SECY 98-077

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

March 31, 1998

FROM: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

Original signed by
Samuel J. Collins

SUBJECT: PROPOSED RULE: RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE, 10 CFR PART 20 (WITS-9700194)

Attached for your signature is the Commission paper transmitting a proposed rule that would amend 10 CFR Part 20 to establish new rules for the use of respiratory protection consistent with ALARA. This rulemaking has been awaiting completion by ANSI of comprehensive guidance on respiratory protection.

The rulemaking would recognize new devices and procedures that have been proven to be effective, would establish more performance based requirements, and is estimated to reduce burden to licensees by about $2 million per year with no reduction in worker safety.

Coordination: This Commission Paper was coordinated with the Offices of Administration, Nuclear Material Safety and Safeguards, Nuclear Reactor Regulation, State Programs, Information Resources Management, and Enforcement. The Office of the General Counsel has no legal objection. The Office of the Chief Financial Officer concurs that there will be no resource impacts. The Office of the Chief Information Officer concurs that there will be no information technology or management impacts.

Attachments: Commission Paper w/atts.

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March 19, 1998

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: Malcolm R. Knapp, Acting Director Original Signed By:
Office of Nuclear Regulatory Research

SUBJECT: PROPOSED RULE: RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE, 10 CFR PART 20 (WITS-9700194)

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The rulemaking would recognize new devices and procedures that have been proven to be effective, would establish more performance based requirements, and is estimated to reduce burden to licensees by about $2 million per year with no reduction in worker safety.

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FOR: The Commissioners

FROM: L. Joseph Callan, Executive Director for Operations

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

PURPOSE:

To obtain Commission approval to publish a notice of proposed rulemaking in the Federal Register.

BACKGROUND:

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

DISCUSSION:

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

CONTACT:
Alan K. Roecklein, DRPM/NRR
(301) 415-3883

SECY NOTE: TO BE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

The proposed rule also recognizes new respiratory protection devices that have been proven effective, adopts new Assigned Protection Factors (APFs) based on ANSI determinations, and revises requirements for respiratory protection procedures, such as fit testing, to reflect current industry good practice. The proposed changes are believed by the staff to be a burden reduction that may save NRC licensees an estimated $2 million per year. The proposed rule would be considerably less prescriptive with no reduction in worker health or safety.

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

The proposed amendments include the following:

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

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

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

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

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

3. The proposed rule would specify the "fit factors" that licensees need to achieve in fit tests in order to apply the "assigned protection factors" specified for different types of devices pursuant to ANSI guidance. The proposed rule would also specify the frequency of fit testing. The NRC staff is proposing a retest frequency not to exceed 3 years. This differs from the ANSI recommendation for annual fit testing. The staff believes that the relaxation of the frequency of fit testing would contribute a significant cost savings with no reduction in worker health and safety. The regulatory guide accompanying this rulemaking will elaborate on the physiological changes such as weight loss, facial changes, and other conditions in certain individuals that might suggest that more frequent fit testing should be done.

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

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

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

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

A Regulatory Analysis (Attachment 3) was prepared to evaluate the cost/benefit of the proposed rulemaking. This analysis concludes that a cost reduction for all affected licensees on the order of $2 million per year will result from the proposed rule changes. The cost savings are found to result from a reduction in the frequency of fit testing, permitting the use of low-cost disposable masks rather than more expensive half-masks, deleting a requirement to issue a policy statement, and deleting the report to the region on startup of a respiratory program.

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

The backfit analysis performed for these proposed amendments concluded that although the net effect of the changes is a reduction in burden, changes in licensee procedures would be required, constituting a potential backfit. However, the OGC advised that because the proposed rule is redefining the level of adequate safety regarding the use of respirators for radiation protection, it meets one of the exceptions listed in 10 CFR 50.109(a) (4)(iii).

RESOURCES:

Resources needed for this rulemaking are included in the current budget.

COORDINATION:

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

RECOMMENDATION:

That the Commission:

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

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

3. NOTE:

   a. The rulemaking would be published in the Federal Register for a 75-day public comment period;

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

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

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

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

   f. A public announcement will be issued (Attachment 6); and

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

L. Joseph Callan
Executive Director
for Operations

Attachments:
1. Federal Register Notice
2. Regulatory Guide 8.15
3. Regulatory Analysis
4. Environmental Assessment
5. Congressional Letters
6. Public Announcement

Rev. 03/01/98

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SECY-98-_____

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NOTE: Classified - (1) to each Commission office, OGC (2), SECY (3), & Central Files (1)

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RETURN ORIGINAL TO: Alan Roecklein and extra copies to o-10H5

ATTACHMENT 1

FEDERAL REGISTER NOTICE

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-AF81

Respiratory Protection and Controls to Restrict Internal Exposures

AGENCY: Nuclear Regulatory Commission.

ACTION: 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.

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 Y 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 respirators 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) 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) 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 facepiece 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(i) 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, PFs 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(i).

Current footnote b, which permits the use of devices only when nothing interferes with the seal of a facepiece, 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(i). 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 PFs 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 PFs 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 PFs 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 facepiece 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 facepiece eliminated by this requirement is the so-called "quarter-mask" which seals over the bridge of the nose, around the cheeks and between the point of the chin and the lower lip. These devices 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 facepiece self-contained breathing apparatus (SCBA), when operating in the pressure-demand mode, to be used as an emergency device in unknown concentrations. This provision would be retained in footnote i to the proposed Appendix A to Part 20 and full facepiece SCBA operating in positive pressure, recirculating mode is added.

Current footnote l requires quantitative fit testing with a leakage less than 0.02 percent for the use of full facepiece, 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 l 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 l 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 l 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 facepiece 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 facepiece 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 facepiece, 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-facepiece 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 facepiece 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 facepiece, 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 facepiece 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-facepiece 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 facepiece 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 facepiece 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 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. Used 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 facepiece leakage when operating in the negative pressure mode is considerably higher than .hen 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) is designated as compatibility category C 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, and the provision in § 20.1704 are designated as compatibility category D and therefore are not required for purposes of compatibility.

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.

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 "environmental justice": the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. 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).

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 pr ssure 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 equipment[2]; 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 $\geq$ 10 times the APF for negative pressure devices, and a fit factor $\geq$ 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 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:

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.

ATTACHMENT 2

REGULATORY GUIDE 8.15

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

DRAFT REGULATORY GUIDE

February 1998
Division 8
Draft DG-8022

Contact: A.K. Roecklein (301)415-6223

8th TD 1-23-98

DRAFT REGULATORY GUIDE DG-8022

(Proposed Revision 1 to Regulatory Guide 8.15)

ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION

A. INTRODUCTION

The proposed revision of Subpart H, "Respiratory Protection and Controls To Restrict Internal Exposure in Restricted Areas," of 10 CFR Part 20, "Standards for Protection Against Radiation," would specify the conditions under which respiratory protection equipment may be used and list the procedural requirements that must be met by a licensee when using respirators to limit intakes of radioactive material and to take credit for the protection assigned to a respirator in limiting and estimating exposures of individuals to airborne radioactive materials. If an ALARA (as low as reasonably achievable) evaluation shows that further exposure reduction is appropriate, and no other practicable means are available to reduce exposure to airborne radioactive materials, respiratory protective equipment may be assigned or its use may be permitted consistent with the intent of the guidance provided in this regulatory guide. This guide describes the elements of a respiratory protection program that is acceptable to the NRC.

