



# RULEMAKING ISSUE

## (Affirmation)

August 5, 1999

SECY-99-207

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations

SUBJECT: FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT  
INTERNAL EXPOSURES, 10 CFR PART 20"

### PURPOSE:

To obtain the Commission's approval to publish a final rule in the Federal Register that amends 10 CFR Part 20. The amendments recognize new respiratory protection devices and procedures that have been proven effective, adopt new national consensus standards from the American National Standards Institute (ANSI), conform NRC requirements to new Occupational Safety and Health Administration (OSHA) regulations, reduce licensee burden without reducing worker safety, and are consistent with the Commission's intent to promulgate performance-based rules.

### BACKGROUND:

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

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

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

#### DISCUSSION:

This revision to the respiratory protection requirements contained in Part 20 reaffirms the Commission's intent to apply ALARA principles to the sum of external and internal doses and to reduce the use of respirators when their use may cause more risk. The use of process or engineering controls, decontamination of work areas, access control, and other procedures are stressed. The automatic use of respiratory protection devices, which tends to increase worker external dose and stress, would be reduced correspondingly.

The final rule also recognizes new respiratory protection devices that have been proven effective, adopts new Assigned Protection Factors (APFs) based on ANSI determinations, and revises requirements for respiratory protection procedures, such as fit testing, to reflect current industry good practice and to conform to new regulations publishing by OSHA. The changes are believed by the staff to be a reduction of unnecessary regulatory burden that may save NRC licensees an estimated 1.5 million dollars per year. The rule is considerably less prescriptive while the staff believes that it will result in a reduction in risk to worker health and safety.

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

1. The rule clarifies that a respiratory protection program is required if a licensee issues respiratory protection equipment to limit the intake of radioactive material. Some licensees have misunderstood the intent of the existing rule and believe that a respiratory protection program is needed only if the licensee "takes credit" for the use of respirators in estimating dose.
2. The rule makes extensive changes to Appendix A to 10 CFR Part 20. Appendix A lists the respirator types considered acceptable by the NRC and lists the Assigned Protection Factors (APFs) (i.e., approved measures of respirator effectiveness). The current list is out of date. Some new and effective devices are not recognized in the Appendix and many of the APFs are no longer correct. The major changes to Appendix A, discussed in more detail in the Federal Register notice, are listed here.
  - Several footnotes that contain general programmatic requirements are moved to the body of the rule. Several are deleted because they are considered to be redundant with the National Institute of Occupational Safety and Health (NIOSH) certification requirement.

- Several devices, such as single-use disposable and air-supplied suits, are now recognized as being useful in respiratory protection and are listed with no APFs to provide licensees with greater flexibility in selecting respirators when limiting the intake of radioactive material is not the primary concern.
  - Several APFs are revised to be consistent with the new ANSI guidance.
3. The rule specifies the "fit factors" that licensees need to achieve in fit tests in order to apply the APFs specified for different types of devices pursuant to ANSI guidance and to be consistent with OSHA. The rule also specifies the frequency of fit testing. The NRC staff is retaining a requirement for a retest frequency not to exceed 1 year. The proposed rule had specified a retest frequency not to exceed 3 years. Several public commenters had objected to this proposal and recent OSHA regulations retained the one year retest frequency. The NRC staff decided not to change the currently required annual retest.
  4. The rule deletes the current requirement for licensees to issue a written policy statement on respiratory protection because the staff believes that all of the essential elements addressed by a policy statement are already addressed in required written licensee procedures. This change results in some reduction of unnecessary burden.
  5. The rule deletes a requirement that a licensee notify in writing the director of the NRC Regional Office 30 days before the date that respiratory protection is first used. The only purpose of this notification was to alert inspectors of the need to look at a licensee's respiratory protection program. This requirement contributes little to worker safety. This change results in a minor reduction of unnecessary burden.

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

A Regulatory Analysis (Attachment 2) was prepared to evaluate the cost/benefit of the proposed rulemaking. This analysis concludes that a cost reduction for all affected licensees on the order of 1.5 million dollars per year will result from the rule changes. The cost savings are found to result from permitting the use of low-cost disposable masks rather than more expensive half-masks, deleting a requirement to issue a policy statement, and deleting the report to the region on startup of a respiratory program.

