



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

Marking

MEMORANDUM TO: Carl J. Paperiello, Director
Office of Nuclear Material Safety and Safeguards

William T. Russell, Director
Office of Nuclear Reactor Regulation

Edward L. Jordan, Director
Office of Analysis and Evaluation of Operational Data

William J. Olmstead, Associate General Counsel
for Licensing and Regulations
Office of the General Counsel

Gerald F. Cranford, Director
Office of Information Resources Management

James Lieberman, Director
Office of Enforcement

Richard L. Bangart, Director
Office of State Programs

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

FROM: David L. Morrison, Director
Office of Nuclear Regulatory Research

SUBJECT: OFFICE REVIEW AND CONCURRENCE: PROPOSED AMENDMENTS TO
SUBPART H OF 10 CFR PART 20, "RESPIRATORY PROTECTION AND
CONTROLS TO RESTRICT INTERNAL EXPOSURE" AND APPENDIX A, AND
PROPOSED REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE
PROGRAMS FOR RESPIRATORY PROTECTION."

Your concurrence is requested on the attached rulemaking package including a Federal Register notice, for the subject proposed rule, the draft revised Regulatory Guide 8.15, and the several associated supporting documents.

The following is a summary of this request:

1. TITLE: Proposed Rule and Regulatory Guide on Respiratory Protection.
2. RES Task Leader: Alan K. Roecklein (415-6223).

C. Paperiello et al.

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3. Cognizant Individual:

NMSS - Sami S. Sherbini
NRR - James E. Wigginton
OSP - Dennis M. Sollenberger
OGC - Stuart A. Treby

4. Requested Action: Review, comment and provide office concurrence.

5. Requested Completion Date:

6. Background: This proposed rule and associated draft regulatory guide revision were developed with considerable input and review by the cognizant individuals and an outside contractor, expert in current respiratory protection practice, Mr. Paul Steinmeyer. Because of the extensive involvement of staff from other offices, RES is assuming division concurrence. A revision of NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials" is ongoing and is expected to be ready for publication when the rule and regulatory guide revision are final. No additional NRC resources are anticipated to implement the rule. The draft regulatory analysis indicates an estimated reduction of licensee burden of about 2 million dollars per year.

Attachments: Rulemaking Package and
Draft Regulatory Guide

cc: w/atts.

R.M. Scroggins, OC
L. J. Norton, IG
W. Beecher, PA
D. K. Rathbun, CA

FOR: The Commissioners

FROM: James M. Taylor, Executive Director for Operations

SUBJECT: PROPOSED AMENDMENTS TO SUBPART H OF 10 CFR PART 20, "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES," AND APPENDIX A

PURPOSE:

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

Background:

The Nuclear Regulatory Commission (NRC) has not made substantive changes in its regulation of the use of respiratory protection by licensees in several decades. When 10 CFR Part 20 was comprehensively revised in 1991, 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 is essentially the technical base for this proposed rulemaking.

The proposed changes reaffirm the Commission's intention to eliminate the unnecessary and detrimental use of respirators by applying ALARA principles to the sum of the Deep Dose Equivalent (DDE) and the Committed Effective Dose Equivalent (CEDE), or the Total Effective Dose Equivalent (TEDE). The use of process or engineering controls, decontamination of work areas, access control, and other procedures are stressed instead of the automatic use of respiratory protection devices, which tend to increase external dose and stress.

CONTACT:
Alan Roecklein, RES
415-6223

The proposed rulemaking recognizes new respiratory protection devices that have been proven effective, discourages the use of other devices that are now considered less effective, adopts new Assigned Protection Factors (APFs) based on ANSI determinations and revises 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 with savings to NRC licensees estimated to be 2 million dollars per year. The proposed rule would be considerably less prescriptive with no reduction in worker health or safety.