Licensees are encouraged to limit the use of respirators to those situations when their use is shown to keep total effective dose equivalent (TEDE) ALARA. Other methods of respiratory protection, such as the use of process or other engineering controls, limitation of exposure times, decontamination and so on, should be considered before the assignment of respirators.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the

Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received complete staff review and do not represent official NRC staff positions.

The information collections contained in this draft regulatory guide are covered by the requirements of 10 CFR Part 20, which were approved by the Office of Management and Budget, Approval No. 3150-0014. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

Summary of Regulatory Requirements

It is widely recognized among safety professionals that the use of respiratory protection devices in the workplace can impose physiological and psychological stresses on workers, obstruct their vision, hinder their movements, and make effective communications difficult. These factors increase the risk of physical injury to respirator wearers that, in many cases, far exceeds any potential risk associated with the inhalation of a small quantity of airborne radioactive material. Therefore, in Section 20.1703 the NRC proposes to require a minimum respirator program to control the risks associated with respirator use, even if the licensee does not intend to take credit for the protection provided by the respirators.

In Section 20.1701, process or engineering controls would be required to be used to the extent practicable to control the concentration of radioactive material in air. This suggests that the use of respiratory protection devices should be considered only after other measures to limit intake are exhausted.

Further, Section 20.1702 builds on Section 20.1701 by stating that if process or other engineering controls are judged not practicable, the licensee must increase monitoring and limit intakes by using access controls, limiting exposure times, or using respiratory protection or other (unspecified) controls to keep TEDE ALARA. Guidance for performing ALARA evaluations (that is, determining whether the use of respirators optimizes the sum of internal and external dose) is provided in this regulatory guide.

Licensees who use respiratory protection equipment to limit intakes of radioactive material must follow Section 20.1703. If a respiratory protection device is assigned or permitted to be used, the device is considered by the NRC as being used to limit intakes of airborne radioactive materials unless the device is clearly and exclusively used for potection against nonradiological hazards. Whether or not credit is taken for use of the device to reduce intake and dose, Section 20.1703 would apply whenever respiratory protection devices are used. (See NUREG/CR-6204, "Questions and Answers Based on Revised 10 CFR Part 20"[1] (USNRC, May 1994), page 44, Question 9.) The minimum respiratory protection program expected of any licensee who assigns or permits respirator use is outlined in Section 20.1703.

While the NRC does not regulate the use of respiratory protection devices against nonradiological hazards (except, for example, when fire or a toxic gas release could affect plant conditions), licensees are reminded that the respiratory protection requirements of OSHA apply to most industrial situations and that these requirements are similar in many respects to NRC requirements (see Appendix R to 10 CFR Part 50). The memorandum of understanding (MOU) between NRC and OSHA requires that NRC-identified violations of OSHA regulations that are significant safety concerns must be reported to OSHA.

Section 20.1703 also contains requirements that must be met before a licensee may use an assigned protection factor (APF) to take credit for the use of any respiratory protection device to reduce intake and dose.

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

The proposed Section 20.1705 would specify that a licensee must obtain authorization from the NRC before using assigned protection factors in excess of those specified in Appendix A to 10 CFR Part 20. The required application must describe the need for the higher APF and demonstrate that the proposed equipment provides the higher APF.

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[1]Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

Additional Information

When a licensee permits or assigns the use of respiratory protection devices, use of such devices should be in accordance with the manufacturer's instructions and should be consistent with the intent of the guidance provided in this regulatory guide, which describes the elements of a respiratory protection program that is acceptable to the NRC. More detailed advice and technical information can be found in NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials,"[2] which is currently being revised; Revision 1 will be available soon.

C. REGULATORY POSITION

1. ANSI STANDARD Z88.2-1992

The American National Standards Institute standard, ANSI Z88.2-1992, "For Respiratory Protection,"[3] contains information that may be used by licensees in respiratory protection programs, with the exceptions noted in this regulatory guide

2. ALARA REQUIREMENT

Section 20.1101(b) states that licensees must use, to the extent practicable, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses that are ALARA.

Section 20.1702 provides that licensees limit intakes by means of engineering controls or procedures, including the use of respirators, consistent with maintaining the total effective dose equivalent ALARA.

The NRC views the TEDE-ALARA requirement as a subset of the general ALARA requirement of 10 CFR 20.1101. That is, the focus should be on programmatic controls. The NRC does not expect or require that each action taken by the licensee be ALARA, nor does the

[2]Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

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

NRC require that all doses be ALARA, or that the licensee use all possible ways and means to reduce the TEDE. The NRC does not expect the worker TEDE to be ALARA in all cases. However, each licensee must have an ALARA program that is integrated into the site radiation protection program. Each licensee must track doses and take reasonable measures to maintain worker doses ALARA. The NRC recognizes that, when evaluations are needed to comply with Section 1702, those evaluations (and the factors needed to make them) are not exact science. Assumptions for worker efficiency, stay time hours, estimated intakes, etc., are by their very nature not precisely known. Therefore, when the evaluation results do not show a clear, obvious direction (to use or not use respirators), the NRC expects the licensee to use professional judgment as to whether or not to assign respirators.

2.1 ALARA Evaluation

Licensees who perform analyses to determine whether or not the use of respirators will optimize the sum of internal and external dose and who record these ALARA evaluations in accordance with the following guidance will be considered to be in compliance with the requirements for such evaluations.

2.1.1 The licensee should establish a reasonable threshold value for prospective external deep dose equivalent (DDE) (in rem) for an individual from a task or job *below* which a record of such an evaluation is not needed, and

2.1.2 The licensee should establish a reasonable threshold value for prospective collective external DDE (person-rem) for a task or job *below* which the record of such an evaluation is not needed.

When the licensee plans to use respiratory protection equipment, the licensee does *not* need to record ALARA evaluations for situations in which the projected external DDE dose to any individual or group of individuals is below the thresholds established for both the projected individual external dose (2.1.1 above) and projected collective external dose (2.1.2 above).

The licensee does not need to record ALARA evaluations when the intake is below the threshold if the licensee has established a threshold value for possible intake of radioactive material (as a fraction of ALI or as some number of DAC-hours) for an individual or group of individuals from a task/job *below* which a record of the evaluation is not needed.

Regardless of the magnitude of the projected external dose, the licensee does *not* need to perform or record such evaluations before requiring the use of respiratory protection equipment as a precautionary measure when there is a large uncertainty about the magnitude of the projected concentrations of airborne radioactive material to which the workers will be exposed (e.g., a new job with significant airborne contamination potential, but with no history of previous similar jobs). (See NUREG/CR-6204,[1] Question 60.)

2.2 Findings of ALARA Evaluation

When a specific ALARA evaluation is performed to justify the use or nonuse of respirators, the evaluation should consider the following:

2.2.1 Use of process and engineering controls, filtered ventilation systems, and decontamination instead of respiratory protection devices,

2.2.2 Control of access, limitation of exposure time, or the use of other types of exposure controls instead of respiratory protection devices, and

2.2.3 The estimated benefit. The evaluation should show that the TEDE for the job will be ALARA; that is, the internal dose avoided by using the respiratory protection equipment is likely to be greater than any additional external dose that may result from the use of these devices from respirator-induced inefficiency and other factors.

