



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

MEMORANDUM TO: David L. Meyer, Chief
Rules Review & Directives Branch
Division of Freedom of Information
and Publications Services
Office of Administration

FROM: Thomas H. Essig, Acting Chief
Generic Issues and Environmental
Projects Branch
Division of Reactor Program Management
Office of Nuclear Reactor Regulation

SUBJECT: IMPLEMENTATION OF COMMISSION ACTION: PROPOSED NEW
10 CFR PART 20, SUBPART H, "RESPIRATORY PROTECTION AND
CONTROLS TO RESTRICT INTERNAL EXPOSURES."

By memorandum dated June 18, 1998, the Secretary of the Commission indicated that the Commission (with all Commissioners agreeing) has approved publication of the proposed rule on Part 20 set out in SECY-98-077.

Please implement the Commission's action by arranging for publication of the attached proposed rule in the Federal Register allowing 75 days for public comment.

Attached are comparative text versions of the Federal Register Notice, the press release and a Congressional letter showing Commission-requested changes for transmittal to the Office of the Secretary.

Also attached is a Congressional letter package for transmittal to OCA and two copies of the press release for transmittal to OPA.

Attachments:

1. SRM
2. FR Notice + 3 Copies & Diskette
3. Marked-up Copy of FR Notice, Press Release
and Congressional Letter
4. Congressional Letter Package
5. Press Release (2)

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

June 18, 1998

SECRETARY

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: *J. C. Hoyle*
John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-98-077 - PROPOSED RULE:
"RESPIRATORY PROTECTION AND CONTROLS TO
RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20"

The Commission has approved publication of the proposed rule for public comment subject to the comments and changes noted below.

(EDO) (NRR) (SECY Suspend: 7/10/98) 9700194

The Federal Register notice (FRN) should specifically ask for public comment on whether the technical aspects of the rule should be addressed through alternative approaches other than the proposed rule, such as a simple performance-based rule with a Regulatory Guide to permit a more rapid regulatory response by the NRC to technical developments and changes in industry consensus standards (subject to legal constraints).

The staff should re-review its conclusions with respect to compatibility categories for this rule, in particular for consistency. The staff should exercise discretion and propose compatibility categories that assure internal consistency and provide appropriate justification for departing from the policy and procedure in cases where implementation of the adequacy and compatibility policy statement results in inconsistencies within a proposed rule. The FRN should specifically solicit public comment on the resulting inconsistencies so that this issue can be resolved prior to issuance of the final rule. In addition, any comments previously received from the Agreement States as a result of the proposed amendments being made available on the NRC bulletin board should be briefly summarized in the FRN.

In paragraph 3 of the public announcement, lines 3 and 4, delete 'new.' At the end of paragraph 3, add a sentence: "The Commission's proposed rule is consistent with the general mandate of the Technology Transfer Act of 1996 (Public Law 104-113) to utilize consensus standards."

The Congressional letters should be modified to add the following sentence at the end of the letter: "The Commission's proposed rule is consistent with the general mandate of the

SECY NOTE: THIS SRM, SECY-98-077, AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

Technology Transfer Act of 1996 (Public Law 104-113) to utilize consensus standards.”

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-AF81

Respiratory Protection and Controls to Restrict Internal Exposures

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations regarding the use of respiratory protection and other controls to restrict internal exposure to radioactive material. The proposed amendments are intended to 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), and make the requirements less prescriptive without reducing worker protection. The proposed amendments would provide greater assurance that worker exposures 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 are thus clearly approved for use by licensees.

DATES: Submit comments by (Insert date 75 days after publication date). Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

The NRC staff specifically requests comment on whether the technical aspects of the rule should be addressed through alternative approaches other than the proposed rule, such as a simple performance-based rule with a Regulatory Guide endorsing ANSI standards to permit a more rapid regulatory response by the NRC to future technical developments and changes in industry consensus standards.

In addition to comments on this proposed rule, the NRC staff requests specific comments and suggestions regarding the content and scope of a planned revision of NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials."

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland between 7:30 am and 4:15 pm Federal workdays.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (<http://www.nrc.gov>). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received and the environmental assessment and finding of no significant impact, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

Single copies of the environmental assessment and finding of no significant impact and the regulatory analysis may be obtained from Antoinette Walker, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415-1282.

Single copies of the draft revision of Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection," which is related to this rulemaking, may be obtained by writing to: U.S. Nuclear Regulatory Commission, Printing and Graphics Branch, Washington, DC 20555-0001; or by fax at (301) 415-5272.