DISCUSSION:

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

The proposed amendments:

1. Add "decontamination" to the list of process or engineering controls that can be used to reduce airborne radioactive material instead of issuing respiratory protection devices.
2. Make it clear that the provisions of § 20.1703(a) are required if a licensee issues respiratory protection equipment and that § 20.1703(b) are additional requirements that must be met if a licensee is to take credit for use of a respiratory device in estimating worker dose. This change does not add requirements, but rather rearranges respiratory program requirements in a more logical structure.
3. Delete several references to having respirator certification extended by NIOSH/MSHA because these extensions have expired and no new extensions will be granted.
4. Would revise § 20.1703(a)(3)(iv) in order to bring together all of the remaining elements of the required written respiratory protection procedures currently found in different parts of the rule.
5. Would move a requirement to fit test tight fitting, face-sealing respirators prior to first field use from a footnote in Appendix A to the body of the rule. Section 20.1703(a)(3)(vi) would also specify the "fit factors" needed for different types of devices and the frequency of retesting.

Note that the NRC staff is proposing a retest frequency not to exceed 3 years, which differs from the ANSI recommendation and current requirement of annual. The staff believes that the relaxation of the frequency of fit testing and the fact that fit testing is one of the items of transferability among licensees in the nuclear power

- industry*, contribute a significant cost savings with no reduction in health and safety. The regulatory guide accompanying this rulemaking will elaborate on the physiological changes and other conditions to be observed in individuals that might suggest more frequent fit testing.
6. Would delete a requirement for licensees to issue a written policy statement on respiratory protection because the staff believes that all of the elements addressed by this policy statement are either addressed elsewhere in required licensee procedures, or are not needed. This is considered a burden reduction.
 7. Would clarify and elaborate on existing requirements that provision be made for vision correction, adequate communications and preventing low temperature caused equipment malfunctions. This continuing requirement, restated for clarity, is intended to facilitate the safe use of respiratory protection equipment.
 8. Would delete an existing reference to "skin protection" as an element of respiratory protection. Skin protection is not considered by the staff as an appropriate reason for the use of respirators. Slight facial contamination can be prevented by contamination cleanup in the work area and may even entail lower risk than the larger dose incurred during cleanup or by using respirators.
 9. Would retain a requirement to have standby rescue persons available whenever one-piece atmosphere-supplying suits are used, or whenever workers might require assistance in removing protective equipment in an emergency. This requirement is moved from a footnote to Appendix A, to the body of the rule.
 10. Would retain specification of quality and quantity of supplied breathing air consistent with the National Institute for Operational Safety and Health (NIOSH) guidelines. This requirement is, however, moved from Appendix A to the body of the rule.
 11. Would retain a provision that prohibits the use of tight fitting respirators whenever any material or substance might interfere with the seal of the respirator. This provision is moved from Appendix A to the body of the rule and is intended to prevent facial hair, cosmetics, eyeglass earpieces, etc. from interfering with the respirator seal.

*Fit testing is an element in the Personnel Data System (PADS) under development by the nuclear industry which will enable transfer of required worker training and dosimetry records.

12. Would make a change in the language used to permit licensees to use Assigned Protection Factors (APFs) in estimating dose incurred by workers. The proposed language, "may take credit for" in § 20.1703(b) is more widely used in the field and is more accurate than the current "may make allowance for." Also an existing reference in § 20.1703(b) to § 20.1702 is deleted because the reference could be interpreted to mean that an approved respiratory protection program is needed only when concentrations in air exceed those that define an airborne radioactivity area.
13. Would revise § 20.1703(b)(1) so that licensees can assume initially that inhaled concentrations when respirators are worn will be the ambient concentration in air without respiratory protection, divided by the APF. This change would clarify this important point and also provides an adequate definition of APF so that footnote D.1. to Appendix A can be deleted.
14. Would delete a current requirement at § 20.1703(c) that licensees use as emergency devices only respiratory protection equipment that is specifically certified for emergency use by NIOSH. Acceptable types of emergency and escape equipment will be discussed in the revisions to Regulatory Guide 8.15 and NUREG-0041. Because section 20.1703(a)(1) and (2) specify that only equipment approved by NIOSH or the NRC can be used, this requirement is considered by the staff to be redundant.
15. Would delete a requirement at § 20.1703(d) that a licensee notify in writing the director of the NRC Regional Office 30 days before the date that respiratory protection is first used. This requirement is considered by the staff to be redundant with existing licensing and inspection and enforcement procedures, and contributes little to worker safety. This change is a minor burden reduction.
16. Would revise § 20.1704(a) to make it clear that any restriction imposed by the Commission in addition to those found in §§ 20.1702, 20.1703 and Appendix A, must take into account the need to maintain total effective dose equivalent ALARA.
17. Would modify Appendix A to 10 CFR Part 20 extensively. The major changes which are discussed in more detail in the Federal Register notice are listed here.
 - Several footnotes which contain general and useful requirements are moved to the body of the rule. Several are deleted because they are no longer needed.
 - Several devices such as single-use disposable and air-supplied suits are now recognized as being useful in respiratory protection and are listed with APFs of 1 to provide greater flexibility to licensees.