In performing an ALARA evaluation, when deciding which respirator is to be considered for assignment during a specific task, the licensee should divide the average ambient concentration of radioactive material in work place air (or the estimated average) by the appropriate DAC value for the contaminants present. The number obtained may be considered initially as an ideal minimum APF for the selected device. If the ALARA evaluation determines that use of a respiratory protection device might be justified, a device with this APF or greater should be considered. If selection of a respirator with this APF is inconsistent with ALARA, however, the licensee may select a device with a lower APF. Worker safety factors other than radiological factors should also be taken into account when performing such an ALARA evaluation.

The extent and level of detail addressed in TEDE ALARA evaluations should be commensurate with the potential radiological and physical risks involved in the activity. Consideration should be given to the potential consequences of performing the work or of not performing the work. The following factors should be considered in a respirator-TEDE ALARA evaluation.

- Environmental conditions,
- Protective equipment and clothing, including the respirator, to be required for the activity being evaluated, and their effects on worker efficiency,
- Comfort level of the workers regarding the use of respirators,
- Experience and skill level of the individual with respect to the task,
- Process and engineering controls to be used,
- Specific details of the task to be performed (e.g., dose rates, estimated average airbone condentrations),
- Potential post-activity negative impacts (e.g., personnel decontamination and skin dose assessments, portal monitor alarms).

Such evaluations should be documented in accordance with implementing procedures, but they may either be job-specific or be performed for general job types. Additional details on TEDE ALARA evaluations will be included in NUREG-0041. ALARA evaluations performed for general job types should be reviewed periodically to ensure that none of the assumptions or parameters upon which the evaluation is based have changed. The licensee, however, should be able to support the decision to use or not to use respirators in each circumstance. Supporting information could include the results of surveys, measurements and calculations, previous history with this or similar jobs, or other reasonable methods. The judgment of individuals with extensive knowledge and experience in the field may also be sufficient in circumstances that are not amenable to quantitative analysis.

For ALARA evaluations, a respirator-induced worker inefficiency factor of up to 15% may be used without further justification. Larger worker inefficiency factors may be used, but the licensee should have test data to support them.

2.3 Exceptions to Respirator-ALARA Requirement

The ALARA principle must be applied in a reasonable fashion when making respirator use decisions. The NRC staff recognizes that there may be situations when the dose evaluation clearly indicates that respirators not be used, but the licensee makes a professional decision to use respirators in spite of the evaluation for reasons that are valid but may not be quantifiable (or vice versa). The following paragraphs provide some additional examples of reasonable exceptions to the respirator-ALARA requirement.

When the use or non-use of respirators has no clear impact on TEDE, the licensee should opt to not use respirators in most circumstances. There could be some reasonable exceptions to this, however. For example, respirator use could be considered if a nonradioactive nuisance dust exists in the work area. In these cases, the respirators should be selected to have the least possible impact on worker stress, vision, and ability to communicate.

Other valid exceptions would be certain respiratory protection devices used to reduce heat stress on workers or used as contamination-control devices in high contamination but relatively low airborne radioactivity areas (e.g., the use of airline-supplied hoods for steam generator entries).

Also, a reduction in TEDE for a worker would not be *reasonable* if an attendant increase in the worker's industrial health and safety risk (from a vision limitation or other respirator-related problem) would exceed the benefit to be obtained by reducing the risk associated with the reduction in the TEDE. (See NUREG/CR-6204,[1] Question 387.) This determination is likely to be based on judgment rather than any quantitative comparison.

The NRC is aware of existing State OSHA regulations that *require* an employer to provide a worker with a respirator upon request. Compliance with such State regulations is acceptable to the NRC. (See NUREG/CR-6204,[1] Question 386.)

3. PROCEDURES AND PROGRAMS

3.1 Applicability

Pursuant to the proposed Subpart H of 10 CFR Part 20, a licensee may assign or permit the use of, and take credit for the use of, respiratory protective equipment to limit intakes of airborne radioactive material. Unless the licensee can clearly show otherwise, any use of respirators is considered to be for the purpose of limiting intake of radioactive material.

Therefore, if respirators are assigned or permitted, the licensee's respiratory protection program must include all the requirements contained in Section 20.1703 as a minimum.

3.2 Written Procedures

Section 20.1703 requires that written procedures be in place. These procedures are to address and implement the following respiratory protection program elements:

- Monitoring, including air sampling and bioassays,
- Training of respirator users, including the requirement for each user to inspect and fit check a respirator each time it is donned,
- Fit testing,
- Selecting respirators,
- Breathing air quality,
- Inventory and control of respiratory protection equipment,
- Storage and issuance of respiratory protection equipment,
- Maintenance, repair, testing, and quality assurance of respiratory protection equipment,
- Recordkeeping,
- Limitations on periods of respirator use and relief from respirator use.

Written procedures should also be in place for:

- Performing and documenting the required medical evaluation,
- Supervision of the program, including program audits,
- Training and minimum qualifications of respirator program supervisors and implementing personnel,
- Maintaining TEDE ALARA and performing ALARA evaluations with regard to respiratory protection.

Written procedures should also include a description of the following applications of respirators:

- Routine respirator use (e.g., while engineering controls are being established)
- Nonroutine respirator use (e.g., nonrecurring tasks for which engineering controls are not justified); and
- Emergency respirator use (e.g., recovery of an injured person in an unassessed portion of the restricted area or an area that may become immediately dangerous to life or health (IDLH)).

3.3 Application of Assigned Protection Factors

If the APF of a respirator is greater than the multiple by which average ambient concentration of airborne radioactive material in the workplace exceeds the applicable DAC value, and the licensee's respiratory protection program meets all the requirements of Subpart H, no record of internal exposure (DAC hours) or internal dose (mrem) need be kept, calculated, or retained.

3.4 Surveys

The proposed Paragraphs 20.1703(c)(1) and (2) require a survey program that is adequate to identify potential respiratory hazards, to permit selection of the proper respiratory protection method (not necessarily the assignment of respirators), and to evaluate actual or suspected intakes. Survey programs include (but are not necessarily limited to) surveys for radiation, contamination, airborne radioactive materials, and bioassay measurements.

3.5 Supervisory Requirements

A program should be established that identifies the individuals who have supervisory and technical responsibilities in the respiratory protection program (including the respirator program administrator), specifies minimum training and retraining requirements for each position, and identifies the minimum qualifications for appointment or assignment to these positions. The radiological and nonradiological respiratory protection programs may have different administrators, so long as adequate communication and coordination exist between the programs. [This is an exception to paragraph 4.5.1 of ANSI Z88.2-1992.]

3.6 Inappropriate Uses of Respirators

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

1. For performing routine tasks or tasks that are accomplished frequently or repetitively, unless unusual circumstances exist. Exposure to airborne contaminants during routine or repetitive tasks should normally be controlled in other ways.

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

3. For eye protection only;

4. For protection from surface contamination in excess of certain levels without additional justification. Consideration should also be given to other factors that would affect the potential for the contamination to become airborne.

4. EQUIPMENT

4.1 NIOSH-Approved Equipment

The National Institute for Occupational Safety and Health (NIOSH) issues approvals for respiratory protection devices. A list of the manufacturers and model numbers of such devices are available from NIOSH.[4] The NRC requires that only NIOSH-approved equipment be used in a radiological respiratory protection program, unless a variance has been granted as described in 10 CFR 20.1703(b). In addition, the licensee must use, maintain, and store these devices in such a manner that they are not modified and are in like-new condition at the time of issue (see "NIOSH Approval Requirements for Respiratory Protection Equipment," *Radiation Protection Management,* Vol. 14, September/October 1997). A reasonable amount of wear that does not affect performance is acceptable.

