From: Alan Roecklein
To: TWP8.CJP1, TWP8.DAC, TWP8.SXS2, WND2.WNP4.SJC1, WN...
Date: 4/29/97 3:29pm
Subject: Rulemaking Plan:Respiratory Protection(Subpart H)

At a meeting on April 28 the EDO directed that RES withdraw the subject Rulemaking Plan and proceed with a proposed rule. No further action is required on the Rulemaking Plan. The Office of Research appreciates the input from your office on that effort.

CC: TWP0.JAM1, ANT, CAT1, LBR

From: Alan Roecklein
To: WND1.WNP1.PAS2, WND1.WNP1.NKS
Date: 5/7/97 2:10pm
Subject: Respiratory Protection Rulemaking

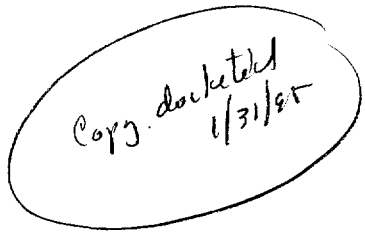
A meeting was held on 4/28/97 with Hugh Thompson and Ed Jordan regarding the ongoing Part 20 rulemaking on respiratory protection. RES was directed to meet with OGC and OE to investigate whether the assigned protection factors for respirators currently in Appendix A would be enforceable if Appendix A were removed from Part 20 and placed in a regulatory guide.

A meeting was held on 5/6/97 with OGC and OE representatives. The conclusions were that regulatory guides cannot be enforced, that placing requirements in a guidance document would be confusing and would not result in more performance based rules, and that any future changes in approved respirators or assigned protection factors would require not only a reg guide change but also a minor rule change to revise the rule reference to the reg guide revision. In addition it was noted that the Federal Register does not permit encorporation of agency guidance documenmts by reference.

RES will now proceed with the existing draft proposed rule and revised regulatory guide.

CC: Sub 20H

1/25



Proposed Change to

Subpart H

10 CFR 20

Submitted by:

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INTRODUCTION

This work is presented in partial fulfillment of contract 04-90-073 as amended, between Radiation Safety Associates, Inc. and the U.S. Nuclear Regulatory Commission.

This suggested change to Subpart H of 10 CFR 20 is presented in three-column format. The first column contains the wording of the current rule (effective January 1, 1994) sometimes referred to as the new 10 CFR 20. The second column contains the proposed wording, and bold print has been used to indicate the words and phrases which are different from the new 10 CFR 20 Subpart H. Paragraph numbers have been slightly modified (e.g., §20.1701 is labeled §20.X1701 in the proposed revision) in an attempt to avoid confusion when commenting on this proposed rule. Bracketed numbers follow words or phrases which are explained or justified in the Statements of Consideration. The third column contains the Statements of Consideration (reasons or justifications for the proposed changes).

Significant changes have been made to Appendix A, Protection Factors for Respirators. Therefore no attempt has been made to present these in side-by-side fashion. A copy of Appendix A from the new 10 CFR 20 is included with notes explaining which sections have either been moved to the body of the proposed rule, changed or deleted. This section is assigned page numbers beginning with "A (New)-1."

A proposed version of Appendix A is also included, which incorporates the changes noted. The Statements of Consideration for Appendix A are listed separately at the end of the appendix, and are numbered "A (Proposed)-1" etc.

Subpart H - Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

§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 or ventilation) to control the concentration of radioactive material in air.

§ 20.1702 Use of other controls.

When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in 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:

(a) Control of access;

(b) Limitation of exposure times;

(c) Use of respiratory protection equipment; or

(d) Other controls.

Subpart H - Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

§20.X1701 Use of process or other engineering controls.

The licensee shall use, to the extent practicable, process or other engineering controls (e.g., containment, **decontamination [1]**, ventilation) to control the concentration of radioactive material in air.

§ 20.X1702 Use of other controls.

When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in 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:

(a) Control of access;

(b) Limitation of exposure times;

(c) Use of respiratory protection equipment; or

(d) Other controls.

Statements of Consideration

[1] The word "decontamination" has been added to § 20.1701 to encourage licensees to consider decontamination as a means of reducing internal exposures instead of using respirators.

§ 20.1703 Use of individual respiratory protection equipment.

(a) If the licensee uses respiratory protection equipment to limit intakes pursuant to § 20.1702-

(1) The licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(2) If the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of the equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

§ 20.X1703 Use of individual respiratory protection equipment.