- Several Assigned Protection Factors (APFs) are revised to be consistent with the new ANSI guidance or to facilitate field use of these numbers to estimate doses.
- Several requirements are made less prescriptive, being stated as performance objectives with guidance to be provided in Regulatory Guide 8.15 and NUREG-0041.

The NRC staff believes that this updating and revision of the regulations for the use of respiratory protection constitute a significant burden reduction, result in a set of requirements and guidance documents that will be easier to implement, and that when implemented will make worker protection more effective and consistent.

A Regulatory Analysis (Attachment 2) was prepared to evaluate the cost/benefit of the proposed rulemaking. This analysis concludes that a cost reduction on the order of 2 million dollars per year will result from the proposed rule changes. The major 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, and deleting the policy statement and the report to the region on startup of a respiratory program.

An environmental assessment (Attachment 3) 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 to conduct and implement this rulemaking are included in the FY 1995-1999 Five-Year Plan.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

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 proposed rule contains deletion of information collection requirements that are subject to review by OMB. Upon Commission approval, the OMB supporting statement (Attachment 7) will be submitted to OMB for approval;
 - f. The appropriate Congressional Committees will be informed (Attachment 5);
 - g. A public announcement will be issued (Attachment 6); and

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- h. 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.

James M. Taylor
Executive Director
for Operations

- Attachments:
- 1. Federal Register Notice
 - 2. Draft Regulatory Guide 8.15
 - 3. Draft Regulatory Analysis
 - 4. Draft Environmental Assessment
 - 5. Draft Congressional Letters
 - 6. Draft Public Announcement
 - 7. OMB Supporting Statement

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- Attachments:
1. Federal Register Notice
 2. Draft Regulatory Guide 8.15
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RECORD NOTE: A draft copy of the proposed rule was sent to OIG for information on: _____.

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ATTACHMENT 1
Federal Register Notice

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-

Subpart H - Respiratory Protection and Controls
To Restrict Internal Exposure and Appendix A

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 make these regulations more consistent with the philosophy of controlling the sum of internal and external radiation exposure, to reflect current and new guidance on respiratory protection from the American National Standards Institute (ANSI) and to make Subpart H of 10 CFR Part 20 less prescriptive without reducing public and worker health and safety. The amendments will provide greater assurance that the sum of worker's exposures is maintained as low as is reasonably achievable (ALARA) and that recent technological advances in respiratory protection equipment and procedures are endorsed in NRC regulations and are available to 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

September 10, 1996

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: Docketing and Service Branch.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland between 7:45 am and 4:15 pm Federal workdays.

The public may examine comments received, the environmental assessment and finding of no significant impact, and the regulatory analysis at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Single copies of the environmental assessment and finding of no significant impact and the regulatory analysis may be obtained from Jayne McCausland, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415-6219.

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: Distribution and Mail Services Section, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; or by fax at (301) 415-2260.

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6223; email AKR@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The major revision of 10 CFR Part 20, "Standards for Protection Against Radiation," was published in May of 1991. Although the NRC staff 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. At that time a major ANSI standard in preparation was intended to provide state-of-the-art guidance on acceptable respiratory protection devices and procedures. A decision was made to proceed with the Part 20 rulemaking and to address Subpart H when the ANSI guidance was complete.

In response to public comments that were received on the proposed 10 CFR Part 20 revision, several changes were made to Subpart H in the final rule that were necessary to make it consistent with the new philosophy and science underlying the new Part 20. Subpart H was changed to require that the practice of ALARA apply to the sum of internal and external dose, to permit correction of both high and low initial intake estimates if subsequent bioassay results indicated, and the rule was modified to make clear that a respiratory protection program consistent with Subpart H is required whenever respirators are used to limit intakes.