According to Section 20.1703(e), the licensee is to provide adequate equipment or material as necessary to supplement respiratory protective equipment to reduce the likelihood that respirator use might contribute to workplace accidents or injury. Examples of such equipment would be spectacle adapters, voice amplification equipment, material or equipment to prevent or reduce fogging of respirator lenses, and body-cooling equipment in environments with high temperature and high humidity.

Other safety or protective equipment used in conjunction with respirators should not interfere with the proper fit or operation of the respirator.

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[4]This list is available from Publications Dissemination, DSST, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

4.2 Non-NIOSH-Approved Equipment

If a licensee identifies a need for a respiratory protection device that would adequately provide the needed protection but the device is not NIOSH-approved, is not listed in Appendix A to 10 CFR Part 20, and no comparable NIOSH-approved device exists, the licensee may apply to the NRC to use the nonapproved device (Sections 20.1703(b) and 20.1705). NRC approval is required whether or not APF credit will be used. This application should include an explanation of why no existing NIOSH-approved device meets the licensee's need, and it should include evidence that the material quality and performance characteristics of the proposed device are capable of providing adequate respiratory protection to the wearer under the proposed conditions of use, while not subjecting the wearer to undue physical or psychological stress or undue hazard.

Such test information may be provided by the licensee, the equipment manufacturer, or by a reliable third party. The manufacturer of such a device should have previous experience with the design and manufacture of respiratory protection equipment. The licensee may use such devices under controlled test conditions to develop information for the authorization application. When an authorization for such a device has already been granted to a licensee by the NRC, subsequent applications by additional licensees may make use of test information that was submitted previously. As a minimum for devices that have not yet been authorized for use by the NRC, the licensee should be involved in at least one operational test of the device.

4.3 Inventory, Inspection, and Storage

Respirator facepieces that are routinely available for issue should be visually inspected at least every month. If such devices are stored in clear plastic bags, they should be handled and examined, but need not be removed from the bags for this inspection as long as the licensee can determine that the device is ready for issue. Respirator facepieces (face-sealing types) must be checked for leakage prior to each use (Section 20.1703(c)(3)). A fit check performed by the person being issued the respirator fulfills this requirement.

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

Emergency respiratory protection equipment (SCBA) should be donned and operationally tested frequently (at least quarterly). Other respiratory protection devices designated for

emergency use (e.g., escape-only devices, air-purifying respirators specifically designated for emergency use, such as at the Emergency Operations Center at a commercial power reactor facility) should be removed from any protective bag and thoroughly examined periodically (2-3 times per year).

Repair and replacement parts for respiratory protection devices should be inventoried and inspected periodically as recommended by the manufacturer.

When in storage and not available for use, respirators and component parts of respiratory protection devices should be stored in such a way as to prevent damage to such components and devices. Devices in storage should be inspected prior to being made available for issue.

4.4 Maintenance and Repair

Respirators and component parts of respiratory protection devices should be maintained and repaired only by persons specifically trained to perform this work. Such repairs and maintenance should be accomplished in accordance with the manufacturer's instructions, but in general, training by the device manufacturer is not required. Maintenance and repair of some components of certain devices require manufacturer-certified training (e.g., SCBA regulator, SCBA low-pressure alarm function). These components are specified by the device manufacturer.

Records of all maintenance and repairs should be maintained in a manner consistent with good quality assurance practices. Records of other aspects of the program should be kept in a manner that shows compliance with the requirements of the applicable regulations.

4.5 Control and Issuance

Licensees should maintain positive control over the issuance of respiratory protection devices. Sufficient control should be established and maintained so that persons not authorized to wear such devices are effectively prevented from obtaining them.

4.6 Half-Mask Respirators (APF = 10)

A relatively new variation on the half-mask respirator is referred to variously as a "reusable," "reusable-disposable," or "maintenance-free" device. In these devices, the filter

medium is an integral part of the facepiece and is not replaceable. The four-point suspension straps are adjustable. Also, the face-sealing capabilities are enhanced by the application of plastic, rubber, or a similar elastomeric material to the entire facepiece seal area. (Note that the presence of an exhalation valve does not automatically put a device into this category.) These devices are considered half-masks (APF = 10). They are acceptable to the NRC as long as they are made of high efficiency (≥99%) filter media, a fit check can be properly performed by the wearer upon donning, and all other requirements (e.g., fit testing, training) are fulfilled. It is important to follow manufacturer's recommendations and contamination control procedures to establish the length of time such facepieces may be used before being discarded.

The use of quarter-mask respirators (which seal over the bridge of the nose, around the cheeks, and between the point of the chin and the lower lip) is not acceptable to the NRC.

4.7 Single-Use Disposable Respirators (No APF)

Characteristics of single-use disposable respirators are

- Nonadjustable suspension straps
- Relatively thin layer of filter media
- Metal strip near the top intended to be pinch-fitted over the bridge of the wearer's nose
- Packaged 10 or more to a box or bag, rather than individually
- Efficiency of filter medium is <99%.

While a few respirators of this type may lack one or more of the characteristics listed above, an experienced respirator program administrator should be able to easily distinguish between single-use disposable respirators and those that qualify as half-mask respirators in an NRC-regulated program. [This is an exception to ANSI Z88.2-1992, Table 1. The standard does not differentiate between single-use disposables and half-masks, but allows an APF = 10 to all disposables, quarter- and half-masks.]

Single-use disposable respirators are inexpensive; have little or no impact on worker vision, cardiopulmonary stress, heat stress, and ability to communicate verbally; and they create very little solid radioactive waste. These devices are now permitted for use in a radiological respiratory protection program, but no credit may be taken for their use. Licensees are also relieved of the requirement to medically screen and fit-test the wearers of such devices. Since it is very difficult to effectively perform a standard fit check on these devices prior to use, this requirement does not apply. All other applicable program requirements listed

in 10 CFR 20.1703 apply. Devices must be NIOSH-approved, and wearers must be trained in the proper use and limitations of the devices. The availability of the devices should be controlled so that untrained individuals cannot obtain these devices and so that these devices are not mistakenly substituted for a more protective device in the field.

The proposed rule would pemit a licensee to use an APF of 10 for these devices if the licensee can demonstrate a fit factor of at least 100 by using a validated or evaluated, qualitative or quantitative fit test. Acceptable protocols for qualitative fit testing can be found in Sections B1 through B5 of Appendix A to OSHA's 1910.134, "Respiratory Protection."

Single-use respirators might be appropriate in situations when a respirator is not necessary but one is requested by a worker. Single-use respirators could limit intakes of nuisance dusts when use of a more protective device cannot be TEDE ALARA-justified. These devices should be discarded each time they are removed, and a new device should be used for subsequent work.

4.8 Respirator Filters

NIOSH has changed the way nonpowered air-purifying respirator filters are certified and designated. Under the old rule (30 CFR Part 11), respirator filters for protection against airborne radionuclides were required to be 99.97% efficient for the collection of 0.3 μm mass median aerodynamic diameter particles, the particles being produced by the vaporization and condensation of dioctyl phthalate (DOP). Filters that meet this criterion are commonly designated high-efficiency particulate air (HEPA) filters. Under the new rule (42 CFR Part 84), filters are divided into three categories based on their performance characteristics when used against oil-containing and non-oil-containing airborne hazards. The categories are N (non-oil-resistant), R (oil-resistant), and P (oil-proof). Within each category, three levels of efficiency are defined: 95 (95% minimum efficiency), 99 (99% minimum efficiency), and 100 (99.97% minimum efficiency). Some examples of filter designations would be N-99, P-95, R-99. The judgment as to whether N, R, or P filters should be used is left to the licensee. For air-purifying respirators operating in the negative-pressure mode, with APF $\leq$100, filters of at least 99% efficiency should be used (e.g., N-99).