An environmental assessment (Attachment 3) was performed and concluded that the amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. This finding is based on the observation that the amendments are focused on technical and procedural improvements in the use of respiratory protection devices and that all of the impacts occur on site with no effect on any places or entities off the licensed site.

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

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

RESOURCES:

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

COORDINATION:

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

RECOMMENDATION:

That the Commission:

1. Approve the notice of final rulemaking for publication (Attachment 1).
2. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. NOTE:
  - a. The rulemaking would be published in the Federal Register to become effective 120 days after publication;
  - b. A Regulatory Analysis will be available in the Public Document Room (Attachment 2);
  - c. An Environmental Assessment and a finding of no significant impact have been prepared (Attachment 3);
  - d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act;
  - e. The appropriate Congressional committees will be informed (Attachment 4);

- f. A press release will be issued (Attachment 6); and
- g. Copies of the Federal Register notice of final rulemaking and the Regulatory Guide revision will be distributed to all Commission licensees likely to use respiratory protection and each Agreement State. The notice will be sent to other interested parties upon request.



William D. Travers  
Executive Director  
for Operations

Attachments:

1. Federal Register Notice
2. Regulatory Analysis
3. Environmental Assessment
4. Congressional Letters
5. Congressional Review Act Forms
6. Press Release

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Monday, August 23, 1999.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT August 16, 1999, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for affirmation at an Open Meeting during the Week of August 23, 1999. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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**ATTACHMENT 1**

**FEDERAL REGISTER NOTICE**

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-AF81

Respiratory Protection and Controls to Restrict Internal Exposures

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the use of respiratory protection and other controls to restrict intake of radioactive material. The amendments make these regulations more consistent with the philosophy of controlling the sum of internal and external radiation exposure, reflect current guidance on respiratory protection from the American National Standards Institute (ANSI), are consistent with recently effective revisions to OSHA's respiratory protection rule, and make NRC requirements for radiological protection less prescriptive 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: (Insert date 120 days from date of publication in FR).

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

SUPPLEMENTARY INFORMATION:

I. Background

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

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

After 10 CFR Part 20 was revised, the American National Standards Institute approved publication of ANSI Z88.2-1992, "American National Standard for Respiratory Protection". This document provides an authoritative consensus on major elements of an acceptable respiratory protection program, including guidance on respirator selection, training, fit testing, and assigned protection factors (APF). The NRC is amending Subpart H of Part 20 to make the regulations less prescriptive without reducing worker protection. This rule is consistent with the 1992 ANSI guidance and is consistent with new regulations on respiratory protection published by the Occupational Safety and Health Administration (OSHA).

## II. Analysis of Public Comments and Staff Response

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

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

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

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

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

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

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

In addition, the NRC regulation includes the Assigned Protection Factors (APFs) recommended by the American National Standards Institute (ANSI) with some modifications. Because, in radiological applications, using APFs to generate an estimate of intake of radioactive materials is an acceptable method to demonstrate compliance with NRC dose limits, APFs must be included in the regulation. However, OSHA rules do not specify APFs because this section of the OSHA rules is still under development.

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

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

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

With changes to the proposed rule discussed here, 10 CFR Part 20, Subpart H will be consistent in almost all respects with ANSI guidance. The final Regulatory Guide 8.15,

“Acceptable Programs for Respiratory Protection”, will endorse, with 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. There is little practical difference between a 5 and a 100, and, because a higher fit factor will then be required for their use, workers will not be put at greater risk.

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

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

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

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

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

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

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

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

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

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

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

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

A commenter questioned the statement in footnote 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 in the negative or positive pressure mode.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The commentator 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 commentator states that the term “adequate communication” in § 20.1703(e) may be difficult to demonstrate due to the limited communication 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 commentator questioned the requirement in § 20.1703(f) for “direct” communication between the standby rescue person and the worker because it might be necessary for the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### III. Summary of Changes

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

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

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

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

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

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

The term "limit intake of radioactive material" is not specifically defined in this rule. The licensee must determine whether the use of a respirator for protection against non-radiological airborne hazards or at the request of a worker also limits the intake of radioactive material. If so a §20.1703 program is required. An acceptable approach is for the licensee to evaluate the existing or potential airborne concentrations of radioactive material (from routine operations, likely operational occurrences, 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"  $\geq 10$  times the APF is required for tight fitting, negative pressure devices. A fit factor  $\geq 500$  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. All licensees who possess radioactive material in a form that requires a respiratory protection program are required to submit a program description during the license application, amendment, or renewal processes. Their programs would be reviewed during this process. A 30-day notification requirement imposes a needless administrative burden on licensees with no increase in worker health and safety. This change is considered to be a burden reduction.