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 provided 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). Based on the publication of

ANSI Z88.2-1992 and a determination by the NRC staff that Subpart H of Part 20 could be less prescriptive without reducing public and worker health and safety, the NRC is proposing this revision.

II. Summary of the Proposed Changes

This section summarizes the changes to the regulation that are being proposed. They are proposed to amend §§ 20.1701 through 20.1704 in Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure," of Part 20, of Title 10, "Energy," of the Code of Federal Regulations and Appendix A, "Assigned Protection Factors for Respirators," to Part 20.

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 in parenthesis. The intent is to encourage licensees to consider decontamination as an effective means of reducing resuspension of radioactive material in the work place as a means of reducing internal exposure instead of using respirators.

Section 20.1702 would remain unchanged.

Section 20.1703 states the requirements for licensees who use respiratory protection equipment to limit intake. The proposed structure of § 20.1703 is that paragraph (a) is required if a respiratory protection device is assigned or permitted to be used. The staff believes that such use 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 is immaterial, it is the use of the respiratory protection device which would activate the requirements of § 20.1703(a). Thus this paragraph can be

viewed as defining the minimum respiratory protection program expected of any licensee who assigns or permits the use of respirators.

Paragraph 20.1703(b) states requirements, in addition to those stated in § 20.1703(a), which must be met before a licensee may use the assigned protection factor (APFs) in Appendix A to take credit for the use of any respiratory protection device for reduction of dose.

In § 20.1703(a), the phrase "pursuant to § 20.1702" would be deleted. This language has been interpreted to mean that if respirators are used when concentrations of radioactive material in air are already below values that define an airborne radioactivity area, an approved respiratory protection program is not needed. This is not the case and § 20.1703 should make it clear that if a licensee uses respiratory protection equipment "to limit intakes," the provisions of § 20.1703(a) apply.

In § 20.1703(a)(1), 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), 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 Commission" are added to make it clear that applications for authorized use of respiratory equipment are to be submitted to the Commission. In addition, this paragraph is revised to clarify the description of what is required in the application for authorized use.

In § 20.1703(a)(3), paragraphs (i) through (v) are retained as codified with the exception that paragraph (iv) is reworded to improve clarity, reorder priorities, and bring together all the elements of the required written

procedures and paragraph (v) is revised to make it clear that the workers 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) since fit testing is not needed for these types.

Section 20.1703(a)(3)(vi) would be revised to require fit testing prior to first field use of tight fitting, face sealing respirators and periodically thereafter. This proposed change provides clarification regarding when and how often fit testing is required. This requirement is currently in the footnotes to Appendix A and would be moved to the body of the rule.

The proposed revision of § 20.1703(a)(3)(vi) also would codify NRC staff guidance and ANSI recommendations regarding the test "fit factors" that must be achieved in order to use the APFs. Specifically, fit testing with "fit factors" ≥ 10 times the APF would be required for negative pressure devices, and "fit factors" ≥ 100 would be required for positive pressure and pressure demand devices.

Guidance in Regulatory Guide 8.15 on the frequency of retesting will suggest a retest period not to exceed 3 years. Currently, some licensees perform annual fit testing; very few perform fit testing only once for each worker. This suggestion of 3 year retesting does not agree with the ANSI recommendation for annual retesting because the NRC staff believes 3 year intervals is adequate to protect workers under normal circumstances. Regulatory Guide 8.15 will discuss abnormal circumstances such as significant weight loss or gain, facial changes, etc.

All of § 20.1703(a)(4), which lists requirements for licensees to issue a written policy statement, would be deleted because the NRC staff does not believe this policy statement is needed. This proposed change is based on the

fact that all of the elements required to be in the policy statement are required in the rules, that the requirement is partially redundant with required written procedures (see § 20.1703(a)(3)(iv)), and because the topics would also be discussed in the revision to Regulatory Guide 8.15.

Section 20.1703(a)(5) would be renumbered as § 20.1703(a)(4).