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

4.9 Service Life Limitations

If the respirator equipment manufacturer specifies a service life limit on one or more components of a respiratory protection system, the licensee should take whatever action is recommended by the manufacturer. This will ensure that the device continues to operate properly and that the "like-new condition" criterion is maintained as described in Regulatory Position 4.1 of this guide.

4.10 Supplied-Air Suits

One-piece and two-piece supplied-air suits are permitted for use in nuclear industry respiratory protection programs, but no APF is assigned and no protection credit may be taken. NIOSH does not have a method of testing and certifying these suits, but the NRC believes that in certain nuclear industry applications they might be the best overall choice, taking into account respiratory protection, contamination control considerations, heat stress, and ALARA.

Users of supplied-air suits must still be medically approved and trained; the air supplied to the suit must meet the minimum quality requirements specified for other (NIOSH-approved) supplied-air devices; and the equipment must be stored, maintained, and tested (as applicable) in accordance with the manufacturer's recommendations and the licensee's respirator maintenance and quality assurance program.

When selecting such devices for use in a respiratory protection program, the licensee should determine that the material quality and performance characteristics of the proposed device are capable of providing adequate respiratory protection to the wearer under the proposed conditions of use, while not subjecting the wearer to undue physical or psychological stress or undue hazard.

Such material and performance information may be provided by the licensee, the equipment manufacturer, or by a reliable third party. The manufacturer of such a device should have previous experience with the design and manufacture of respiratory protection equipment. The licensee or applicant may use such devices under controlled circumstances to develop information for the exemption application. When an exemption for such a device has already been granted to a licensee by the NRC, subsequent applications by additional licensees may make use of test information previously submitted. At a minimum, for devices that have not yet been granted an exemption by the NRC, the applicant should be involved in at least one operational test of the device.

4.11 Combination Devices

Some devices are available that combine two respirator types in one unit (e.g., a combination negative-pressure air-purifying and continuous flow airline respirator). When taking credit for use of such a combination device, the licensee must ensure that the proper APF is applied to the exposure time and airborne concentration that exists while the respirator is functioning in each mode of operation.

4.12 Emergency and Escape Equipment

The equipment preferred for emergency entry into an unassessed environment is the open-circuit self-contained breathing apparatus (SCBA) operated in the pressure-demand mode. Also acceptable is the positive-pressure, closed-circuit (recirculating) SCBA.

Other equipment designated for emergency use (e.g., air-purifying devices stored at the Emergency Operations Center at a commercial power reactor facility) must be NIOSH-approved for use against the contaminants that might be encountered during an emergency. Some short-duration SCBAs are approved for escape only, and these may be used for escapes.

5. RESPIRATOR USERS

5.1 Medical Evaluation

According to Section 20.1703(c)(5), the initial medical evaluation to determine a worker's fitness to use respirators must be accomplished prior to respirator fit testing for tight-fitting facepieces, and prior to the first field use for loose-fitting devices. Re-evaluation must be performed either every 12 months thereafter, or at some other frequency established by the determining physician. ANSI Z88.6-1984, "Respirator Use -- Physical Qualifications for Personnel,"[2] provides guidance that is acceptable to the NRC staff for the physician in determining medical fitness. The screening method may include a medical history questionnaire and spirometry testing. The frequency of re-evaluation may range from every 5 years for workers below age 35, to annually for workers over age 45. A re-screening "grace period" of up to 90 days is considered to be reasonable.

A "hands on" physical examination by a physician is not required. A physician (the "determining physician") should determine which screening tests are appropriate, should set

the acceptance criteria for those tests, and should periodically review the implementation of the program. This screening process should be sufficient to identify any persons who should not use respiratory devices for medical reasons.

The medical evaluation program should be carried out by certified, medically trained individuals such as registered nurses (RNs), licensed practical nurses (LPNs), emergency medical technicians (EMTs), or others who, in the judgment of the determining physician, have adequate experience, education, training, and judgment to carry out this program. Potential respirator users who fall outside the range of established acceptance criteria may be examined by the determining physician, who can then make a medical judgment about which types of respirators the individual may or may not wear.

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

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

5.2 Training

A training program, including hands-on training, must be established and implemented for respirator users (Section 20.1703(c)(4)). When face-sealing respirators will be used, this training should take place prior to fit testing. As a minimum, each trainee should:

1. Be informed of the hazard to which the respirator wearer may be exposed, the effects of those contaminants on the wearer if the respirator is not worn properly, and the capabilities and limitations of each device that will be used.
2. Be shown how spectacle adapters, communications equipment, and other equipment that will be used directly in conjunction with the respirator are to be attached and operated properly.
3. Demonstrate competency in donning, using, and removing each type of respiratory protective device that may be used,
4. Be instructed in how to inspect each type of respiratory protective device that may be used, and be instructed to perform such an inspection prior to donning any device,

5. For face-sealing devices, be instructed in how to perform a fit check, and be instructed to perform this fit check each time this type of device is donned,
6. Be informed that each respirator user may leave the work area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communications failure, significant deterioration of operating conditions, or any other condition that might necessitate such relief.

5.3 Fit Testing

A fit testing program is to be implemented for all face-sealing respirators (Section 20.1703(c)(6)), even if they will be used in a positive pressure mode in the field. Quantitative fit-testing (QNFT) is acceptable for testing all such devices. Qualitative fit-testing (QLFT) is acceptable if (1) it is capable of verifying a fit factor of 10 times the APF for facepieces that in the field will operate in the negative pressure mode or (2) it is capable of verifying a fit factor of $\geq$100 (not 100 times the APF) for facepieces that in the field will operate in a positive pressure mode (devices labeled CF, PD, PP, or RP in Appendix A to 10 CFR Part 20). Protocols that can be used for developing QLFT and QNFT procedures may be found in Sections B1 through B5 and in Sections C1 through C3 of Appendix A to OSHA's 29 CFR 1910.134, "Respiratory Protection."

The factor of 10 greater than the APF is considered to be an adequate safety factor. If, for example, a particular QLFT is only sensitive enough to show a fit factor of 500 on a negative-pressure device with APF = 100, a licensee could still allow that device to be used with an APF = 50. Fit-testing should be performed in accordance with an established protocol.[5] Each time fit-testing is required, only a single satisfactory fit test need be performed.

Retesting does not need to be more frequent than annually, but should be at least every three years. This is an exception to the recommendations found in paragraph 9.1.4 of ANSI Z88.2-1992. A retest "grace period" of up to 90 days is considered reasonable. Many years of fit-test experience in the nuclear industry have convinced the NRC staff that face-fit characteristics do not change dramatically over a 3-year period, except as noted in the next paragraph.

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

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

1. A weight change of 10% or more,
2. Significant facial injury or scarring in the area of the facepiece seal,
3. Significant dental changes (e.g., multiple extractions without prosthesis, acquisition of dentures),
4. Reconstructive or cosmetic surgery in the area of the facepiece seal,
5. Any other condition that might change the fit of a face-sealing respirator.

Licensees should take steps to make these retest criteria known to respirator users (e.g., during training and retraining) and should work with site medical or health personnel to identify persons who meet any of the criteria. Adding or revising some questions on a medical screening questionnaire (if used) might be considered. Transient workers may need to be fit tested more often than every three years because the changes listed above are less likely to be apparent to a particular licensee.