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

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

regulatory requirements, previously contained in footnotes in Appendix A, have been moved to the text of Part 20.

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

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

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

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

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

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

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

Footnote d.2(b) stated that APFs are applicable for air-purifying respirators only when high-efficiency particulate filters are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards. This statement is revised and included in footnote b to say that if using a respirator with an APF less than 100, a filter with a minimum efficiency of 95 percent must be used. Air purifying respirators with APF = 100 must use a filter with an efficiency rating of at least 99 percent. Respirators with APF > 100 must use filters with at least 99.97 percent efficiency. Further guidance is provided in Regulatory Guide 8.15 and NUREG-0041. The definitions of filter types and efficiencies are discussed in the revisions of Regulatory Guide 8.15 and NUREG-0041.

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

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

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

Footnote f stated that canisters and cartridges for air purifying respirators will not be used beyond service-life limitations. This observation restates a NIOSH approval criterion and is more appropriate to guidance than to the regulations. This footnote is removed. Service life limitations are addressed in Regulatory Guide 8.15 and NUREG-0041.

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

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

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

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

Footnote h provided several conditions on air-flow rates necessary to operate supplied air hoods effectively. Because all of these requirements are elements of the NIOSH approval

criteria, they are redundant and are removed. These NIOSH requirements are discussed further in the revision to NUREG-0041.

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

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

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

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

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

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

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

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

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

Although ANSI suggested an APF = 10 for all half-mask filtering facepiece disposable respirators, disposables that do not have seal-enhancing elastomeric components and are not equipped with two or more adjustable suspension straps are permitted for use but do not have an APF assigned (i.e., no credit may be taken for their use). The NRC believes that without these design features it is difficult to maintain a seal in the workplace. These devices have little

physiological impact on the wearer, may be useful in certain situations, and they may accommodate workers who request respiratory protection devices as is required by OSHA. Medical screening is not required for each individual prior to use because the devices impose very little physiological stress. In addition, fit testing is not required because an APF is not specified (i.e., no credit may be taken for their use). However, all other aspects of an acceptable program specified in § 20.1703 are required including training of users in the use and limitations of the device. The NRC believes that this provision allows the flexible and effective use of these devices without imposing conditions that are burdensome.

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

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

The APF for full facepiece air purifying respirators operating in the negative pressure mode is increased from 50 to 100. This change is consistent with ANSI recommendations based on review of industry test results. Appendix A previously listed a protection factor of 50 because one design that was tested at Los Alamos in 1975 did not meet the protection factor criterion of 100. This device is no longer available.

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

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

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

The APFs for half-and full-facepiece air-line respirators operating on continuous flow are reduced from 1,000 to 50 and from 2,000 to 1,000 respectively. The APF for a full facepiece air-line respirator operating in pressure-demand mode is reduced from 2,000 to 1,000. These changes are based on ANSI recommendations and the results of field and laboratory experiences indicating that these devices are not as effective as originally thought. This change is expected to have little impact on licensees because typical workplace concentrations encountered are far less than 1000 times the derived air concentrations (DACs). However, licensees may apply for higher APFs if needed and justified. A half-mask air-line respirator operating in pressure-demand mode is added to Appendix A with an APF of 50 based on ANSI recommendations. The helmet/hood air-line respirator operating under continuous flow is retained with the APF listed as 1,000. Footnote h which specified NIOSH certification criteria for flow rates is removed. The criteria for air flow rates are part of the NIOSH approval and are addressed in the revision to NUREG-0041.

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

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

accordance with § 20.1703(b). Requirements for standby rescue persons apply to operations where these devices are used (§ 20.1703(f)).