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

A major revision of 10 CFR Part 20, "Standards for Protection Against Radiation," was published on May 21, 1991 (56FR23360). 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, minimal changes were made because an ANSI standard was being prepared that was expected to provide state-of-the-art guidance on acceptable respiratory protection devices and procedures. 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 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, permitted correction of both high and low initial intake estimates if subsequent, more accurate bioassay 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, ANSI Z88.2-1992, "American National Standard for Respiratory Protection" was approved for publication by the American National Standards Institute. 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). Consistent with the publication of ANSI Z88.2-1992 the NRC is proposing these changes to Subpart H of Part 20 to make the regulations less prescriptive without reducing worker protection.

II. Summary of the Proposed Changes

The Commission is proposing to amend § 20.1003, §§ 20.1701 through 20.1704 in Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," of 10 CFR Part 20, and Appendix A to Part 20, "Protection Factors for Respirators.

In § 20.1003, Definitions, definitions are proposed for Assigned protection factor (APF), Disposable respirator, Fit check, Fit factor and Fit test. These added definitions are needed to add clarity to the proposed regulations at §§ 20.1701 through §§ 20.1705.

In § 20.1701, Use of process or other engineering controls, the word "decontamination" would be added to the list of examples of process or engineering controls that should be considered for controlling the concentration of radioactive material in air. The intent is to encourage licensees to 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 exposure instead of using respirators.

Section 20.1702 would be revised by adding a footnote (2) to § 20.1702(c) to clarify that if a licensee performs an ALARA analysis to determine whether or not respirators should be used, safety factors other than radiological may be taken into account. A reduction in the TEDE for a worker is not reasonably achievable if an attendant increase in the workers' industrial health and safety risk would exceed the benefit obtained by the reduction in the radiation risk. Regulatory Guide 8.15 (DG-8022) and NUREG-0041 will address in more detail how factors such as heat, discomfort, reduced vision, etc., associated with respirator use, might reduce efficiency or increase stress thereby increasing external dose or health risk. Considerable licensee judgment is necessary in determining an appropriate level of respiratory protection in many cases.

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, it is the use of the respiratory protection device to limit intake of radioactive material and associated physiological stresses that would activate the requirements of § 20.1703. Thus § 20.1703 can be viewed as defining the minimum respiratory protection program expected of any licensee who assigns or permits the use of respirators.

In § 20.1703(a), the phrase "pursuant to § 20.1702" would be deleted. 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 air are already below values that define an airborne radioactivity area. This is not the case and the proposed § 20.1703 should make it clear that, if a licensee uses respiratory protection equipment "to limit intakes," the provisions of § 20.1703 apply as a minimum.

In § 20.1703(a)(1), (proposed § 20.1703(a)), licensees are permitted to use only respirators that have been tested and certified "or had certification extended" by NIOSH. The words "or had certification extended" would be deleted because all these extensions have expired and no new extensions will be granted.

In § 20.1703(a)(2), (proposed § 20.1703(b)), licensees are permitted to apply for authorization to use equipment that has not been tested or certified by NIOSH and "has not had certification extended by NIOSH/MSHA." The words "has not had certification extended by NIOSH/MSHA" would be deleted because all these extensions have expired and no new extensions will be granted. The words "to the NRC" are added to make it clear that applications for authorized use of respiratory equipment are to be submitted to the Commission.

In § 20.1703(a)(3), (proposed § 20.1703(c)), paragraphs (c)(1) through (5) are retained as presently codified with the exception of some minor editing and that paragraph (c)(4) would be reworded to improve clarity, reorder priorities, and bring together in one paragraph all of the elements of the required written procedures. Paragraph (5) would be revised to clarify that the worker's medical evaluation for using non-face sealing respirators occurs prior to first field use rather than prior to first fitting (as required for tight fitting respirators) because fit testing is not needed for these types.

A new § 20.1703(c)(6) would be added to require fit testing prior to first field use of tight fitting, face sealing respirators and periodically thereafter. This proposed change would clarify when and how often fit testing is required. The licensee is to specify a frequency of retest in the procedures, not to exceed 3 years. This differs from the ANSI recommendation of annual fit testing. The NRC believes that if a licensee is alert to physiological changes that might affect an individual's ability to wear a respirator safely, annual fit testing is an excessive burden. A requirement to wear properly fitted respirators is currently in the footnotes to Appendix A to Part 20 and would be moved to the body of the rule. Several general programmatic requirements currently found in footnotes to Appendix A to Part 20 would be moved to the text of the rule where they more appropriately belong and to ensure that they are not overlooked by licensees.