Section 20.1703(6) would become (5) and would be clarified and expanded to emphasize the existing requirements that provisions be made for vision correction, adequate communications and low temperature consideration. 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 inability of the wearer to read postings, operate equipment and/or instrumentation or properly identify hazards is considered by the NRC staff to be an unacceptable degradation of personnel safety.

A requirement for licensees to consider low temperature work environments when selecting respiratory protection devices would be added to this paragraph. 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. This open valve would provide a pathway for unfiltered air into the respirator inlet covering without the user being aware of the malfunction. Lens fogging leading to reduced vision in a full facepiece respirator is another problem that can be caused by low temperature.

The reference to skin protection currently found in § 20.1703(a)(6) would be deleted from the proposed § 20.1703(a)(5). Skin protection is more appropriately dealt with elsewhere in the rule as a skin dose limitation or

internal dose pathway issue. It is considered inappropriate by the NRC staff and inconsistent with ALARA to use tight fitting respirators solely to prevent facial contamination that might be prevented by cleanup or that might be preferable to the larger dose incurred during cleanup or by using respirators.

A new § 20.1703(a)(6) would be added to bring a requirement, currently found in a footnote to Appendix A, 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 and be immediately available to provide needed assistance.

A new § 20.1703(a)(7) would move a requirement from a footnote to Appendix A, into the rule. This section would specify the quality and quantity of breathing air, consistent with National Institute for Occupational Safety and Health (NIOSH) approval requirements found in 42 CFR Part 84, to be provided whenever atmosphere-supplying respirators are used.

A new § 20.1703(a)(8) is added to clarify and move a requirement from the footnotes of Appendix A, 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.

Section 20.1703(b) would be modified for clarity. The expression, the licensee "may take credit for" respiratory protection equipment would be used

instead of the current "may make allowance for." This change would clarify that assigned protection factors (APFs) may be applied to estimates of internal dose when the requirements of this subpart are met. The term "take credit for" is more widely used in the field than the words currently in the rule. In addition, the reference to § 20.1702 would be deleted to avoid confusion regarding when the provisions of § 20.1703 would be applicable. The current reference to § 20.1702 might permit the interpretation that the requirements for a respiratory protection program found in § 20.1703(b) apply only when concentration in air exceed those that define an airborne radioactive materials area.

Currently, § 20.1703(b)(1) includes the statement, "If the selection of a respiratory protection device with a protection factor greater than the peak concentration." An assigned protection factor cannot be compared to a concentration. This sentence would be changed to:

"... an assigned protection factor greater than the multiple defined in the preceding sentence" The preceding sentence correctly states, "an assigned protection factor (see Appendix A to §§ 20.1001-20.2402) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B of §§ 20.1001-2402, Table 1, Column 3."

The current § 20.1703(b)(1) states that "The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor." This is problematic because the estimate is often made before the exposure, the average concentration in air is not clearly stated as that outside the

respirator, and average is difficult to define. This paragraph is revised for clarity as follows:

"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." Note also that a new designation of § 20.1703(b)(2) would be given for this important provision. This change also provides an adequate definition of assigned protection factor (APF) which permits deletion of the footnote to Appendix A at d.1.

Section 20.1703(b)(2) would become § 20.1703(b)(3) and be revised to incorporate the new ANSI terminology for assigned protection factor.

Paragraph 20.1703(c) would be deleted 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. Since only equipment approved by NIOSH or NRC can be used in the respiratory protection program pursuant to § 20.1703(a)(1) and (2), this provision is considered redundant.

Paragraph 20.1703(d) would be deleted. This paragraph 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 § 20.1703(a) or (b). All licensees who possess radioactive material in a form that requires a respiratory protection program are identified during license application, amendment or renewal processes: their programs would be reviewed during this

process. A 30-day notification requirement imposes a redundant and needless administrative burden on licensees with no increase in worker or public health and safety. This proposed change is considered by the staff to be a burden reduction.

Section 20.1704(a) would be revised to make it clear that any restrictions imposed by the Commission in addition to those found in §§ 20.1702, 20.1703 and Appendix A on the use of respiratory protection equipment for the purpose of limiting exposures of individuals to airborne radioactive materials must take into account the need to maintain total effective dose equivalent ALARA.