(a) If the licensee uses respiratory protection equipment to limit intakes pursuant to § 20.X1702-,

(1) The licensee shall use only respiratory protection equipment that is tested and certified **[2]** by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(2) If the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee shall submit an application **to the Commission [3]** for authorized use of the equipment. The application shall 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 shall be shown either by licensee testing, or on the basis of reliable test information.

[2] The words "...or had certification extended..." have been deleted. All of these extensions have expired.

[3] "...to the Commission..." These words are added to the allowance to apply for authorization to use uncertified equipment to clarify to whom the application should be sent.

"...The application shall 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 shall be shown either by licensee testing, or on the basis of reliable test information...." This wording replaces existing wording to improve clarity.

(3) The licensee shall implement and maintain a respiratory protection program that includes-

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

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(iii) Testing of respirators for operability immediately prior to each use;

(iv) Written procedures regarding selection, fitting, issuance, maintenance and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(v) Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.

(4) The licensee shall issue a written policy statement on respirator usage covering -

(i) The use of process or other engineering controls, instead of respirators;

(ii) The routine, nonroutine, and emergency use of respirators; and

(iii) The periods of respirator use and relief from respirator use.

[4]

(3) The licensee shall issue a written policy statement on respirator usage covering -

(i) The use of **practicable [5]** process or other engineering controls, instead of respirators;

(ii) The routine, nonroutine, and emergency use of respirators;

(iii) **Limitations on [6]** periods of respirator use and relief from respirator use; and

(iv) **A commitment to maintaining total effective dose equivalent ALARA by balancing internal and external dose** [7]

[4] The order in which the program requirements are currently listed in § 20.1703(a)(3) through (a)(6) has been changed for the sake of prioritization and emphasis. All of the existing requirements are included in the wording of this proposed rule, except that the reference to skin protection has been deleted. Skin protection is more appropriately dealt with elsewhere in the rule as a skin dose limitation or ingestion pathway issue. It is inappropriate to use respirators solely to prevent facial contamination caused by poor work practices. Other requirements which appear in the proposed version of the rule are currently contained in the footnotes to Appendix A. Since these constitute significant requirements for licensees, they have been incorporated into the body of the rule.

[5] The word "practicable" is added to the requirement for process of other engineering controls instead of respirators. Without this modifier, it appears that respirators are not acceptable.

[6] The words "limitations on" are added to the requirement for policy statements regarding periods of respirator use to clarify the position that licensees must take into consideration the effects of the physical stress on personnel when respirators are to be used.

[7] This adds a clear requirement for licensees to develop written ALARA policies with respect to their respiratory protection programs, including the requirement to balance internal and external dose to keep total effective dose equivalent ALARA.

(5) 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.

(6) The licensee shall use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

(4) The licensee shall implement and maintain a respiratory protection program that includes-

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

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(iii) Written procedures regarding monitoring, including air sampling and bioassays; **medical evaluation [8]; supervision, training and minimum qualifications of respirator program personnel [9];** training of respirator users; **the requirement for the user to perform a visual inspection and a fit check each time a respirator is donned [10];** fit testing; selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing and quality assurance of respiratory protection equipment; recordkeeping; and **maintaining total effective dose equivalent ALARA by balancing internal and external dose [11];**

[8] Paragraph 20.1703(a)(4)(iii) adds the requirement for procedures covering the requirements of a respiratory protection program. The added requirements are for: "medical evaluation"—The wording is changed from "screening" to "evaluation" to more clearly state the requirement for licensees to evaluate the medical condition of potential respiratory users. The screening (i.e., separating those who may wear respirators from those who may not) is left to the physician.

[9] "supervision, training and minimum qualifications of respirator program personnel"—A new requirement is added to proceduralize the supervision, training and minimum qualifications of respiratory protection program personnel. In a complex, safety-related program such as respiratory protection, it is the NRC staff's position that the personnel supervising and implementing this program should meet certain minimum levels of training and experience. More details will be provided in Regulatory Guide 8.15 and/or NUREG 0041.

[10] "visual inspection and fit check each time a respirator is donned"—The term "fit check" is used to conform to ANSI terminology and to clarify the meaning. Also added to the fit check requirement is a visual inspection to be performed by the respiratory user.

[11] "maintaining total effective dose equivalent ALARA by balancing internal and external dose"—A requirement is added for proceduralization of the total effective dose equivalent/ALARA program. This would require the evaluation of internal dose saved *because of* respirator use, versus additional external dose received *on account of* respirator use (inefficiency in task performance due to reduced visibility, discomfort, communication restrictions, etc.). Other risks associated with respirator use should also be considered. While this requirement is implied in §§ 20.1101(b) and 20.2102 of 10 CFR Part 20, it should be reiterated here.