In Appendix A to Part 20, APFs for SCBA devices remain unchanged except for those operating in demand or demand recirculating modes. APFs for these two devices have been changed from 5 to 100 to be consistent with ANSI and in response to public comment. Use of SCBA in demand open circuit and demand recirculating mode requires considerable caution. In the NRC's view, the performance level and reliability of these devices in the demand mode is questionable. The chance of facepiece leakage when operating in the negative pressure mode is considerably higher than when operating in a positive pressure mode. This is especially critical for devices that could be mistakenly used in immediately dangerous to life and health (IDLH) areas during emergency situations. Although ANSI lists relatively high APFs for these devices, they are not recommended by the NRC for use and acceptable alternative devices are readily available. Footnote h requires that controls be implemented to assure that these devices are not used in IDLH areas.

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

#### IV. Issue of Compatibility for Agreement States

In accordance with the Policy Statement on Adequacy and Compatibility of Agreement State Programs published September 3, 1997 (62 FR 46517) and implementing procedures,

the modifications to § 20.1701 through § 20.1703 (except 20.1703(c)(4)), have health and safety significance and Agreement States should adopt the essential objectives of these rule modifications. Therefore, these provisions are assigned to the "Health and Safety (H&S)" category. The definitions (added to § 20.1003), of Air Purifying respirator, Atmosphere-supplying respirator, Assigned Protection Factor (APF), Demand respirator, Disposable respirator, Fit factor, Fit test, Filtering facepiece (dust mask), Helmet, Hood, Loose-fitting facepiece, Negative pressure respirator, Positive pressure respirator, Powered air-purifying respirator, Pressure demand respirator, Qualitative fit test, Quantitative fit test, Self-contained breathing apparatus, Supplied-air respirator, Tight-fitting facepiece, and User seal check (fit check), because of their precise operational meanings, are designated as compatibility category B to help insure effective communication and to promote a common understanding for licensees who operate in multiple jurisdictions. Therefore, Agreement States should adopt definitions that are essentially identical to those of NRC.

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

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

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

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the

amendments are not a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

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

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

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

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

## VI. Paperwork Reduction Act Statement

This final rule decreases the burden on licensees by eliminating reporting requirements in § 20.1703(a)(4) and (d). The burden reduction for this information collection is estimated to be 250 hours annually. Because the burden reduction for this information collection is insignificant, compared to the overall burden of 10 CFR Part 20, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-0014.

## VII. Public Protection Notification

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

## VIII. Regulatory Analysis

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

## IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that, this rule will not have a significant economic impact on a substantial number of small entities. The anticipated impact of the changes will not be significant because the revised regulation basically represents a continuation of current practice. The benefit of the rule is that it provides relief from certain reporting and recordkeeping requirements, incorporates several ANSI recommendations for improved programmatic procedures, and permits the use of new, effective respiratory devices, thus increasing licensee flexibility.

## X. Backfit Analysis

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

The Regulatory Analysis that was prepared for this rule concluded that the rule would result in a net benefit to industry of about \$1.5 million dollars per year, including the cost of revising procedures. The largest savings result from eliminating the need for a written policy statement and permitting the use of disposable, filtering facepieces instead of more expensive respirators. For most of the other changes made in this final rule, the costs of implementing the change are equal to the estimated cost savings. 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 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, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule the NRC is using the following voluntary consensus standard, "American National Standard for Respiratory Protection," (ANSI Z88.2), American National Standards Institute, 1992.

### List of Subjects in 10 CFR Part 20

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

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

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

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

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

2. Section 20.1003 is amended by adding the definitions Air-purifying respirator, Assigned protection factor (APF), Atmosphere-supplying respirator, Demand respirator, Disposable respirator, Filtering facepiece (dust mask), Fit factor, Fit test, Helmet, Hood, Loose-fitting facepiece, Negative pressure respirator, Positive pressure respirator, Powered air-purifying respirator (PAPR), Pressure demand respirator, Qualitative fit test (QLFT), Quantitative fit test (QNFT), Self-contained breathing apparatus (SCBA), Supplied-air respirator (SAR) or airline respirator, Tight-fitting facepiece and User seal check (in alphabetical order) to read as follows:

§ 20.1003 Definitions.

\* \* \* \* \*

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

*Assigned protection factor (APF)* means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to

properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

*Filtering facepiece (dust mask)* means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

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

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

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

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

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

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

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

sufficient number of standby rescue persons must be available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

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

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

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

6. Section 20.1704 is revised to read as follows:

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

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

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

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

7. Section 20.1705 is added as follows:

§ 20.1705 Application for use of higher assigned protection factors.

