applies, such individual shall, unless otherwise authorized by the Chairman or the General Counsel, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this regulation.

(c) A person who desires testimony or other statement from any person to whom this part applies may make written request therefor, verified by oath, directed to the Chairman setting forth his or her interest in the matter to be disclosed and designating the use to which such statement or testimony will be put in the event of compliance with such request: provided, that a written request therefor by an official of any federal, state or tribal entity, acting in his or her official capacity need not be verified by oath. If it is determined by the Chairman or the General Counsel that such statement or testimony will be in the public interest, the request may be granted. Where a request for a statement or testimony is granted, one or more persons to whom this part applies may be authorized or designated to appear and testify or give a statement with respect thereto.

§ 516.3 When may a person to whom this part applies produce records?

(a) Any request for records of the National Indian Gaming Commission shall be handled pursuant to the procedures established in 25 CFR parts 515 and 517 and shall comply with the rules governing public disclosure as provided in 25 CFR parts 515 and 517.

(b) Whenever a subpoena duces tecum commanding the production of any record has been lawfully served upon a person to whom this part applies, such person shall forward the subpoena to the General Counsel. If commanded to appear in response to any such subpoena, a person to whom this part applies shall respectfully decline to produce the record on the ground that production is prohibited by this part and state that the production of the record(s) of the National Indian Gaming Commission is a matter to be determined by the Chairman or the General Counsel.

§ 516.4 How are records certified or authenticated?

(a) Upon request, the person having custody and responsibility for maintenance of records which are to be released under this part or 25 CFR parts 515 or 517 may certify the authenticity of copies of records that are requested to be provided in such format.

(b) A request for certified copies of records or for authentication of copies of records shall be sent to the National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005, Attention: Freedom of Information Act Officer.

Authority and Signature

This proposed rule was prepared under the direction of the Commissioners, National Indian Gaming Commission, 1441 L St. NW, Suite 9100, Washington DC 20005.

Signed at Washington, DC this 28th day of September, 1999.

Montie R. Deer,

Chairman, National Indian Gaming Commission.

[FR Doc. 99–25747 Filed 10–6–99; 8:45 am]

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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 Occupational Safety and Health Administration (OSHA's) respiratory protection rule, and make NRC requirements for radiological protection less prescriptive while reducing unnecessary regulatory burden 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: February 4, 2000.

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 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 adopt 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 some minor 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.

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 unless a licensee commits to use specific regulatory guides in its license. Although many materials licensees and some nuclear power plant licensees do commit to use specific regulatory guidance, thus making the guidance enforceable, it is not required that all licensees incorporate regulatory guides.

In addition, APFs, as established by ANSI, are considered to be the maximum allowable measure of protection associated with each respirator type and mode of operation. These measures are used to select a licensee's inventory of available respiratory protection devices as well as to select respirators for a particular job. The NRC believes it is important to worker safety that APFs not be flexible as they might be if they were contained only in regulatory guidance.

During the information collection phase of this rulemaking, the NRC staff was advised by several licensees that they would hesitate to use a device unless it were specifically ''permitted'' in the NRC regulations. Appendix A is needed in the regulation to specify those respiratory devices that are permitted to be used in an NRC licensed facility. For example, quarter facepieces although approved by NIOSH and ANSI, are not permitted for use in NRC licensed facilities. On the other hand, air-supplied suits, that are not tested or certified by NIOSH or listed in ANSI, are in Appendix A to Part 20 thus permitting their use by licensees.

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 limitations of the devices and correct methods of use are required.

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 that will not be 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 e 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 on filtering facepiece respirators 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 Immediately Dangerous to Life and Health (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 ≥ 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,* that are under the control of the respirator wearer, are 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 most 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.

In May of 1991 the Commission published a major revision to 10 CFR Part 20 that required a licensee to implement and maintain a respiratory protection program that includes * * * Determination by a physician* * * that the individual user is physically able to use the respiratory protection equipment.'' In the statement of considerations for that final rule, the Commission noted ''* * *the decision on the physical ability of an individual to wear a respirator is a subjective judgement that in the Commission's opinion, requires the decisionmaker to have a medical degree.'' In 1995 the Commission reaffirmed this position in a rulemaking that revised the required frequency of medical examination. However, the statement of considerations for that rulemaking stated ''* * *The NRC staff believes that physicians need not administer each test personally, but that the physician may designate someone such as an office nurse to certify medical fitness as long as it is clear that the physician is ultimately responsible for

the fitness determination. Likewise the NRC staff believes that the physician should be involved in the supervision of the fitness program, the review of overall results and individuals cases that fall outside certain physician determined parameters, and supervision of personnel performing the tests.''

This position is in agreement with ANSI recommendations as stated in ANSI—Z88.6 1984. Regulatory Guide 8.15, Rev. 1, ''Acceptable Programs for Respiratory Protection states that, ''The medical evaluation program should be carried out by the physician, or 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 judgement of the licensee's physician, has adequate experience, education, training, and judgement to administer the screening program.'' This is consistent with OSHA's regulations that permit a ''licensed health care professional'' to administer the fitness screening program.

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 immediately 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. Any other differences between the ANSI recommended APFs and those specified by the NRC in the proposed rule have been eliminated in this final rule in the interest of providing greater consistency with ANSI recommendations.