(iv) Determination by a physician prior to the initial fitting of respirators, **[12]** and either every 12 months thereafter, or periodically at a frequency determined by a physician, **[13]** that the individual is **medically fit [14]** to use the respiratory protection equipment,

[12] This change is already in process.

[13] "...periodically at a frequency determined by a physician..." Regulatory Guide 8.15 will make reference to the ANSI Z88.6 method of determining frequency of medical evaluations. ANSI Z88.6-1984 suggests a frequency of five years between examinations for workers to age 35, every 2 years to age 45, and annual examinations thereafter.

[14] "...medically fit..."—The words "medically fit" replace the words "physically able" to more precisely state the intent of the Rule. Reg Gude 8.15 and/or NUREG-0041 will contain additional information as outlined below. A "hands on" physical examination by a physician is not required. A local physician, available to the licensee on an ongoing basis, must establish the screening methods to be used, must set the acceptance criteria for those tests, and must periodically review the implementation of the program. The medical evaluation program must be carried out by certified, medically trained individuals such as registered nurses (RN's), licensed practical nurses (LPN's) or emergency medical technicians (EMT's) or others who, in the judgement of the determining physician, have adequate experience, education and judgement to carry out this program. Those individuals who fall outside the bounds of the acceptance criteria for respirator use may be examined or evaluated by the physician who can then make a medical judgement about which type(s) of respirator(s) the individual may or may not wear.

(v) Fit testing prior to first field use of respirators, and periodically thereafter. [15]

[15] The requirement for fit testing has been taken out of the footnotes in Appendix A and placed in the body of the Rule where it properly belongs. Quantitative fit testing (QNFT) is permitted for all types of face-sealing devices. Qualitative fit testing (QLFT) is acceptable for devices which have an Assigned Protection Factor of no more than 10, or for which a Protection Factor of no more than 10 will used, even if the device has an APF greater than 10. A validated QLFT protocol must be used and must be properly performed. Currently, no validated QLFT protocols exist which can demonstrate a fit factor of more than 100, which is required to use a Protection Factor of 10, and the minimum required fit factor is 10 times the protection factor which will be used. If a QLFT protocol is validated in the future which can measure a fit factor of more than 100, a protection factor up to 1/10 of the fit factor may be used for any device so tested, as long as the APF for the device is not exceeded.

Guidance on the frequency of retesting will indicate a retest period not to exceed three years. Currently, some licensees perform annual fit testing, a few perform fit testing only once for each worker.

All fit testing will be accomplished with the facepiece operating in the negative pressure mode, regardless of the mode of operation in which it will be used. (ANSI Z88.2-1992)

If quantitative fit testing is used to test facepieces, which in the field will operate in the negative pressure mode, a fit factor which is at least 10 times greater than the assigned protection factor (Appendix A) must be demonstrated before an individual is permitted to use that facepiece in the field.

If quantitative fit testing is used to test facepieces, which in the field will operate in a positive pressure mode, a fit factor of at least 1000 must be demonstrated with the facepiece operating in the negative pressure mode before an individual is permitted to use that facepiece in the field.

(5) 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.

(6) The licensee shall use equipment within limitations for type and mode of use and shall **make provision for vision correction [16], adequate** communication, **high temperature and/or high humidity work environments [17], low temperature work environments (below 32° F) [18] and the concurrent use of other safety or radiological protection equipment in such a way as to not interfere with the proper operation of the respirator.**

[16] "...make provisions for vision correction, adequate communication..."—The licensee must 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 inability of the wearer to read postings, operate equipment and/or instrumentation, or properly identify hazards is considered by the NRC staff to be an unacceptable degradation of personnel safety.

[17] "...and/or high humidity..."—Add the requirement for licensees to consider high humidity environments when selecting respiratory protection devices. High humidity, combined with the use of respirators and protective clothing, has an impact on the body's self-cooling capability in that evaporative cooling becomes less effective. Specific guidance on heat stress monitoring and limitation will be included in NUREG 0041.

[18] "...low temperature work environments (below 32°F)..." —Add the requirement for licensees to consider low temperature work environments when selecting respiratory protection devices. The exhalation valve on negative pressure respirators could potentially freeze in the open position due to the presence of moisture from exhaled air when temperatures are below freezing. This would provide a pathway for unfiltered air into the respirator inlet covering without the user being aware of the malfunction. Lens fogging leading to reduced vision in a full facepiece respirator is another problem exacerbated by low temperatures.