The new § 20.1703(c)(6) ^{would} also codifies existing NRC staff guidance and ANSI recommendations regarding the test "fit factors" that must be achieved in order to use the APFs and the frequency of fit testing. Specifically, fit testing with "fit factors" ≥ 10 times the APF would be required for negative pressure devices. A fit factor ≥ 100 would be required for all tight fitting face pieces used with positive pressure, continuous flow, and pressure-demand devices. This provision is intended to maintain a sufficient margin of safety to accommodate the greater difficulty in maintaining a good "fit" under field and work conditions as compared to fit test environments.

The proposed § 20.1703(c)(6) ^{would} also requires retesting at a frequency not to exceed 3 years. Guidance in the proposed revision of Regulatory Guide 8.15 (DG-8022) on the frequency of fit testing suggests a retest period not to exceed 3 years. Currently, most licensees perform annual fit testing. The proposed 3-year retesting does not agree with the ANSI recommendation for annual retesting. The NRC believes that a 3-year interval between fit

tests is adequate to protect workers under normal circumstances, given adequate surveillance of workers for physiological changes. Regulatory Guide 8.15 discusses what constitutes an adequate surveillance program, including being alert to circumstances such as significant weight loss or gain, facial changes, etc., that would suggest more frequent fit testing. Transient workers might require more frequent retesting because continuous monitoring for physiological changes is impracticable.

The current § 20.1703(a)(4), which lists requirements for licensees to issue a written policy statement, would be deleted because the NRC believes that this policy statement is not needed. This change is proposed because all of the elements 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 proposed § 20.1703(c)(4)).

Section 20.1703(a)(6) would become § 20.1703(e) and would be clarified and expanded to emphasize the existing requirements that provisions be made for vision correction, adequate communications, and low-temperature work environments. In order to comply with these requirements, a licensee would need to take into account 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 would be added to the proposed § 20.1703(e). For example, 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 face piece respirator is another problem that can be caused by low temperature.

The reference to skin protection currently found in § 20.1703(a)(6) would be deleted in the proposed § 20.1703(e). The NRC does not consider skin protection 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 for example in § 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 facelets instead of respirators or decontamination should be considered. Facial contamination may result in a less significant dose than that received as a result of respirator use or prior decontamination of the area.

A new § 20.1703(f) would be added to bring a requirement for standby rescue persons, currently found in a footnote in Appendix A to Part 20, into the rule. This new section would retain a requirement for the presence of standby rescue persons 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 unassisted. Standby rescue workers would also need to be in direct communication with such workers, be equipped with appropriate protective clothing and devices, and be immediately available to provide needed assistance in the event that the air supply fails. Without continuous air supply, unconsciousness can occur within seconds.

A new § 20.1703(g) would move a requirement from a footnote in Appendix A to Part 20, into the rule. This section would specify 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," 1989 (ANSI-CGA G-7.1, 1989), that must be provided whenever atmosphere-supplying respirators are used. This change to recognizing 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 proposed rule.

A new § 20.1703(h) is added to clarify and move a requirement from the footnotes of Appendix A to Part 20, into the rule. This section prohibits the use of respirators whenever any material or substance might 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 and/or proper operation of the respirator.

Currently, § 20.1703(b)(1) discusses selection of respiratory protection equipment so that protection factors are adequate to reduce intake. This paragraph permits selection of less protective devices if that would result in optimizing TEDE. The NRC believes that this requirement is redundant with the requirement to be ALARA. These recommendations are being removed and will be discussed in the revised Regulatory Guide 8.15.

The remainder of § 20.1703(b)(1) would become § 20.1703(l) and be revised to incorporate the new ANSI terminology for "assigned protection factor" and to retain the provision for changing intake estimates if later, more accurate bioassay measurements show that exposure was greater or less than initially estimated.

Current § 20.1703(b)(2), specifying procedures for applying to the NRC to use higher APFs, is renumbered as § 20.1705.

Current § 20.1703(c) would be removed because it requires licensees to use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH. This approval category no longer exists. Acceptable types of emergency and escape equipment will be discussed in the revisions of Regulatory Guide 8.15 and NUREG-0041. 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 considered redundant.