Appendix A to Part 20 - "Assigned Protection Factors (APF) for Respirators," would be modified extensively. In general, new devices are recognized, APFs are adjusted to be consistent with current technical knowledge, and the footnotes to Appendix A are moved, deleted, revised, or adjusted so that they explain the table. Other footnotes that are instructive or that facilitate implementation of the rule are moved to Regulatory Guide 8.15. Several footnotes are considered to be redundant in that they reiterate NIOSH certification criteria. These will be discussed in NUREG-0041 and are proposed to be deleted from the rule. Regulatory requirements previously in Appendix A footnotes, that the staff believes are generic and should be retained, would be moved to the body of the regulation.

The column headed "Tested and Certified Equipment," is proposed for deletion. NIOSH is in the process of revising its regulations and renumbering them in 42 CFR rather than 30. It would be difficult to provide accurate references at this time. These references to 30/42 CFR apply primarily to respirator manufactures and are therefore 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.

This discussion of the proposed revision of Appendix A will address the current version, identify changes to be made, and then address the proposed version. Some of these changes have already been discussed.

Current footnote a to Appendix A 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(a)(3)(i) and § 20.1703(b)(1) and (2).

Current footnote b, which permits the use of devices only when nothing interferes with the seal of a facepiece, would be deleted. This requirement has been moved to the body of the rule at § 20.1703(a)(8).

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 deleted because the essential information regarding the meaning and use of APF is found in the proposed rule at § 20.1703(b)(2). 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) observes 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 deleted. Adequate provisions for training, fit-testing, and equipment maintenance are found in the proposed rule at § 20.1703(a)(3)(iv).

Current footnote d.2(b) observes that APFs are applicable for air-purifying respirators only when high efficiency particulate filters are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards. The definition of high efficiency filters is found in NIOSH approval requirements in 42 CFR Part 84, and is discussed in the revisions of Regulatory Guide 8.15 and NUREG-0041. Given that the rule requires an adequate respiratory protection program and that Regulatory Guide 8.15 and NUREG-0041 provide extensive guidance on implementing the rule, this tutorial information is not needed in the rule and is proposed for deletion.

Current footnote d.2(c) makes it clear that APFs cannot be used for sorbents against radioactive gases and/or vapors (e.g., radioiodine). This is considered to be an important qualifier and is retained as part of proposed footnote d.

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 is moved to the rule at § 20.1703(a)(7) and further discussed in Regulatory Guide 8.15 and NUREG-0041.

The current footnote e makes it clear that the APFs for atmosphere supplying respirators and self-contained breathing apparatus are not applicable in the case of contaminants that present a skin absorption or submersion hazard. This statement would be retained in the proposed Appendix A in footnote d. However, the current exception provided for tritium oxide requires correction in that the effective protection factor cannot exceed 3, rather than 2 as stated, if one-third of intake occurs by absorption

through the skin, as shown in the following calculation. The effective protection factor is correctly calculated as follows:

S = skin absorption

I_o = Inhalation intake w/o respirator

I_w = Inhalation intake w/respirator

$$\text{Effective Protection factor} = \frac{S + I_o}{S + I_w}$$

$$\text{also, } I_w = \frac{I_o}{APF}$$

If 1/3 is absorbed through the skin, let S = 1 and I_o = 2

$$EPF = \frac{3 APF}{APF + 2}$$

If APF is 10, EPF = 2.5

If APF is 100, EPF = 2.94

If APF is 1000, EPF = 2.99

This correction has been made in footnote d of the proposed Appendix A.

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.

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 is important and it would be retained as footnote (f) to the proposed new Appendix A. 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. Since this is a continuation of a prohibition of long standing, it will have no impact on licensees.

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 of this part. Because § 20.1703(b)(1) already includes this limitation, this redundant part of footnote g is deleted.

The third issue in this footnote 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 staff finds no technical or scientific basis for continuing this prohibition in view of current knowledge and proposes to delete it.

Finally this footnote requires that this type mask be tested for fit with irritant smoke prior to each use. This provision would be deleted as being redundant because the rule at § 20.1703(a)(3)(iii) requires a user to perform a fit check (e.g., negative pressure check, positive pressure check, irritant smoke check) each time a respirator is used. Requiring an irritant smoke

check to the exclusion of all other fit checks places an unnecessary burden on licensees.