Licensees are cautioned that Federal regulations that apply to some nonradiological hazards (e.g., 29 CFR 1910.1001 on asbestos) may require retesting at more frequent intervals, and they may require more than one satisfactory fit-test.

Fit testing must be accomplished with the facepiece operating in the negative pressure mode, regardless of the mode of operation in which it will be used in the field. Some respirators used for fit testing may need to be modified to accomplish this. While this modification voids the NIOSH approval for the testing device, approval is not required for respirators used during fit testing since occupational exposures are not involved. Filters used during fit testing should be 99.97% efficient, even if only 99%-efficient filters will be used in the work place. The fit test is intended to measure only face to facepiece leakage, so filter efficiency should be as high as possible. The size of the particles that make up the challenge aerosol during fit testing is unimportant. Corn oil, sodium chloride, and ambient dust particles are all acceptable so long as the sensitivity of the detection system meets the previously stated criteria.

If quantitative fit testing is used to test facepieces that will operate in the negative pressure mode in the field, a fit factor of at least 10 times the APF (given in Appendix A to 10 CFR Part 20) should be demonstrated before an individual is permitted to use that facepiece in the field. For combination devices (e.g., a combination negative-pressure air purifying and continuous-flow airline device), the minimum acceptable fit factor is 10 times the APF for the

negative pressure mode of operation. If quantitative fit-testing is used to test facepieces that in the field will operate only in the positive pressure mode (e.g., powered air-purifying respirators), in the continuous-flow mode (e.g., air line respirators), or in the pressure demand mode (e.g., air line respirators, SCBA), a fit factor of at least 100 (not 100 times the APF) should be demonstrated with the facepiece operating in the negative pressure mode before an individual is permitted to use that facepiece in the field.

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

During training or operation, perceptible outward leakage of breathing gas from the face-to-facepiece seal area of any self-contained breathing apparatus is unacceptable, and the wearer should not be permitted to continue to use the device.

If irritant smoke is used as the challenge aerosol during qualitative fit testing, the licensee should take steps to protect the person administering the test from repeated exposures to the irritant smoke. These steps could include using a containment chamber around the head and torso of the fit test subject to contain the smoke, test area ventilation or air filtration, assignment of a respiratory protection device to the person performing the fit testing, or other measures.

5.4 Fit Checks (User Seal Checks)

With the exception of single-use disposable respirators when no credit for protection is allowed and for which the requirement is waived, each respirator wearer must perform at least one type of fit check each time a face-sealing respirator is donned. A fit check is performed immediately prior to exposure to ensure that the respirator is properly seated on the face. Some licensees may require the respirator user to perform such a fit check at the point of respirator issue to ensure that the respirator is in good working order before the worker proceeds to the job site. A fit check is no substitute for a fit test. Acceptable fit checks are a positive-pressure check, negative-pressure check, and checks performed using an irritant or odorous test agent.

5.5 Operational Checks

Non-face-sealing respirators (e.g., airline-supplied hoods) should be operationally checked to ensure proper operation a short time before the wearer enters the radiological environment for which the device is to be used for protection.

6. SAFETY

6.1 Standby Rescue Persons

Section 20.1703(f) would require that, when standby rescue persons cover workers wearing suits and other protective equipment that are difficult to remove without assistance, the standby persons must be equipped with respiratory protection devices appropriate for the potential hazards, must observe or otherwise be in direct communication with such workers, and must be immediately available to assist them in case of a failure of the air supply or any other reason that necessitates relief from distress. A sufficient number of standby rescue persons (not necessarily one-for-one) must be available to effectively assist all users of this type of equipment.

6.2 Face-to-Facepiece Seal Integrity

The prohibition in 10 CFR 20.1703(h) against anything under the control of the respirator user that might interfere with the seal of a respirator includes (but is not necessarily limited to) facial hair of any kind in the seal area (the worker must be clean-shaven), hair from the head that might interfere, cosmetics, spectacle temple bars, protective clothing, and equipment. A respirator wearer should not be required to shave more than once during each 12-hour period.

6.3 Unassessed Environments

For entry into areas where the level of hazard has not been assessed because of the existence of unusual conditions, the licensee must use only SCBA operated in the pressure-demand mode. The use of SCBA to circumvent the pre-exposure sampling requirement is not permitted for nonemergency activities.

6.4 Emergency Escape

For emergency escape from normally safe environments, where a respiratory hazard might develop suddenly, any type of device authorized for use in Appendix A may be used as long as it provides adequate short-term protection against the type of hazard that might be encountered. Single-use disposable respirators would not be appropriate for this application.

6.5 Breathing Air Quality

The quality of the air delivered to atmosphere-supplying respirators must meet the requirements of Grade D air as defined in ANSI/CGA G-7.1-1989, "Commodity Specification for Air,"[6] as a minimum [10 CFR 20.1703(g)] in order for NIOSH certification to be applicable. The quality of the air should be tested periodically at time intervals that are reasonable under the circumstances and conditions of use. Intake points for breathing air compressors should be located and protected in such a way as to prevent airborne contaminants from being drawn in.

6.6 Use of Higher Assigned Protection Factors

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

6.7 OSHA Requirements

Licensees are reminded that OSHA regulations, many of which are listed in Appendix A to this guide, may contain requirements for using respiratory protection equipment and for monitoring or controlling workplace hazards that might occur concurrently with airborne radiological hazards. Some hazards to be considered are heat stress, oxygen deficiency, and confined spaces.

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

6.8 Limiting Duration of Respirator Use

Licensees should establish reasonable limits on the length of time that individuals are required to work while using respirators. The NRC recognizes that such limits will vary considerably and will depend on a variety of factors such as temperature and humidity in the work area and the type of respirator being used. Limits may be based on input from medical personnel and from experienced respirator users. Additional guidance for limiting duration of respirator use will be provided in the revision to NUREG-0041.

7. ANSI Z88.2-1992, EXCEPTIONS

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

7.1 Paragraph 4.5.1

Paragraph 4.5.1 of ANSI Z88.2-1992 states "The responsibility and authority for the respiratory protection program shall be assigned by the employer to a single person." It is acceptable to the NRC staff if the individual who administers the 10 CFR Part 20 Subpart H program is different from the person who administers the industrial respiratory protection program.

7.2 Table 1 -- Assigned Protection Factors

In ANSI Z88.2-1992, Table 1, "Assigned Protection Factors," permits the use of quarter-mask respirators (which seal over the bridge of the nose, around the cheeks, and between the point of the chin and the lower lip). These are not listed in Appendix A and may not be used in an NRC-regulated respiratory protection program.

ANSI also lists various APFs for atmosphere-supplying respirators that operate in the demand mode. The NRC's position is that, since these devices operate in the demand mode, any face-to-facepiece seal leakage will permit contaminants to enter the respiratory inlet covering where they could be inhaled. Since these devices are air-supplied, individuals might perceive them to be more protective than they really are and attempt to use them in situations

in which a device with a much higher APF is indicated. This is especially true of demand SCBA. The NRC, therefore, is adopting the APFs recommended by ANSI, but urges licensees to ensure that these devices are not used in areas that are immediately dangerous to life and health (IDLH).

7.3 Paragraph 9.1.4

Paragraph 9.1.4 states "A respirator fit test shall be carried out for each wearer of a tight-fitting respirator at least once every 12 months." The NRC staff's position is that the retest period in a radiological respiratory protection program may be as long as three years, with surveillance of workers as described in Regulatory Position 5.3 of this guide.