Current § 20.1703(d) would be deleted. This section currently requires a licensee to notify in writing the director of the appropriate NRC Regional Office at least 30 days before the date that respiratory protection equipment is first used under the provisions of either current § 20.1703(a) or (b). All licensees who possess radioactive material in a form that requires a respiratory protection program are identified 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 proposed change is considered to be a burden reduction.

Section 20.1704(a) would be revised to clarify that ALARA considerations are included in any restrictions imposed by the Commission in addition to those found in §§ 20.1702, 20.1703, and Appendix A to Part 20 on the use of respiratory protection equipment for the purpose of limiting exposures of individuals to airborne radioactive materials.

Appendix A to Part 20 - "Protection Factors (PF) for Respirators," would be 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 would be 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 would be removed. Generic regulatory requirements, previously contained in footnotes in Appendix A to Part 20 would be moved to the codified text of Part 20.

The column headed "Tested and Certified Equipment," would be deleted. 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 will be provided in the revision to NUREG-0041.

Current footnote a to Appendix A to Part 20 would be deleted because it is considered to be redundant with air sampling requirements and requirements for estimating possible airborne concentration addressed in the proposed rule at § 20.1703(c)(1) and § 20.1703(l).

Current footnote b, which permits the use of devices only when nothing interferes with the seal of a face piece, would be moved to the codified text at § 20.1703(h).

Current footnote c, which defines the symbols for modes of operation would be revised to fit the new list of respiratory devices in Appendix A consistent with ANSI Z88.2-1992 and become footnote b.

Current footnote d.1 would be removed because the essential information regarding the meaning and use of APF is found in the proposed rule at § 20.1703(l). Further guidance regarding the application and limitation of APFs would be provided in the revisions of Regulatory Guide 8.15 and NUREG-0041.

Current footnote d.2(a) states that APFs are only applicable for trained individuals who are properly fitted and for properly maintained respirators. This footnote is redundant with the current and proposed § 20.1703 and would be removed. Adequate provisions for training, fit-testing, and equipment maintenance are found in the proposed rule at § 20.1703(c)(4).

Current footnote d.2(b) states 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 would be revised in proposed footnote c to say that if using a respirator with an APF greater than 100, a filter with a

minimum efficiency of 99.97 percent must be used. Further guidance will be provided in Regulatory Guide 8.15 and NUREG-0041. The definitions of filter types and efficiencies will be discussed in the revisions of Regulatory Guide 8.15 and NUREG-0041.

Current footnote d.2(c) states 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 would be made in the new proposed footnote d for licensees to apply to the Commission for the use of an APF greater than 1 for sorbent cartridges.

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

The current footnote e makes 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 would be retained in footnote d in the proposed 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 stated. This correction would be made in footnote d of the proposed Appendix A to Part 20. A discussion of the basis for this change will be found in revised NUREG-0041.

Current footnote f observes 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 would be deleted. Service life limitations are addressed in Regulatory Guide 8.15 and NUREG-0041.

The current footnote g addresses four issues. The first limits the use of half-mask face piece air purifying respirators to "under-chin" types only. This limitation would be retained as footnote (f) to the proposed new Appendix A to Part 20. The only type of face piece 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 exhibit erratic face-sealing characteristics, especially when the wearer talks or moves his/her mouth.

The second issue precludes this type of respirator if ambient airborne concentrations can reach instantaneous values greater than 10 times the pertinent values in Table 1, Column 1 of Appendix B to Part 20. Because respirator assignment is now based on TEDE, ALARA, and other consideration, this part of current footnote g would be deleted from the proposed footnote f.

The third issue precludes 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 proposes to remove it.

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

Current footnote h provides 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 would be removed. However, these NIOSH requirements will be discussed in the revision to NUREG-0041.

Current footnote I specifies 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 proposed revision of Appendix A to Part 20. Guidance on the use of these devices would be included in the revision to Regulatory Guide 8.15. Current footnote I also requires 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 would be deleted from the footnotes to Appendix A and moved to the body of the rule at § 20.1703(f).

Current footnote j states that NIOSH approval schedules are not available for atmosphere-supplying suits. This information and criteria for use of atmosphere supplying suits would be addressed in footnote g to the proposed Appendix A to Part 20. Note that an APF is not listed for these devices. Licensees would be permitted to apply to the Commission for the use of higher APFs in accordance with § 20.1703(b).

Current footnote k permits the full face piece self-contained breathing apparatus (SCBA), when operating in the pressure-demand mode, to be used as an emergency device in unknown concentrations. This provision would be retained in footnote I to the proposed Appendix A to Part 20 and full face piece SCBA operating in positive pressure, recirculating mode is added.