The reference to skin protection has been deleted.

(7) Whenever one-piece atmosphere-supplying suits (or any combination of respiratory protection device and personnel protective equipment from which an individual would have difficulty extricating himself unaided) are used, a standby rescue person is required. This person must be equipped with a respiratory protection device appropriate for the potential hazards, shall observe or otherwise be in direct communication with such workers, and shall 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 shall be available to effectively assist all users of this type of equipment. [19]

[19] This requirement has been taken out of the footnotes in Appendix A and placed in the body of the Rule where it properly belongs. It has been expanded to more clearly state the requirements for standby rescue persons when equipment is being used of a type that is difficult or impossible to extricate oneself from unaided.

(8) Whenever atmosphere-supplying respirators are used, they must be supplied with respirable air of the minimum quality specified in the Code of Federal Regulations 30 CFR 11. The maximum and minimum quantities of air supplied are listed in the specific NIOSH/MSHA approval for each device. [20]

[20] This requirement has been taken out of the footnotes in Appendix A and placed in the body of the Rule where it properly belongs. It has been expanded to more clearly state the requirements for quality and quantity of breathing air.

(9) 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. [21]

[21] This requirement has been taken out of the footnotes in Appendix A and placed in the body of the Rule where it properly belongs. It has been expanded and generalized to more clearly state the requirement. It is intended to disallow the presence of facial hair, cosmetics, facelets, spectacle bars, surgeons caps and other things from interfering with the respirator seal and/or proper operation of the respirator. More detail and examples will be given in Regulatory Guide 8.15 and/or NUREG 0041.

(b) In estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to § 20.1702, provided that the following conditions, in addition to those in § 20.1703(a), are satisfied:

(b) In estimating exposure of individuals to airborne radioactive materials, the licensee may **take credit [22]** for respiratory protection equipment used to limit intakes pursuant to § 20.X1702, provided that the following conditions, in addition to those in § 20.X1703(a), are satisfied:

[22] "...take credit for..."—This wording clarifies the intent that assigned protection factors (APF's) may be applied when the requirements of this subpart are met. This term is more widely used than the words currently in the rule.

(1) The licensee selects respiratory protection equipment that provides a protection factor (see appendix A to §§ 20.1001-20.2401) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in appendix B to §§20.1001-20.2401, table 1, column 3. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in § 20.1702 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA.

(1) The licensee selects respiratory protection equipment that provides an assigned protection factor (see appendix A to §§20.1001-20.2401) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in appendix B to §§20.1001-20.2401, table 1, column 3. If the selection of a respiratory protection device with a protection factor greater than the **multiple defined in the preceding sentence [22A]** is inconsistent with the goal specified in §20.X1702 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA.

[22A] Wording change currently in process.

The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the 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.

(2) 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 divided by the assigned protection factor[23]**. 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.

[23] This wording defines how assigned protection factors are applied to airborne concentration values to determine the airborne concentration to which the wearer is exposed.

(2) The licensee shall obtain authorization from the Commission before assigning respiratory protection factors in excess of those specified in appendix A to §§20.1001-20.2401. The Commission may authorize a licensee to use higher protection factors on receipt of an application that -

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

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

(3) The licensee shall obtain authorization from the Commission before **using assigned protection** factors in excess of those specified in appendix A to §§20.1001-20.2401. The Commission may authorize a licensee to use higher **assigned [24]** protection factors on receipt of an application that -

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

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

[24] "...assigned..." This wording conforms to ANSI Standard wording.

(c) The licensee shall use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

Paragraph Deleted[25]

[25] Subparagraphs (c) has been deleted since no such NIOSH/MSHA approval category exists. Acceptable types of emergency and escape equipment will be specified in Regulatory Guide 8.15 and/or NUREG-0041. Since only NIOSH/MSHA-approved equipment can be used in the respiratory protection program, this level of detail is no longer required in the rule.

(d) The licensee shall notify, in writing, the Director of the appropriate NRC Regional Office listed in appendix D to §§20.1001-20.2401 at least 30 days before the date that respiratory protection equipment is first used under the provisions of either §20.1703(a) or (b).