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

- (a) Describes the situation for which a need exists for higher protection factors; and
- (b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

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

APPENDIX A TO PART 20

ASSIGNED PROTECTION FACTORS FOR RESPIRATORS<sup>a</sup>

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

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

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

- b. Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs > 100 must be equipped with particulate filters that are at least 99.97 percent efficient.
- c. The licensee may apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).
- d. Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in § 20.1703 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.
- e. Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.
- f. The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.
- g. No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., § 20.1703).

- h. The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).
- i. This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

Dated at Rockville, Maryland this \_\_\_ day of \_\_\_\_\_, 1999.

For the Nuclear Regulatory Commission.

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Annette Vietti-Cook,  
Secretary of the Commission.

**ATTACHMENT 2**

**REGULATORY ANALYSIS**

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

January 29, 1999

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Attachment 2

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## 1. Statement of the Problem

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

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

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

## 2. Objectives of the Rulemaking

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

## 3. Alternatives

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

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

## 4. Consequences

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 5. Value Impact Analysis

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

is known from dosimetry reports that the existing respiratory protection rules as implemented are effective in protecting licensee's employees from inhalation exposure to airborne radioactive materials, and that these rule changes constitute of respiratory protection. Although the changes marginally add to worker safety and health, there is no attempt to quantify added value or impact to employee health. Rather, the values and impacts of the changes are all related to potential saving or added cost in operating effective respirator programs at licensee sites. This analysis considers both power reactor licensees and materials licensees, and impacts and benefits of the new rules on respiratory protection programs are considered to be the same for both types of licensees. In making the estimates, the following general assumptions are made:

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

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

#### (1) Elimination of Policy Statements

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

$$(\$145/\text{hr} \times 2.5 \text{ hr}/\text{licensee} \times 1 \text{ licensee}) + (\$116/\text{hr} \times 2.5 \text{ hr}/\text{licensee} \times 2 \text{ licensees}) \sim \$1,000$$

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

$$(\$145/\text{hr} \times 0.25 \text{ hr}/\text{review} \times 100 \text{ reviews}/\text{year}) + (\$116/\text{hr} \times 0.25 \text{ hr}/\text{review} \times 150 \text{ reviews}/\text{year}) = \$7,975$$

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

$$\$70/\text{hr} \times 0.1 \text{ hr}/\text{review} \times 250 \text{ reviews}/\text{year} = \$1,750/\text{year}$$

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

$$\text{Total cost savings} = \$10,835/\text{year}$$

## (2) Provision for Low-Temperature Usage

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

$$\$145/\text{hr} \times 80 \text{ licensees}/\text{year} \times 0.2 \text{ hr}/\text{licensee} = \$2,320/\text{year}$$

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

$$\$116/\text{hr} \times 80 \text{ licensees}/\text{year} \times 0.2 \text{ hr}/\text{licensee} = \$1,856/\text{year}$$

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

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

$$\$6/\text{nose cup} \times 5 \text{ nose cups}/\text{reactor-year} \times 80 \text{ reactors} = \$2,400/\text{year}$$

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

## (3) Deletion of Requirement for First Time Notification of Respirator Usage

This change could result in cost savings for a few licensees and the NRC. For most current licensees, these notifications have already been made. However, to permit potential new licensees or decontamination and decommissioning efforts that would require respirator use to begin in the future, it was assumed that two licensees per year (one reactor and one non-

reactor licensee) would prepare notifications at 0.5 hour per notification, the annual cost savings would be:

$$(\$145/\text{hr} \times 1 \text{ licensee/year} \times 0.5 \text{ hr/licensee}) + (\$116/\text{hr} \times 1 \text{ licensee/year} \times 0.5 \text{ hr/licensee}) = \$130.5/\text{year}$$

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

$$\$70/\text{hr} \times 0.2 \text{ hr/licensee} \times 2 \text{ licensees/year} = \$28/\text{year}$$

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

$$\$70/\text{hr} \times 2.5 \text{ hr/licensee} \times 2 \text{ licensees/year} = \$350/\text{year}$$

Total savings would be about \$508/year.

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

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

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

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

The current rule requires a medical exam and fit testing before the use of any respirator. If a disposable respirator is provided under the proposed rule, the employee would not need a medical examination or fit test. Permitting the use of a disposable mask without all of the requirements of an approved respirator program, such as medical examinations and fit tests,

could save substantial costs to licensees (especially power reactor licensees) with no reduction in worker safety.