Current footnote I requires quantitative fit testing with a leakage less than 0.02 percent for the use of full face piece, positive pressure, recirculating mode SCBA. This requirement would be removed from the rule to be consistent with ANSI guidance and addressed in the revision to Regulatory Guide 8.15.

Current footnote I also states 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 would be retained in footnote I to the proposed Appendix A to Part 20.

Current footnote I also requires 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 would be removed.

Note 1 to the current Appendix A to Part 20 discusses conditions under which the protection factors in the appendix may be used, warns against assuming that listed devices are effective against chemical or respiratory hazards other than radiological hazards, and states the need to take into account applicable approvals of the U.S. Bureau of Mines/NIOSH when selecting respirators for nonradiological hazards. Note 1 would be retained as footnote (a) to the proposed Appendix A to Part 20 and would be revised to reference Department of Labor (DOL) regulations at 29 CFR 1910. The NRC believes that these conditions are essential to the safe use of APFs and that the DOL regulations are also applicable whenever other than radiological respiratory hazards are present.

Note 2 to the current Appendix A to Part 20 warns 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 would be retained as the second paragraph of footnote a to the proposed Appendix A to Part 20.

In the title of Appendix A, and throughout the proposed 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 face piece disposable respirators, disposables that do not have seal enhancing elastomeric components and are not equipped with two or more adjustable suspension straps would be permitted for use but would not have

an APF assigned (i.e., no credit may be taken for their use). The NRC believes that without these components 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 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 impracticable. However, for those licensees who would like to use the ANSI recommended APF of 10, proposed footnote e to Appendix a to Part 20 would permit 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 appropriate because fit testing is an implicit component of the ANSI approval process.

The half-mask face piece respirator would continue to be approved, but relatively new variations are referred to in the industry as "reusable," "reusable-disposable," "face-piece-filtering" or "maintenance-free" devices. In these devices, including those considered to be disposables, the filter medium may be an integral part of the face piece, is at least 99 percent efficient, and may not be replaceable. Also, the seal area is enhanced by the application of plastic or rubber to the face-to-face piece seal area and the 2 or more suspension straps are adjustable. These devices are acceptable to the NRC, are considered half masks, may be disposable, and would be given an APF = 10, consistent with ANSI recommendations.

The assigned protection factor for full face piece air purifying respirators operating in the negative pressure mode would be increased from 50 to 100. This change is consistent with ANSI recommendations and industry test results. The current Appendix A to Part 20 lists a protection factor of 50 because one design that was tested at Los Alamos in 1975 did not meet the PF 100 criterion. This device is no longer available.

A fit factor of 10 times the APF for 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 would be required under the proposed rule; that is, 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. Use of a fit factor of 10 times the APF effectively limits internal dose and accounts for any respirator leakage that might occur during workplace activities. Fit factors of 10 times the APF were previously not required for such devices.

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

The half-mask and the full face piece air-line respirators operating in demand mode would be listed with APF unchanged at 5. 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-face piece air-line respirators operating on continuous flow would be reduced from 1,000 to 50 and from 2,000 to 1,000 respectively. The APF for a full face piece air-line respirator operating in pressure-demand mode would be reduced from 2,000 to

1,000. These changes are based on ANSI recommendations and the results of field measurements indicating that these devices are not as effective as originally thought. This change would 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 would be added to Appendix A with an APF of 50 based on ANSI recommendations. The helmet/hood air-line respirator operating under continuous flow would be retained with the APF listed as 1,000. Current footnote h which specifies NIOSH certification criteria for flow rates would be removed. The criteria for air flow rates are part of the NIOSH approval and would be addressed in the revision to NUREG-0041.

The new loose fitting face piece design is also included as an air-line respirator operating under continuous flow. This device would be assigned an APF of 25 in the proposed Appendix A to Part 20 consistent with ANSI recommendations.

The air-line atmosphere-supplied suit ^{would} ~~will~~ not be assigned an APF. These devices have been used for many years in radiological environments such as control rod drive removal at boiling water reactors with no APF. These devices are primarily used as contamination control devices, but they are supplied with air that the wearer breathes. No 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 would still have an option to apply to the Commission for higher APFs in accordance with proposed § 20.1703(b). Requirements for standby rescue persons apply to these devices (§ 20.1703(f)).