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 considered redundant and would be deleted from the rule, but will be discussed in the revision to NUREG-0041.

Current footnote i specifies that appropriate protection factors shall 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. Further, technical 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(a)(6).

Current footnote j observes that NIOSH approval schedules are not available for atmosphere-supplying suits. Criteria for supplied air suits are addressed in footnote g to the proposed Appendix A. Note that an assigned protection factor of 1 is proposed for these devices to formally permit their use. Licensees would be permitted to apply to the Commission for the use of higher APFs in accordance with § 20.1703(a)(2).

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 is retained in footnote (h) to the proposed Appendix A.

Current footnote 1 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 is deleted from the rule to be consistent with ANSI guidance, and will be addressed in the revision to Regulatory Guide 8.15.

Current footnote 1 also observes that perceptible outward leakage of breathing gas from this or any positive pressure SCBA whether open circuit or closed circuit is unacceptable, because service life will be reduced substantially. This provision is retained in footnote h to the proposed Appendix A.

Current footnote 1 also requires that special training in the use of this type of apparatus be provided to the user. The NRC staff believes that the training requirement that would be retained at § 20.1703(a)(3)(iv) is adequate to assure the training necessary for the use of SCBA devices, and this element of footnote 1 would be deleted.

Note 1 to the current Appendix A 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 in footnote (a) to the proposed Appendix A and would be revised to reference Department of Labor (DOL) regulations at 29 CFR 1910.134. The staff believes that these conditions are essential to the safe use of APFs and that the DOL regulations

are applicable whenever other than radiological respiratory hazards are present.

Note 2 to the current Appendix A 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 is retained as the second paragraph of footnote a to the proposed Appendix.

The proposed text of Appendix A to § 20.1001-20.2402, "Assigned Protection Factors for Respirators," is found in Section IX of this Federal Register notice. This part of the discussion will focus on the proposed changes to Appendix A not already discussed and NRC staff justification for the changes.

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

Single-use disposable respirators (e.g., disposable dust mask) would be permitted for use with an APF of 1 (i.e., no credit may be taken). These devices have little physiological impact on the wearer and may be useful in certain situations for ALARA reasons, or they may accommodate workers who request respiratory protection devices. Medical screening and fit testing are not required for each individual prior to use, because the devices impose very little physiological stress and because a measurable seal is not possible. However, all other aspects of an acceptable program specified in § 20.1703(a) are required and users should be trained in the use and limitations of the device. The licensee should take steps to ensure that untrained individuals are not permitted to use these devices.

The half-mask facepiece respirator continues to be approved, but relatively new variations are referred to in the industry as "reusable," "reusable-disposable," or "maintenance-free" devices. In these devices, the filter medium is an integral part of the facepiece and is not replaceable. Also, the seal area is generally enhanced by the application of plastic or rubber to the face-to-facepiece seal area. These devices are acceptable to the NRC staff and are considered half masks.

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 lists a PF of 50 because one design that was tested at Los Alamos in 1975 did not meet the PF 100 criterion. That device is no longer available.

A fit-test safety factor of 10 for negative-pressure air-purifying respirators, which will be obtained as a result of required fit testing under § 20.1703(a)(3)(vi), is required; that is, a person would have to achieve a minimum of 1,000 on a quantitative fit test in order to use an APF of 100 in the field. The current 10 CFR Part 20 requires or permits licensees to revise committed effective dose equivalents upward or downward based on whole body counting or invitro bioassay and other data. Use of the safety factor effectively limits internal dose and accounts for any respirator leakage. Finally, APFs in exact multiples of 10 are easier to apply in the field, thereby reducing the chances for miscalculation. The devices commonly used in the nuclear industry affected by this rulemaking will all have APFs of 10; 100; 1000; or 10,000. The devices listed in the proposed Appendix A with APFs that are not even multiples of 10 are not widely used in nuclear facilities.