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

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

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

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

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

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

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

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

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

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

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

$$\$145/\text{worker} \times 0.2 \text{ hours} \times 1,000 \text{ workers} = \$29,000/\text{year}$$

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

$$40,000 \text{ uses/year} \times 5/60 \text{ hr/use} \times \$145/\text{hr} = \$483,300/\text{year}$$

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

$$40,000 \text{ uses/year} \times \$7/\text{use} = \$280,000/\text{year}$$

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

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

$$2 \text{ hrs/plant} \times 100 \text{ plants} \times \$145/\text{hr} = \$29,000 \text{ the first year only} \\ \text{(or } \$6,000/\text{year over a period of 5 years)}$$

#### Cost Savings From Permitting Use of Disposables

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

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

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

At the present time, essentially no power reactor licensees are using half-mask respirators in the NP mode (APF = 10). Current NRC guidance discourages the use of such devices as part

of licensed activities because they must be checked for fit with irritant smoke each time they are put on. Thus, licensees typically use a more expensive full facepiece respirator in the NP mode with an APF = 50, because they are not required to perform irritant smoke tests each time those devices are donned. Under the new rule change that requirement would be removed for half-masks, and licensees would have an opportunity to replace current full facepiece respirators with half-mask disposable or reusable-disposable respirators.

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

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

$$\$25/\text{mask} / 7.5 \text{ year} \times 5,000 \text{ uses/year} = \$16,650/\text{year}$$

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

$$5,000 \text{ uses/year} \times 5/60 \text{ hr/use} \times \$145/\text{hr} = \$60,417/\text{year}$$

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

$$5,000 \text{ uses/year} \times \$7/\text{use} = \$35,000/\text{year}$$

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

$$5,000 \text{ uses/year} \times \$7/\text{device} = \$35,000/\text{year}$$

### Cost Savings For Permitting Use of Reusable-Disposable Masks

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(14) Exclusion of Noble Gases from Respiratory Protection Considerations

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

$$\$145/\text{hr} \times 1 \text{ hr}/\text{licensee} \times 5 \text{ licensees}/10 \text{ years} = \$73/\text{year}$$

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

6. Decision Rationale

1. All of the alternatives are acceptable according to generally accepted radiation protection principles expressed by NRC, NCRP, and ICRP.
2. Compared to practice under the current Part 20, Subpart H, each proposed change either involves no change in value/impact, or represents an improvement in regulatory protection of worker health and safety without any significant added costs (i.e., all value), or presents the potential for reductions in regulatory burden and/or increased operational flexibility with net savings to licensees and the NRC.
3. Many of the proposed changes only clarify existing requirements (i.e., reduce the potential for licensee misunderstandings) or formally adopt the current ANSI standard Z88-1992 (with a few exceptions) to which most licensees already comply.

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

**ATTACHMENT 3**

**ENVIRONMENTAL ASSESSMENT**

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

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

February, 1999

I. The Action

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

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

## II. Need for the Rulemaking Action

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

## III. Alternatives Considered

The following alternatives to rulemaking have been considered.

### Alternative 1: No Action

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

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

### Alternative 2: Revise Regulatory Guidance Only

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

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

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

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

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

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

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

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

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

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

## VI. List of Agencies and Persons Consulted

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

K. Paul Steinmeyer, Radiation Safety Associates, Inc.

Robert daRosa, Lawrence Livermore Laboratory, (Retired)

**ATTACHMENT 4**

**CONGRESSIONAL LETTERS**



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

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

Dear Mr. Chairman:

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

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

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

Sincerely,

Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosures:

1. Federal Register Notice
2. Press Release

cc: Representative Ralph M. Hall



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

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

Dear Mr. Chairman:

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

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Sincerely,

Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosures:

1. Federal Register Notice
2. Press Release

cc: Senator Bob Graham

**ATTACHMENT 5**

**CONGRESSIONAL REVIEW  
ACT FORMS**

# Submission of Federal Rules Under the Congressional Review Act

President of the Senate

Speaker of the House of Representatives

GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency

U.S. Nuclear Regulatory Commission

2. Subdivision or Office

Office of Nuclear Reactor Regulation

3. Rule Title

Respiratory Protection and Controls to Restrict Internal Exposures, 10 CFR part 20

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)

RIN 3150-AF81

5. Major Rule  Non-major Rule

6. Final Rule  Other

7. With respect to this rule, did your agency solicit public comments? Yes  No  N/A

8. Priority of Regulation (fill in one)

Economically Significant; or  
Significant; or  
Substantive, Non Significant

Routine and Frequent or  
Informational/Administrative/Other  
(Do not complete the other side of this form  
if filled in above.)