In the proposed Appendix A to Part 20, APFs for SCBA devices would remain unchanged. 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 is questionable. The chance of face piece 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 emergency situations. Although ANSI lists 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 immediately dangerous to life and health (IDLH) areas.

In proposed footnote d, a specific statement would be added to exclude radioactive noble gases from consideration as an airborne hazard and advising that external (submersion) dose considerations should be the basis for protective actions. In the current rule, 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.

The complete proposed changes to Part 20, Subpart H and Appendix A to Part 20 are presented in the codified text section of this document.

III. Issue of Compatibility for Agreement States

In accordance with the new adequacy and compatibility policy and implementing procedures approved by the Commission on June 30, 1997, the proposed modifications to §§ 20.1701 through 20.1703, and § 20.1705 have health and safety significance and Agreement States

should adopt the essential objectives of these rule modifications in order to maintain an adequate program. Therefore, these provisions are assigned to the "Health and Safety (H&S)" category. The proposed definition of Assigned Protection Factor (APF) because of its precise operational meaning, is designated as compatibility category C to help insure effective communication. Therefore, Agreement States should adopt the essential objectives of this provision to avoid conflicts, duplication or gaps. The proposed definitions of Disposable respirator, Fit check, Fit factor and Fit test, are stated in general terms and are therefore designated as compatibility category D, not required for purposes of compatibility. Flexibility is also provided to States regarding § 20.1704 in how they handle imposition of additional restrictions on the use of respiratory protection. Therefore, this provision is designated as compatibility category D. Comments are specifically requested on whether assigning different compatibility categories to the proposed new definitions creates any implementation problems or inconsistencies.

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These proposed amendments were provided to the Agreement States during the NRC staff review process via the use of the NRC rulemaking bulletin board and notification to the States of its availability. Two comments were received. One suggested assigning compatibility categories to the five new definitions, which has been done in this proposed rule. A second

noted that removal of generic requirements from the footnotes to Appendix A greatly improved the rule.

IV. 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 proposed amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

The proposed amendment addresses 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 proposed 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

of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of the environmental assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

The draft environmental assessment is available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Single copies of this document are available as indicated in the ADDRESSES heading.

V. Paperwork Reduction Act Statement

This proposed rule contains amendments to reduce the information collection requirements contained in 10 CFR Part 20 that are considered to be insignificant, (250 hours annually) when compared with the overall requirements of the CFR Part (210, 205 hours annually). NRC does not consider this reduction in the burden to be significant enough to trigger the requirements of the Paperwork Reduction Act of 1995 (44. U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0014.

Public Protection Notification

If 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.

VI. Regulatory Analysis

The NRC has prepared a regulatory analysis for the proposed amendment. 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. Single copies are available as indicated under the ADDRESSES heading.

VII. Regulatory Flexibility Certification

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

The NRC is seeking public comment on the initial regulatory flexibility certification. The NRC is seeking comment particularly from small entities as defined under the NRC's size standards 10 CFR 2.810, as to how the proposed regulations would affect them and how the regulations may be implemented or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety. Any small entity subject to this regulation who determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should offer comments that specifically discuss the following items:

(a) The licensee's size and how the proposed regulation would result in a significant economic burden or whether the resources necessary to implement this amendment could be more effectively used in other ways to optimize public health and safety, as compared to the economic burden on a larger licensee;

(b) How the proposed regulation could be modified to take into account the licensees' differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, could more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety.

The comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. ATTN: Rulemakings and Adjudications Staff.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm Federal workdays.

VIII. Backfit Analysis

Although the NRC staff has concluded that some of the changes being proposed constitute a reduction in burden, the implementation of these and other changes will require revisions to licensee procedures constituting a potential backfit under 10 CFR 50.109(a)(1). Under § 50.109(a)(2), a backfit analysis is required unless the proposed rule meets one of the exceptions listed in § 50.109(a)(4). This proposed rule meets the exception at § 50.109(a)(4)(iii) in that it is redefining the level of adequate protection as regards the use of respirators for radiological protection.

Section II, Summary of the Proposed Changes, summarizes the proposed changes to Subpart H of 10 CFR Part 20. The reasons for making these changes are also provided. Many of the proposed changes are considered by the NRC to constitute a redefinition of adequate level of protection 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.

In conclusion, the Commission believes that the proposed changes constitute a burden reduction with the exception of the need to revise procedures to implement the requirements.

The proposed changes also clearly redefine the level of adequate protection required for workers who use respiratory protection and are, therefore, the type of change for which a backfit analysis is not required under § 50.109(a)(4)(iii).

