidance developed by the American National Standards Institute and are consistent with new respiratory protection regulations published recently by the Occupational Safety and Health Administration (OSHA). These amendments provide greater assurance that recent technological advances in respiratory protection equipment and procedures are reflected in NRC regulations, and that worker's exposures will be maintained as low as is reasonably achievable.

The rules redefine the level of adequate protection, establish a less prescriptive framework and are estimated to reduce licensee burden by about $1.5 million per year with no reduction in worker health or safety. The Commission's rule is consistent with the general mandate of the Technology Transfer and Advancement Act of 1995 (Public Law 104-113) to utilize consensus standards.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Federal Register Notice
2. Press Release

cc: Representative Ralph M. Hall

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Chairman, Subcommittee on Energy
Committee on Commerce
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

Mr. Robert P. Murphy
General Counsel
General Accounting Office
Room 7175
441 "G" Street, N.W.
Washington, DC 20548

Dear Mr. Murphy:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a final rule amending its regulations in 10 CFR Part 20 dealing with respiratory protection and other controls to restrict internal exposure of radiation workers. The amendment will be published in the Federal Register. The new rules will become effective 120 days from the date of publication.

We have determined that this rule is not a "major rule" as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

Enclosed is a copy of the final rule that is being transmitted to the Office of the Federal Register for publication. The Regulatory Flexibility Certification is included in the final rule.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Final Rule

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WASHINGTON, D.C. 20555-0001

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States Senate
Washington, DC 20510

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable J. Dennis Hastert
Speaker of the United States
House of Representatives
Washington, DC 20515

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## NRC ISSUES FINAL REVISIONS TO REGULATIONS ON RESPIRATORY PROTECTION

The Nuclear Regulatory Commission (NRC) is amending its regulations governing the use of respiratory protection equipment and other controls to restrict internal exposure.

The revised rules provide greater assurance that workers' radiation exposures will be maintained as low as is reasonably achievable and approve for licensee use advances in respiratory protection equipment and procedures. The new rules are more performance based, more flexible and easier to implement. The NRC believes the new rules will save licensees about $1.5 million per year, with no reduction in worker health and safety.

When the Commission's overall radiation protection regulations were significantly revised in 1992, the rules for respiratory protection were not similarly revised because the American National Standards Institute (ANSI) was working on consensus guidance in this area. The ANSI guidance, "American National Standard Practice for Respiratory Protection," is now available and is essentially the technical basis for this rule. The Commission's rule is consistent with the general mandate of the Technology Transfer and Advancement Act of 1995 (Public Law 104-113) to utilize consensus standards. The new rules are also consistent with new respiratory protection regulations published recently by the Occupational Safety and Health Administration (OSHA).

The changes emphasize the use of process or engineering controls, decontamination of work areas, access controls, and other procedures instead of the use of respiratory protection devices, which tend to increase external radiation doses and worker stress.

The rules also recognize new respiratory protection devices that have been proven effective, discourage the use of other devices that are now considered less effective based on field tests, and revise requirements for respiratory protection procedures such as testing to evaluate the fit of a respirator on a particular individual.

The rules also revise the "assigned protection factors" --expected workplace levels of respiratory protection that would be provided to properly fitted and trained users by properly functioning respirators--to be consistent with ANSI evaluations.

Further details of the final rules are contained in a Federal Register notice to be published shortly.

# # # #