9. Effective Date (if applicable) 120 Days From Publication

10. Concise Summary of Rule (fill in one or both) attached  stated in rule

Submitted by: \_\_\_\_\_ (signature)

Name: \_\_\_\_\_

Title: \_\_\_\_\_

For Congressional Use Only:

Date Received: \_\_\_\_\_

Committee of Jurisdiction: \_\_\_\_\_

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C. § 605(b)?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
F. Did you discuss any of the following in the preamble to the rule?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
● E.O. 12612, Federalism	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● E.O. 12866, Regulatory Planning and Review	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● E.O. 12875, Enhancing the Intergovernmental Partnership	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● E.O. 12988, Civil Justice Reform	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)			
_____			
_____			
_____			

# Submission of Federal Rules Under the Congressional Review Act

President of the Senate

Speaker of the House of Representatives

GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency

**U.S. Nuclear Regulatory Commission**

2. Subdivision or Office

**Office of Nuclear Reactor Regulation**

3. Rule Title

**Respiratory Protection and Controls to Restrict Internal Exposures, 10 CFR part 20**

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)

**RIN 3150-AF81**

5. Major Rule  Non-major Rule

6. Final Rule  Other

7. With respect to this rule, did your agency solicit public comments? Yes  No  N/A

8. Priority of Regulation (fill in one)

Economically Significant; or  
Significant; or  
Substantive, Non Significant

Routine and Frequent or  
Informational/Administrative/Other  
(Do not complete the other side of this form  
if filled in above.)

9. Effective Date (if applicable) **120 Days From Publication**

10. Concise Summary of Rule (fill in one or both) attached  stated in rule

Submitted by: \_\_\_\_\_ (signature)

Name: \_\_\_\_\_

Title: \_\_\_\_\_

For Congressional Use Only:

Date Received: \_\_\_\_\_

Committee of Jurisdiction: \_\_\_\_\_

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C. § 605(b)?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
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E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
F. Did you discuss any of the following in the preamble to the rule?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
● E.O. 12612, Federalism	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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● E.O. 12988, Civil Justice Reform	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)			
_____			
_____			
_____			

# Submission of Federal Rules Under the Congressional Review Act

President of the Senate

Speaker of the House of Representatives

GAO

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1. Name of Department or Agency

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**Office of Nuclear Reactor Regulation**

3. Rule Title

**Respiratory Protection and Controls to Restrict Internal Exposures, 10 CFR part 20**

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)

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5. Major Rule  Non-major Rule

6. Final Rule  Other \_\_\_\_\_

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8. Priority of Regulation (fill in one)

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9. Effective Date (if applicable) **120 Days From Publication**

10. Concise Summary of Rule (fill in one or both) attached  stated in rule

Submitted by: \_\_\_\_\_ (signature)

Name: \_\_\_\_\_

Title: \_\_\_\_\_

For Congressional Use Only:

Date Received: \_\_\_\_\_

Committee of Jurisdiction: \_\_\_\_\_

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
B. With respect to this rule, by the final rulemaking stage, did your agency			
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● E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
● Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)			
_____			
_____			
_____			

**ATTACHMENT 6**

**PRESS RELEASE**

## **NRC ISSUES FINAL REVISIONS TO REGULATIONS ON RESPIRATORY PROTECTION**

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

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

When the Commission's overall radiation protection regulations were significantly revised in 1994, the rules for respiratory protection were not similarly revised because the American National Standards Institute (ANSI) was working on consensus guidance in this area. The ANSI guidance, "American National Standard Practice for Respiratory Protection," is now available and is essentially the technical basis for this rule. The Commission's rule is consistent with the general mandate of the Technology Transfer and Advancement Act of 1995 (Public Law 104-113) to utilize consensus standards. The new rules are also consistent with new respiratory protection regulations published recently by the Occupational Safety and Health Administration (OSHA).

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

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

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

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

# # # #