Paragraph Deleted[26]

[26] Subparagraph (d) has been deleted. All current licensees who possess radioactive material in a form which requires a respiratory protection program have been identified. The need for a respiratory protection program will be identified during the license application, amendment and renewal process. A 30-day notification requirement imposes a needless administrative burden on a licensee, with no net increase in worker safety being achieved.

§ 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 §§20.1001-20.2401 to-

(a) Ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials; and

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

§ 20.X1704 Further restrictions on the use of respiratory protection equipment.

The Commission may impose restrictions in addition to those in §§20.X1702, 20.X1703 and appendix A to §§20.1001-20.2401 **in order to- [27]**

(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 **[28]**; and

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

[27] The phrase "in order to" is added for clarity.

[28] Restates the total effective dose equivalent/ALARA requirement.

APPENDIX A TO §§ 20.X1001—20.X2401—ASSIGNED PROTECTION FACTORS FOR RESPIRATORS[a] [A-1]

Description	Modes[b]	Assigned Protection Factors		Tested and certified equipment—National Institute for Occupational Safety and Health/Mine Safety and Health Administration tests for permissibility
		Particulates only[c]	Particulates, gases and vapors[d]	
I. AIR PURIFYING RESPIRATORS				
Single-use disposable[e] [A-2]	NP	1		
Facepiece, half mask[f] [A-3]	NP	10		
Facepiece, full	NP	[A-4] 100		
Facepiece, half mask	PP	50		30 CFR Part 11, Subpart K
Facepiece, full	PP	1000		
Helmet/hood	PP	1000		
Facepiece, loose-fitting	PP	[A-5] 25		
II. ATMOSPHERE SUPPLYING RESPIRATORS				
1. Air-line respirator				
Facepiece, half-mask	D		[A-6] 1	
Facepiece, half-mask	CF		50	
Facepiece, half-mask	PD		50	
Facepiece, full	D		[A-6] 1	
Facepiece, full	CF		1,000	30 CFR Part 11, Subpart J
Facepiece, full	PD		1,000	
Helmet/hood	CF		1,000	
Facepiece, loose-fitting	CF		[A-5] 25	
Suit [A-7]	CF		I[g]	[h]
2. Self-contained breathing apparatus (SCBA)				
Facepiece, full	D		1	
Facepiece, full	PD		10,000[i]	
Facepiece, full	RD		1	30 CFR Part 11, Subpart H
Facepiece, full	RP		5,000[j]	
III. COMBINATION RESPIRATORS Any combination of air-purifying and atmosphere-supplying respirators		Assigned protection factor for type and mode of operation as listed above		30 CFR 11, §11.63(b)

a. These assigned protection factors apply only to individuals in a respiratory protection program which meets the requirements of this Part. They are applicable only to airborne radiological hazards, and may not be appropriate to circumstances where 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 1910.134 and other sections.

b. The mode symbols are defined as follows:
NP = negative pressure (air-purifying respirator)
PP = positive pressure (air-purifying respirator)
CF = continuous flow (atmosphere-supplying respirator)
D = demand (supplied-air respirator)
PD = pressure demand (open circuit, atmosphere-supplying respirator)
RD = demand, recirculating (closed circuit SCBA)
RP = positive pressure, recirculating (closed circuit SCBA).

c. Air purifying respirators must be equipped with high efficiency particulate (HEPA) filters.

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 less than 3 is appropriate when atmosphere-supplying

respirators are used to protect against tritium oxide. If the assigned protection factor for a device is 10, the effective assigned protection factor for tritium is about 2.5; for devices with assigned protection factors of 100, the effective assigned protection factor is about 2.8; for devices with assigned protection factors of 1000 or more, the effective assigned protection factor is about 2.99. 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. No credit (i.e., APF = 1) may be taken for the use of sorbents against airborne radioactive vapors (e.g., radioiodine). **[A-8]**

e. Licensees may permit individuals to use this type of respirator to limit intakes of radioactive material who have not been medically screened or fit tested on the device. All other respiratory protection program requirements (e.g., training, facial hair prohibition, etc.) apply.

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. 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 filter medium is of the high efficiency (HEPA) type, and all other requirements of this Part are met.

g. This equipment may be used in an acceptable respiratory protection program as long as all the other program requirements are met (e.g., medical screening, training, quality assurance, etc.), except for the NIOSH approval.

h. No NIOSH/MSHA approval schedule is currently available for this equipment.