7.4 Paragraphs 9.3.1 and 9.3.2

Paragraphs 9.3.1 and 9.3.2 could be interpreted to mean that respirators from several manufacturers, or several different model respirators from the same manufacturer, are required to be available for use. The NRC staff's position is that one model respirator from one manufacturer is adequate, so long as different sizes of that facepiece are available, and adequate fit factors are obtained for greater than 99% of test subjects who are free of facial characteristics that preclude an adequate respirator fit. For those individuals who achieve a fit factor >100, but who are unable to achieve a fit factor 10 times the APF, consideration should be given to a positive pressure face sealing device or to a device for which a face seal is not necessary.

D. IMPLEMENTATION

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

This draft guide has been released to encourage public participation in its development. Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, the method to be described in the active guide reflecting public comments will be used in the evaluation of applications for new licenses or license amendments and for evaluating compliance with Subpart H of 10 CFR Part 20.

APPENDIX A
OSHA Regulations

The sections of the OSHA regulations listed below, among others, may contain requirements which are in addition to those required by the NRC. They may also contain requirements for limiting or controlling hazards which are not under the jurisdiction of NRC.

29 CFR 1910.120	Hazardous Waste Operations
29 CFR 1910.134	Respiratory Protection-General Industry
29 CFR 1910.146	Permit Entry Confined Spaces
29 CFR 1910.155	Fire Protection
29 CFR 1910.401	Commercial Diving Operations
29 CFR 1910.1000	Air Contaminants (PELs)
29 CFR 1910.1001	Asbestos
29 CFR 1910.1025	Lead
29 CFR 1910.1028	Benzene
29 CFR 1910.1048	Formaldehyde
29 CFR 1926.103	Respiratory Protection-Construction Industry

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. The draft regulatory analysis, "Regulatory Analysis of Proposed Revisions to 10 CFR Part 20, Subpart H, Respiratory Protection and Controls To Restrict Internal Exposure in Restricted Areas," was prepared for the proposed amendments, and it provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the draft regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC, as Enclosure ___ to SECY _____. **CAN YOU FILL IN THE BLANKS YET?**

ATTACHMENT 3

REGULATORY ANALYSIS

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

DRAFT FOR COMMENT

August 27, 1997

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Attachment 3

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1. Statement of the Problem

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

1) non-radioactive nuisance dust in the work area, or
2) workers and/or the health physics department are in a relatively short-term learning process or making a transition from routine use of respirators, or
3) the use of certain respiratory protection devices reduces heat stress on workers, or
4) they are used as contamination control devices in high contamination but relatively low airborne radioactivity areas with the potential for significant resuspension, or
5) they serve as a precautionary measure in which there is a large uncertainty in the magnitude of the projected concentrations of airborne material to which workers might be exposed.

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

2. Objectives of the Rulemaking

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

3. Alternatives

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

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

4. Consequences

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

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

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

The proposed changes should resolve occasional problems with freezing of respirator exhalation valves leading to possible respirator failure and inhalation of unfiltered air, and lens fogging leading to reduced vision. The proposed amendment has the potential for some increase in regulatory burden. For example, if licensees needed special low temperature

attributes not provided by NIOSH and manufacturers, the licensees would be required to apply for approval to NRC under § 20.1703(b). While these changes may be justified on the basis of improved personnel safety under low temperature conditions, the potential impacts are addressed in the following section.

3) The NRC has concluded that, with the exception of events which could change an individual's respirator fit (e.g., weight loss or gain, surgery, etc.), fit tests for tight fitting, face sealing respirators need to be conducted only every 3 years. This position is different from the recommendations of the ANSI Z88-1992 standard for respiratory protection. Currently, NRC licensees are required to perform annual fit testing. For normal circumstances, the NRC now feels a fit test every 1 to 3 years is acceptable and will not result in any loss of worker protection. The proposed rule requires periodic retesting and the draft revision to Regulatory Guide 8.15 suggests a 3 year retest period. Some special cases which NRC feels would require more frequent fit testing would be those which might reasonably degrade respirator fit including:

- a weight change of 10 percent or more;
- significant facial injury or scarring in the area of the facepiece seal;
- significant dental changes (i.e., multiple extractions without prosthesis, or acquiring dentures;
- reconstructive or cosmetic surgery in the area of the facepiece seal;
- any other condition which might change the fit of a face-sealing respirator.

Since increasing the fit test period has the potential to reduce the current costs of licensee fit testing, this proposed change will be addressed in the value/impact analyses.

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

5) It is proposed to delete the part of Footnote g to Table 1 of Appendix A which currently precludes the use of half mask facepiece air purifying respirators for protection against plutonium or other high-toxicity materials. 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 has not identified any current technical or scientific basis for such a prohibition, and deletion may result in some reduction in regulatory burden because the change should increase operational flexibility. This is evaluated further in the value/impact analysis.

6) The proposed addition of single use, disposable respiratory protection devices (e.g., dust masks) to the proposed Appendix A recognizes the utility of disposables and formally permits their use with no protective credit allowed. These devices have minimal physiological impact, accommodate workers who request respirators (some States have OSHA rules which require providing respirators to workers who request them), NRC does not require fit testing or medical screening and although not quantifiable, they have been shown to provide some protection against intake. Although many of these devices cannot be tested for a measurable

seal, licensees should train workers in their use and limitations. Use of such devices by persons desiring but not requiring respiratory protection (i.e., because of engineered control systems, or other factors) could result in substantial savings, and will be addressed further in the value/impact analysis.

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

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

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

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

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

12) The proposed reduction of the Appendix A APF for full facepiece air-line respirators operating in pressure demand mode from 2,000 to 1,000, recommended by ANSI, is not expected to result in a significant increase in regulatory burden. Field concentration seldom presents a need for an APF of 2,000, as opposed to 1,000, and licensees may still petition NRC

to use higher APFs based on measurement and documentation. The potential impacts are addressed below in the regulatory value impact analysis.

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

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

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

5. Value Impact Analysis

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

- There are about 250 licensees affected by the changes; 100 power reactor licensees and 150 non-power reactor licensees
- Labor cost is $145/hr for a power reactor licensee and $116/hr for other licensees
- NRC labor cost is estimated to be $70/hr
- Approximately 200,000 workers at licensee sites (primarily power reactors) are currently monitored for radiation exposure; about half of the monitored workers

are exposed to a measurable dose; of those exposed to a measurable dose, about 10 percent/yr may use respirators (20,000)

- The most predominantly used respirators are the full mask negative pressure (NP) respirator, full mask positive pressure (PP) respirator or powered air-purifying respirator (PAPR), and full mask pressure demand (PD) Self Contained Breathing Apparatus (SCBA); no more than 10 percent currently use half-mask devices

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

1) Elimination of Policy Statements

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

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

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

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

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

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

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

Total cost savings = $10,835/year

2) Provision for Low-Temperature Usage

If a full-mask facepiece NP respirator is to be used for a low-temperature application, revised Regulatory Guide 8.15 recommends that the facepiece should be equipped with a nose cup.