Criminal penalty

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. 553, the NRC is proposing to adopt 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 Assigned protection factor (APF), Disposable respirator, Fit check, Fit factor, and Fit test to read as follows:

§ 20.1003 Definitions.

* * * * *

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.

* * * * *

Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive 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).

* * * * *

Fit check (user seal check) means a performance check conducted by a respirator wearer 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.

Fit factor means a quantitative measure of the fit of a particular respirator to a particular individual.

Fit test means a test, quantitative or qualitative, to evaluate the fit of a respirator on an individual and to determine a fit factor.

* * * * *

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 practicable, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

4. In § 20.1702, paragraph (c) is revised to add the following footnote:

§ 20.1702 Use of other controls.

* * * * *

(c) Use of respiratory protection equipment²; or

² If the licensee performs an ALARA analysis to determine whether or not respirators should be used, safety factors other than radiological may be taken into consideration and the impact of the use of respirators on workers industrial health and safety risk should be considered.

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), or

(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 exposures;

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

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

(4) Written procedures regarding monitoring, including air sampling and bioassays; training of respirator users; fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; recordkeeping; and limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician before the initial fitting of face sealing respirators, before the first field use of non-face sealing respirators, and either every 12 months thereafter, or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment;

(6) Fit testing, with fit factor ≥ 10 times the APF for negative pressure devices, and a fit factor ≥ 100 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 3 years.

(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 use equipment, within limitations for type and mode of use and shall make provision for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection 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 be in direct communication with the workers and must 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 effectively assist all users of this type of equipment.

(g) Whenever atmosphere-supplying respirators are used, they must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association and endorsed by ANSI, in publication G-7.1, "Commodity Specification for Air," 1989, (ANSI-CGA G-7.1, 1989).

(h) No material or substance, the presence or absence of which is under the control of the respirator wearer, may be present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(i) In estimating the exposure of individuals to 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 exposure is later found to be greater than estimated, the corrected value must be used. If the exposure is later found to be less than estimated, 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 those in §§ 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 exposures of individuals to airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

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

7. Section 20.1705 is added ^{to read} as follows:

§ 20.1705 Application for use of higher assigned protection factors.

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

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

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

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

as follows

APPENDIX A TO PART 20

ASSIGNED PROTECTION FACTORS FOR RESPIRATORS^a

Description	Assigned Protection Factors		
	Modes ^b	Particulate ^c	Gases and vapors ^d
I. AIR PURIFYING RESPIRATORS			
Single-use disposable ^e	NP	(e)	
Facepiece, half mask ^f	NP	10	
Facepiece, full	NP	100	
Facepiece, half mask	PP	50	
Facepiece, full	PP	1000	
Helmet/hood	PP	1000	
Facepiece, loose-fitting	PP	25	
II. ATMOSPHERE SUPPLYING RESPIRATORS			
1. Air-line respirator			
Facepiece, half mask	D	5	5
Facepiece, half mask	CF	50	50
Facepiece, half mask	PD	50	50
Facepiece, full	D	5	5
Facepiece, full	CF	1000	1,000
Facepiece, full	PD	1000	1,000
Helmet/hood	CF	1000	1,000
Facepiece, loose-fitting	CF	25	25
Suit	CF	(g)	(g)
2. Self-contained breathing Apparatus (SCBA)			
Facepiece, full	D	50 ^h	50 ^h
Facepiece, full	PD	10,000 ⁱ	10,000 ⁱ
Facepiece, full	RD	50 ^h	50 ^h
Facepiece, full	RP	10,000 ⁱ	10,000 ⁱ
III. COMBINATION RESPIRATORS			
Any combination of air-purifying and atmosphere-supply 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 contained in 29 CFR 1910.

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. The mode symbols are defined as follows:

NP = negative pressure (air-purifying respirator)
PP = positive pressure (air-purifying respirator)
CF = continuous flow (supplied-air respirator)
D = demand (supplied-air respirator)
PD = pressure-demand (open circuit, supplied-air respirator)
RD = demand, recirculating (closed circuit SCBA)
RP = positive pressure, recirculating (closed circuit SCBA).

- c. Air purifying respirators with $APF \leq 100$ must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with $APF > 100$ must be equipped with particulate filters that are at least 99.97 percent efficient.
- d. Excluding 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. The licensee may apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gasses and vapors (e.g., radioiodine).
- e. 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 fit 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.
- f. 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 99 percent efficient and all other requirements of this part are met.