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. ANSI recommended a fit factor of 100 for these devices but OSHA selected 500 to provide an additional safety margin. The NRC staff agrees with the OSHA position and in the interest of consistency is specifying 500. 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, 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. Licensees who possess radioactive material in a form that requires a respiratory protection program are expected 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 l 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 l 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. 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. The Regulatory Analysis further concludes that compared to the practice under the current Part 20, Subpart H, each 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.

Many of the changes only clarify existing requirements (i.e., reduce the potential for licensee misunderstandings) or formally adopt recommendations of the current ANSI standard Z88.2–1992.

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 affect 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, Public Law 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 recommendations from 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* (*fit 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.

* * * * *

Subpart H—Respiratory Protection and Controls to Restrict Internal Exposure

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 a 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 immediately 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 in publication G–7.1, ''Commodity Specification for Air,'' 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include—

(1) Oxygen content (v/v) of 19.5–23.5%;

(2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(3) Carbon monoxide (CO) content of 10 ppm or less;

(4) Carbon dioxide content of 1,000 ppm or less; and

(5) Lack of noticable odor.

(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 to subpart H 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	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	[i] 100
Facepiece, full	Pressure Demand	[i] 10,000
Facepiece, full	Demand, Recirculating	[i] 100
Facepiece, full	Positive Pressure Recirculating	[i] 10,000
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 30th day of September, 1999.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Acting Secretary of the Commission.

[FR Doc. 99–25977 Filed 10–6–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 226–165a; FRL–6448–5]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Santa Barbara County Air Pollution Control District and South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan. This action revises Santa Barbara County Air Pollution Control District (SBCAPCD) Rule 102, Definitions, to include text that was inadvertently omitted and revises the volatile organic compound (VOC) definition in South Coast Air Quality Management District (SCAQMD) Rule 102, Definition of Terms. The intended effect of approving this action is to incorporate changes to the definitions for clarity and consistency with revised federal and state definitions.

DATES: This rule is effective on December 6, 1999, without further notice, unless EPA receives adverse comments by November 8, 1999. If EPA receives such comment, then it will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments must be submitted to Andrew Steckel at Region IX office listed below. Copies of these rules, along with EPA's evaluation report for each rule, are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted requests for rule revisions are also available for inspection at the following locations:

Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW, Washington, DC 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95814

Santa Barbara County Air Pollution Control District, 26 Castilian Drive B–23, Goleta, California 93117

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765

FOR FURTHER INFORMATION CONTACT: Cynthia G. Allen, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone (415–744–1189).

SUPPLEMENTARY INFORMATION:

I. Applicability

The rules being approved into the California SIP are: SBCAPCD Rule 102, Definitions, and SCAQMD Rule 102, Definition of Terms, submitted on May 13, 1999 by the California Air Resources Board.

II. Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included Santa Barbara County and the South Coast Air Basin, see 43 FR 8964, 40 CFR 81.305. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the Santa Barbara County APCD and South Coast AQMD portions of the California SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP–Call). In response to the SIP call and other requirements, the SBCAPCD and SCAQMD submitted many rules which EPA approved into the SIP.

This document addresses EPA's direct-final action for SBCAPCD Rule 102, Definitions, and SCAQMD Rule 102, Definition of Terms. These rules were adopted by SBCAPCD and SCAQMD on January 21, 1999 and June 12, 1998, respectively. These rules were found to be complete on June 10, 1999, pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, appendix V [1] and is being finalized for approval into the SIP. These rules were originally adopted as part of SBCAPCD and SCAQMD's efforts to achieve the National Ambient Air Quality Standards (NAAQS) for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement.

The following is EPA's evaluation and final action for these rules.

III. EPA Evaluation and Action

In determining the approvability of a rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements appears in various EPA policy guidance documents.[2]

EPA previously reviewed many rules from the SBCAPCD and SCAQMD agencies and incorporated them into the federally approved SIP pursuant to section 110(k)(3) of the CAA. The following revisions were made in SBCAPCD and SCAQMD definitions rule:

Santa Barbara County APCD

On March 26, 1999, EPA approved into the SIP a version of Rule 102, Definitions that had been adopted by SBCAPCD on March 10, 1998. SBCAPCD submitted Rule 102, Definitions includes the following changes from the current SIP:

Rule 102 has been revised by reinserting text inadvertently omitted during the April 1997 comprehensive revisions to the District's permitting regulations.

South Coast AQMD

On March 26, 1999, EPA approved into the SIP a version of Rule 102, Definition of Terms that had been adopted by SCAQMD on June 13, 1997. SCAQMD submitted Rule 102, Definitions of Terms includes the following changes from the current SIP:

The March 13, 1998 amendments add difluoromethane (HFC-32), 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxy-butane ($C_4F_9OCH_3$), 2-(difluoromethoxymethyl)-1,1,1,2,3,3,3-heptafluoropropane [$(CF_3)_2CFCF_2OCH_3$], 1-ethoxy-1,1,2,2,3,3,4,4,4-nonafluorobutane ($C_4F_9OC_2H_5$), and 2-(ethoxydifluoromethyl)-1,1,1,2,3,3,3-heptafluoropropane [$(CF_3)_2CFCF_2OC_2H_5$]

[1] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section (110)(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

[2] Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviation, Clarification to appendix D of November 24, 1987 **Federal Register** document'' (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).