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

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

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

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

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

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

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

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

3) Exception to ANSI Z88-1992 Requirement for Annual Fit Testing

This change is expected to reduce the current costs for fit testing of various types of respirators, depending on what is currently being used by licensees, without reducing the current level of worker protection. Thus, the cost savings would be associated with fit testing being performed every 2 or 3 years for most workers versus the current industry practice of about once each year for workers requiring respiratory protection, and with transferring fit test records between licensees (e.g., for refueling operations). As discussed below in item 6), it is estimated that it takes abc 1 hour for training and fit testing new workers prior to respirator use. It is assumed that about half of that time is involved with fit testing (0.5 hr/worker). NUREG-0713, Vol. 17 (Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities) shows that currently there are about 200,000 workers monitored for radiation exposure each year. It is estimated that up to half of those workers use respirators [see also discussion below in 6]). However, it is conservatively assumed that about 10 percent (20,000 workers) currently require fit testing each year. The cost of annual fit testing would be about:

$145/hr x 0.5 hr/worker-year x 20,000 workers = $1,450,000/year

If under the proposed rule, workers were fit tested every 2 or 3 years (2.5 years on average), the cost would be about:

$145/hr x 0.5 hr/2.5 worker-year x 20,000 workers = $580,000/year

Therefore, the potential savings could be on the order of about $870,000/year or more due to reduced frequency of fit testing and transfer of fit testing records between licensee sites.

4) Deletion of Requirement for First Time Notification of Respirator Usage

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

($145/hr x 1 licensee/year x 0.5 hr/licensee) + ($116/hr x 1 licensee/year x 0.5 hr/licensee) = $261/year

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

$70/hr x 0.2 hr/licensee x 2 licensees/year = $27/year

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

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

Total savings would be about $640/year.

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

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

6) Acknowledging the Use of Disposable Dust Masks with no APF

This change will formally acknowledge the utility of providing disposable dust masks to employees who request such equipment in the workplace where respiratory protection against

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

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

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

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

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

Further, assuming full face-piece and half-mask respirators last from 5 - 10 years (7.5 years on average) before being replaced, licensees would replace 50,000 respirators/7.5 years =

6,670 respirators per year. If these respirators were replaced by traditional respirators, the cost for half-mask ($25 each) and full-face mask ($150 each) respirators would be:

[($25 x 0.1) + ($150 x 0.9)] x 6,670 = $917,125/year

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

0.4 x 100,000 masks/yr x $0.8/mask = $32,000/year
(i.e., the net savings would be about $885,125/year)

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

$145/worker-hr x 0.2 hour x 8,000 workers/year = $232,000/year

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

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

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

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

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

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

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

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

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

Cost Savings From Permitting Use of Disposables

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

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

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

At the present time, essentially no power reactor licensees are using half–mask respirators in the NP mode (APF = 10). Current NRC guidance discourages the use of such devices as part of licensed activities because they must be checked for fit with irritant smoke each time they are put on. Thus, licensees typically use a more expensive full facepiece respirator in the NP mode with an APF = 50, because they are not required to perform irritant smoke tests each time those devices are donned. Under the proposed rule change that requirement would be removed for half-masks, and licensees would have an opportunity to replace current full facepiece respirators with half-mask disposable or reusable-disposable respirators.

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

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

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

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

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

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

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

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

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

Cost Savings For Permitting Use of Reusable-Disposable Masks

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

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

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

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

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

ANSI created this new category of devices to accommodate this less protective type of PAPR. The APF was downgraded from 1,000 (which it remains for FF and hood-type PAPRs). Since these devices are already being used in the nuclear industry, there is no expected impact on worker safety and licensee burden, and little opportunity for significant savings. This change

simply recognizes this application and formally permits licensees more choices in selecting proper respiratory equipment for exposure situations where a protection factor of no greater than 25 is needed to safely perform the work.

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

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

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

This addition will provide flexibility in selecting respirators for situations where a protection factor of no greater than 50 is needed and where oxygen deficiency (but not IDLH) is a problem. Cost savings as a result of this additional respirator are negligible since under the current rule there is no specific air-line respirator that will provide a protection factor of up to 50. In most cases, licensees would already have air-line respirators with an APF of 1,000 in stock anyway.

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

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

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

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

14) Addition of Air-line Suit with no APF

This addition formally sanctions the use of air-line suits with no credit for inhalation exposure reduction (i.e., for protection against contamination only). This has been in practice for years without any reported problems. Simply making the existing unsanctioned practice acceptable should add no measurable impact or value to a licensee. However, because the change also

allows licensees to request approval for higher APFs where they can be demonstrated, this change may provide more operational flexibility.

15) Exclusion of Noble Gases from Respiratory Protection Considerations

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

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

A summary of the estimated annual value and impact for each major change is presented below. Total annual increase in value is estimated to be $3,279,615 while the total added cost is estimated at $1,181,576 for net annual savings of $2,098,039.

6. Decision Rationale

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

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

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

	PROPOSED CHANGE	VALUE (per year)	IMPACT (per year)
1.	Eliminating Policy Statement	$10,835	$0
2.	Provision for low temperature use	0	6,576
3.	Exception to annual ANSI fit testing	1,450,000	870,000
4.	Eliminating first time notification requirement	640	0
5.	Allowing half-mask for plutonium use	0	0
6.	Disposable mask with no APF	1,706,000	270,000
7.	Reusable-Disposable mask with APF = 10	112,067	35,000
8.	Increasing APF, 50 to 100. Full mask NP	0	0
9.	Loose fitting PAPR with APF = 25	0	0
10.	Reducing APF, 1,000 to 50. Half-mask Air-line CF; Reducing APF, 2,000 to 1,000. Full-mask Air-line CF	0	0
11.	Half-mask Air-line PD. APF = 50	0	0
12.	Reducing APF, 2,000 to 1,000. Full mask Air-line PD	0	0
13.	Loose fitting Air-line. APF = 25	0	0
14.	Air-line suits. No APF	0	0
15.	Exclusion of Noble Gases from Subpart H	73	0
	TOTAL VALUE/IMPACT	3,279,615	1,181,576

ATTACHMENT 4

ENVIRONMENTAL ASSESSMENT

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

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

AUGUST 1997

I. The Proposed Action

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

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

II. Need for the Rulemaking Action

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

III. Alternatives Considered

The following alternatives to rulemaking have been considered.

Alternative 1: No Action

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

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

Alternative 2: Revise Regulatory Guidance Only

Regulatory guides are intended to assist licensees with complying with regulatory requirements. Several elements of a respiratory protection program are significant health and safety issues and as such need to be codified as requirements. Regulatory guides do not establish requirements.

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

IV. Environmental Impacts of the Proposed Action and the Alternatives

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

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

V. Finding of No Significant Environmental Impact

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the 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 Commission believes that these amendments would result in benefits to workers, flexibility to licensees and would continue to adequately protect public health and safety. There will be no change in radiation exposure to the public or to the environment due to the proposed rule changes.

VI. List of Agencies and Persons Consulted

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

K. Paul Steinmeyer, Radiation Safety Associates, Inc.

Robert daRosa, Lawrence Livermore Laboratory, (Retired)

ATTACHMENT 5

CONGRESSIONAL LETTERS

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

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 Public Announcement 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.

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

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

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a Public Announcement 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.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Bob Graham

ATTACHMENT 6

PUBLIC ANNOUNCEMENT

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 maintain 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 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 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.

# # # #

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

L. Joseph Callan
Executive Director
for Operations

Attachments:
1. Federal Register Notice
2. Regulatory Guide 8.15
3. Regulatory Analysis
4. Environmental Assessment
5. Congressional Letters
6. Public Announcement

RECORD NOTE: A draft copy of the proposed rule was sent to OIG for information on: 11/13/97.

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