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 perceptable outward leakage of breathing gas while wearing the device.

j. Not withstanding other requirements in this Part, quantitative fit testing, with the facepiece operating in the negative pressure mode, shall be performed on each individual prior to first field use of this device and at least annually thereafter. A minimum acceptable fit factor of 1,000 is required to be demonstrated on each subject prior to first field use of this device. This device may not be used by any individual who experiences perceptable outward leakage of breathing gas while wearing the device. **[A-9]**

Statements of Consideration
Proposed 10 CFR 20 Appendix A

[A-1] In the title of the Appendix, and throughout the rule, the term "assigned protection factor" (APF) is used to match the new ANSI Z88.2-1992 terminology.

[A-2] Single-use disposable respirators (e.g., 3M 8710) are permitted for use with an APF of 1 (i.e., no credit may be taken). These have little physiological impact on the wearer and may be useful in certain situations for ALARA reasons. They are certainly at least as good as no respirator at all. Medical screening and fit testing are not required for each individual prior to use, but users must be trained in the use and limitations of the device, and the licensee must take steps to ensure that untrained or unshaven individuals are not able to obtain these devices.

[A-3] Relatively new variations on the half-mask respirator are referred to variously as "reusable," "reusable-disposable," or "maintenance-free" devices. In these devices, the filter medium is an integral part of the facepiece and is not replaceable. Also, the seal area is enhanced by the application of plastic or rubber to the face-to-facepiece seal area. These devices are acceptable to the NRC staff and are considered half masks, as long as they are: (1) made of high efficiency filter media and, (2) a fit check can be properly performed by the wearer upon donning. An effective negative pressure check could not be performed on a few of the models examined because the user's hands were not large enough to completely cover the facepiece as the manufacturer's instructions specified. In this case, the device could still be used if a fit check is accomplished upon donning with irritant smoke. An isoamyl acetate (banana oil) fit check is not appropriate since this challenge aerosol requires an organic vapor medium in order to be removed.

[A-4] Increase the APF for full facepiece negative pressure respirators to 100. An increase to 100 will have no real impact on safety. The reason that Ed Hyatt originally recommended a PF of 50 for this category of devices was because <u>one</u> model of all the facepieces he tested did not meet the 100 criterion. This device is no longer available on the market. Also, an increase to 100 would bring NRC into line with ANSI and with general industry practice. This will help avoid confusion in areas where there are concurrent radiological and non-radiological hazards, where the same respirator is being used for protection against both. A fit-test safety factor of 10 is required; that is, a person would have to achieve a minimum of 1,000 on a quantitative fit test in order to apply an APF of 100 in the field. The new 10 CFR 20 requires licensees to revise committed effective dose equivalents upward based on whole body counting or in-vitro bioassay and other data. This should effectively limit internal dose and account for any serious respirator leakage. Finally, APFs in exact multiples of 10 are easier to apply in the field, thereby reducing the chances for miscalculation. The devices commonly used in the nuclear industry (in this proposed change) will all have APFs of 10; 100; 1,000; or 10,000. Those listed in Appendix A whose APFs are not even multiples of 10 are not widely used in nuclear facilities.

[A-5] An APF of 25 is assigned to this newly defined category of powered air purifying respirators in accordance with ANSI Z88.2-1992.

[A-6] Supplied-air respirators operating in the demand mode should not be used in nuclear applications.

The APF has been reduced from 5 to 1 to discourage their use.

[A-7] These devices have been used for many years, with no APF applied, in radiological environments such as control rod drive removal at boiling water reactors (BWRs). They are primarily used as contamination control devices, but they are supplied with air which the wearer breathes. No problems are known to have occurred which would disallow use of these devices. The allowance of an APF of 1 (i.e., no credit for concentration reduction) at least brings the use of these devices out of a regulatory "grey area," allowing the use of non-NIOSH/MSHA-approved suits, but requiring wearers to meet all other respirator program requirements. Licensees still have an option to apply to the commission for higher APFs in accordance with 20.X1703(a)(2). Requirements for standby rescue persons apply to these devices.

[A-8] A specific statement is added excluding radioactive noble gases from consideration as an airborne hazard. Under the current rule, DAC values are listed for each noble gas isotope. This has led some licensees to assign respirators based in whole or in part on the presence of these gases. The requirement for monitoring external dose occurs in another section of the Rule, and a warning is provided in this footnote (e).

[A-9] Quantitatively fit testing this device as a complete unit (i.e., operating in the recirculating, pressure demand mode) has a number of serious technical problems associated with it. Requiring that the facepiece alone be fit tested in the negative pressure mode, with a minimum acceptable fit factor of 1,000 accomplishes the desired result. ANSI Z88.2-1992 requires fit testing of all tight-fitting facepieces in the negative pressure mode, even though the device will be used in a pressure demand or continuous flow system. The revision to Reg Guide 8.15/NUREG-0041 will contain this same requirement.