- 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 and 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 _____, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

The NRC staff specifically requests comment on whether the technical aspects of the rule should be addressed through alternative approaches other than the proposed rule, such as a simple performance-based rule with a Regulatory Guide endorsing ANSI standards to permit a more rapid regulatory response by the NRC to future technical developments and changes in industry consensus standards.

In addition to comments on this proposed rule, the NRC staff requests specific comments and suggestions regarding the content and scope of a planned revision of NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials."

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland between 7:30 am and 4:15 pm Federal workdays.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (<http://www.nrc.gov>). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received and the environmental assessment and finding of no significant impact, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

Single copies of the environmental assessment and finding of no significant impact and the regulatory analysis may be obtained from Nina M. Barnett, Office of Nuclear Regulatory

is considerably higher than when operating in a positive pressure mode. This is especially critical for devices that could be mistakenly used in emergency situations. Although ANSI lists 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 immediately dangerous to life and health (IDLH) areas.

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communication. ~~and~~ Therefore, Agreement States should adopt the essential objectives of this provision to avoid conflicts, duplication or gaps. The proposed definitions of Disposable respirator, Fit check, Fit factor and Fit test are stated in general terms and are therefore designated as compatibility category D, not required for purposes of compatibility. Flexibility is also provided to States regarding § 20.1704 in how they handle imposition of additional restrictions ^{on} ~~to~~ the use of respiratory protection. Therefore, this provision is designated as compatibility category D. Comments are specifically requested on whether assigning different compatibility categories to the proposed new definitions creates any implementation problems or inconsistencies.

Appendix A to 10 CFR Part 20 is designated as compatibility category B because assigned protection factors (APFs) provide acceptable levels of protection to be afforded by respirators. Additionally, although § 20.1705 permits applying for the use of higher APFs on a case by case basis, 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.

These proposed amendments were provided to the Agreement States during the NRC staff review process via the use of the NRC rulemaking bulletin board and notification to the States of its availability. Two comments were received. One suggested assigning compatibility categories to the five new definitions, which has been done in this proposed rule. A second noted that removal of generic requirements from the footnotes to Appendix A greatly improved the rule.

NRC ISSUES PROPOSED REVISIONS TO REGULATIONS ON RESPIRATORY PROTECTION

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

The revised rules would provide greater assurance that workers' radiation exposures will be maintained as low as is reasonably achievable and would approve for licensee use advances in respiratory protection equipment and procedures. The new rules would be more performance based, more flexible and easier to implement. The NRC believes the proposed rule would save licensees about \$2 million per year, with no reduction in worker health and safety.

When the Commission's overall radiation protection regulations were significantly revised in 1992, the rules for respiratory protection were not similarly revised because the American National Standards Institute (ANSI) was working on new consensus guidance in this area. The new ANSI guidance, "American National Standard Practice for Respiratory Protection," is now available and is essentially the technical basis for the proposed rule. The Commission's proposed rule is consistent with the general mandate of the Technology Transfer Act of 1996 (Public Law 104-113) to utilize consensus standards.

The proposed 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 proposed rule also recognizes the new respiratory protection devices that have been proven effective, discourages the use of other devices that are now considered less

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
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 proposed amendment to 10 CFR Part 20 dealing with respiratory protection and other controls to restrict internal exposure of workers. The proposed amendment will be published in the Federal Register for a 75-day public comment period.

These amendments are based on guidance developed by the American National Standards Institute. These amendments will provide greater assurances 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 proposed rules redefine the level of adequate protection, establish a less prescriptive framework and are estimated to reduce licensee burden by about \$2 million per year with no reduction in worker health or safety. The Commission's proposed rule is consistent with the general mandate of the Technology Transfer Act of 1996 (Public Law 104-113) to utilize consensus standards.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Ralph Hall



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

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The proposed rule also recognizes the new respiratory protection devices that have been proven effective, discourages the use of other devices that are now considered less

effective based on field tests, and revises requirements for respiratory protection procedures such as testing to evaluate the fit of a respirator on a particular individual.

The rule also revises 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 proposed rule are contained in the Federal Register notice to be published shortly. Interested persons are invited to submit written comments on the proposal within 75 days after publication in the Federal Register notice to the Secretary, U.S. Nuclear Regulatory Commission, Washington, Dc 20555-0001, Attention: Rulemaking and Adjudications Staff. Comments may also be submitted electronically, as described in the Federal Register Notice.

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