APPENDIX A TO §§ 20.1001—20.2401—PROTECTION FACTORS FOR RESPIRATORS[a]

Description[b]	Modes[c]	Protection Factors[d]		Tested and certified equipment—National Institute for Occupational Safety and Health/Mine Safety and Health Administration tests for permissibility
		Particulates only	Particulates, gases and vapors[e]	
I. AIR PURIFYING RESPIRATORS[f]				
Facepiece, half mask[g]	NP	10		
Facepiece, full	NP	50		30 CFR part 11, Subpart K
Facepiece, half-mask, full, or hood	PP	1000		
II. ATMOSPHERE SUPPLYING RESPIRATORS				
1. Air-line respirator				
Facepiece, half-mask	CF		1000	
Facepiece, half-mask	D		5	
Facepiece, full	CF		2000	30 CFR art 11, Subpart J
Facepiece, full	D		5	
Facepiece, full	PD		2000	
Hood	CF		([h])	
Suit	CF		([i])	([j])
2. Self-contained breathing apparatus (SCBA)				
Facepiece, full	D		50	
Facepiece, full	PD		[k] 10,000	
Facepiece, full	RD		50	30 CFR Part 11, Subpart H
Facepiece, full	RP		[l] 5,000	
III. COMBINATION RESPIRATORS				
Any combination of air-purifying and atmosphere-supplying respirators		Assigned protection factor for type and mode of operation as listed above		30 CFR 11, §11.63(b)

Footnotes

a. For use in the selection of respiratory protective devices to be used only where the contaminants have been identified and the concentrations (or possible concentrations) are known. **[X-1]**

b. Only for shaven faces and where nothing interferes with the seal of tightfitting facepieces against the skin. (Hoods and suits are excepted.) **[X-2]**

c. The mode symbols are defined as follows:

CF = continuous flow
D = demand
NP = negative pressure (i.e., negative phase during inhalation)
PD = pressure demand (i.e., always positive pressure)
PP = positive pressure
RD = demand, recirculating (closed circuit)
RP = positive pressure, recirculating (closed circuit).

d.1. The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment (usually inside the facepiece) under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula: **[X-3]**

$$\textit{Concentration inhaled} = \frac{\textit{Ambient airborne concentration}}{\textit{Protection factor}}$$

d.2. The protection factors apply:

(a) Only for trained individuals wearing properly fitted respirators used and maintained under supervision in a well-planned respiratory protective program.**[X-4]**

(b) For air-purifying respirators only when high efficiency particulate filters (above 99.97% removal efficiency by thermally generated 0.3 μm dioctyl phthalate (DOP) test) are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards. **[X-5]**

(c) No allowance is to be made for the use of sorbents against radioactive gases or vapors. **[X-6]**

(d) For atmosphere-supplying respirators only when supplied with adequate respirable air. Respirable air shall be provided of the quality and quantity required in accordance with NIOSH/MSHA certification (described in 30 CFR Part 11). Oxygen and air shall not be used in the same apparatus. **[X-7]**

e. Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one half of the intake occurs by absorption through the skin so that an overall protection factor of less than 2 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. If the protection factor for a device is 5, the effective protection factor for tritium is about 1.4; or devices with protection factors of 10 the effective factor for tritium oxide is about 1.7; and for devices with protection factors of 100 or more the effective factor for tritium oxide is about 1.9. Air-purifying respirators are not suitable for protection against tritium oxide **[X-8]**. See also footnote i concerning supplied-air suits. **[X-9]**

f. Canisters and cartridges shall not be used beyond service-life limitations. **[X-10]**

g. Under-chin type only **[X-11]**. This type of respirator is not satisfactory for use where it might be possible (e.g., if an accident or emergency were to occur) for the ambient airborne concentration to reach instantaneous values greater than 10 times the pertinent values in Table 1, Column 1 of Appendix B of this part **[X-12]**. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials **[X-13]**. The mask shall be tested for fit with irritant smoke, prior to use, each time it is donned **[X-14]**.

h. Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than 1000 may be used for tested-and-certified supplied-air hoods when a minimum air flow of 6 cubic feet per minute is maintained and calibrated airline pressure gauges or flow measuring devices are used. A protection factor of up to 2000 may be used for tested and certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, this rate is greater than 6 cubic feet per minute, and calibrated airline pressure gauges or flow measuring devices are used. The design of the supplied-air hood or helmet (with a minimum flow of 6 cfm of air) may determine its overall efficiency and the protection it provides. For example, some hoods aspirate contaminated air into the breathing zone when the wearer works with hands-over-head. This aspiration may be overcome if a short cape-like extension to the hood is worn under a coat or overalls. Other limitations specified by the approval agency shall be considered before using a hood in certain types of atmospheres, such as the design and its permeability to the contaminant under conditions of use. **[X-15]**

i. Appropriate protection factors shall be determined (see 20.103(e)), taking into account the design of the suit and its permeability to the contaminant under conditions of use **[X-16]**. There shall be a standby rescue person equipped with self-contained breathing apparatus and communications equipment whenever supplied-air suits are used **[X-17]**.

j. No approval schedules are currently available for this equipment. Equipment shall be evaluated by testing or on the basis of reliable test information. **[X-18]**

k. This type of respirator may provide greater protection and 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. **[X-19]**

l. Quantitative fit testing shall be performed on each individual and no more than 0.02% leakage is allowed with this type of apparatus **[X-20]**. Perceptible outward leakage of gas from this or any positive pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially **[X-21]**. Special training in the use of this type of apparatus shall be provided to the wearer (see footnote k) **[X-22]**.

m. Protection factor for type and mode of operation as listed above.

Note 1: Protection factors for respirators, as may be approved by the U.S. Bureau of Mines/National Institute for Occupational Safety and Health (NIOSH) according to applicable approvals for respirators for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radiological hazards. The selection and use of respirators for these circumstances should take into account applicable approvals of the U.S. Bureau of Mines/NIOSH. **[X-23]**

Note 2: Radioactive contaminants for which the concentration values in Table 1, column 1, Appendix B of this part 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. **[X-24]**

Explanation of Changes and Deletions

[X-1] Unnecessary statement. Air sampling requirements and requirements for estimating possible airborne concentrations are covered elsewhere in the rule.

[X-2] Facial hair requirements have been moved to the body of the proposed rule [20.X1703(a)(9)].

[X-3] Essential information from footnote d.1 is contained in the proposed rule [20.1703(b)(2). Specifics regarding the application of assigned protection factors (APFs) will be contained in Reg Guide 8.15/NUREG-0041.

[X-4] These requirements are now stated in the proposed rule [fit testing: 20.X1703(a)(4)(v); training and supervision: 20.X1703(a)(4)(iii)]

[X-5] Testing and certification requirements for high efficiency (HEPA) filters are specified in 30 CFR 11 and need not be repeated here.

[X-6] This has been incorporated into proposed footnote d.

[X-7] These requirements are part of the NIOSH approval criteria for supplied air respirators and self-contained breathing apparatus. They need not be repeated here.

[X-8] This corrected statement is in proposed footnote d.

[X-9] Supplied-air suits are addressed in proposed footnotes g and h.

[X-10] This requirement is part of the NIOSH approval criteria for air-purifying respirators. It need not be repeated here.

[X-11] This requirement is contained in proposed footnote f.

[X-12] This restriction was removed by 10 CFR 20.1703(b)(1), and is incorporated unchanged into the proposed rule revision [10 CFR 20.X1703(b)(1)].

[X-13] The prohibition of half-masks for use against airborne plutonium is deleted. There is no technical or scientific basis for this prohibition.

[X-14] This requirement is deleted. The proposed rule revision addresses this concern in 20.X1703(a)(4)(iii) by requiring the user to perform a fit check (e.g., negative pressure check, positive pressure check, irritant smoke check) each time a respirator is donned.

[X-15] All of these requirements are part of the NIOSH approval criteria. This footnote has been deleted.

[X-16] The supplied-air suit issue is addressed in proposed footnotes g and h.

[X-17] Requirements for a standby rescue person are addressed in the proposed rule 20.X1703(a)(7).

[X-18] The supplied-air suit issue is addressed in proposed footnotes g and h.

[X-19] This footnote, slightly reworded, has been incorporated into proposed footnote i.

[X-20] This requirement, reworded, has been incorporated into proposed footnote j.

[X-21] This requirement, reworded, has been incorporated into proposed footnotes h and i.

[X-22] Training requirements are specified in the proposed rule 20.X1703(a)(4)(iii).

[X-23] This requirement has been incorporated into proposed footnote a.

[X-24] This requirement has been incorporated into proposed footnote i.