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

The half-mask and the full facepiece air-line respirators operating in demand mode are listed with assigned protection factors of 1. This means that no protection credit can be taken for the use of these types. The NRC staff believes that supplied-air respirators operating in the demand mode should not be used 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 be used instead of these more protective devices. Based on field observations of leakage in these respirators the APFs have been reduced from 5 to 1 to discourage use of these devices.

The APFs for half-and full-mask air-line respirators operating on continuous flow have been reduced from 1,000 to 50 and from 2,000 to 1,000 respectively. These changes are based on ANSI recommendations and the results of field measurements which indicate that these devices are not as effective as originally thought. 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 APF for a full facepiece air-line respirator operating in pressure demand mode would be reduced from 2,000 to 1,000. This reduction is based on the unlikelihood of needing to differentiate between an APF of 2,000 and 1,000, and on a desire to simplify the estimation of exposure in the field. This change would have little impact on licensees in the field because typical concentrations are far less than 1000 times the derived air

concentrations (DACs). Note also the provision that licensees may apply for higher APFs if needed.

The helmet/hood air-line respirator operating under continuous flow would be retained with the APF listed as 1,000. The criteria for air flow rates 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 consistent with ANSI recommendations.

The air-line atmosphere-supplied suit would be assigned a protection factor of 1. These devices have been used for many years, with no APF applied, in radiological environments such as control rod drive removal at boiling water reactors. 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 that would disallow use of these devices. The allowance of an APF of 1 (i.e., no credit for concentration reduction) brings the use of these devices out of a regulatory "grey area," allowing the use of non-NIOSH-approved suits but requiring wearers to meet all other respirator program requirements in § 20.1703(a) 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(a)(2). Requirements for standby rescue persons apply to these devices.

In the proposed Appendix A, APFs for SCBA devices would remain unchanged except that the entries for demand and demand recirculating mode would both be reduced from 50 to 1. In the staff's view the performance level and reliability of these devices do not justify an APF of 50. The chance of facepiece leakage under negative pressure is considered to be too high,

especially for devices that may be used in emergency situations. These devices are not recommended for use, and acceptable alternative devices are readily available.

Some additional elements in the proposed new footnotes should be mentioned here. In 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 occurs elsewhere in 10 CFR Part 20.

The complete proposed revisions of Subpart H of 10 CFR Part 20 and Appendix A are found at IX. List of Subjects, in this document.

III. Issue of Compatibility for Agreement States

The NRC believes that the proposed modifications to 10 CFR 20.1701 through 20.1704 and Appendix A should be Division 2 items of compatibility because these regulations are intended to help implement compliance with dose limits, are performance based, and States have the option to be more restrictive. 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. Comments from the States were as follows: (Insert prior to EDO)

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 is entirely focused on technical and procedural improvements on the use of respiratory protection devices to maintain total occupational dose as low as is reasonably achievable. All the impacts associated with this rulemaking are inhouse with no effect on any places or entities off a licensed site or outside NRC. 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. 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 draft environmental assessment and finding of no significant impact on which this determination is based 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 amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). The proposed rule would delete some existing recordkeeping and reporting requirements. Paragraph 20.1703(d) currently requires a licensee to notify,

in writing, the director of the NRC Regional Office at least 30 days before the date that respiratory protection equipment is first used. This required notification would be deleted.

The current paragraphs § 20.1703(a)(4)(i) through (iii) require a licensee to issue a written policy statement on respirator usage that the NRC staff believes is not needed. This requirement would be deleted. No other change in recordkeeping or reporting requirements are proposed.

This rule has been submitted to the Office of Management and Budget for review and approval of reduction of the information collection requirements.

The reduction in reporting and recordkeeping burden that would result from these amendments is estimated to be 0.5 hours per notification of intent to initiate a respiratory protection program and 2-3 hours per written policy statement on respirator use. Send comments regarding this burden estimate or any other aspect of this collection of information to the Information and Records Management Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0010), Office of Management and Budget, Washington, DC 20503.

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. As a result of the revised regulation, the impact would not be significant because the revised regulation basically represents a continuation of current practice. The benefit of the proposed rule is that it provides relief from certain reporting and recordkeeping requirements and permits the use of new, effective respiratory devices, thus increasing flexibility.

The NRC is seeking public comment on the initial regulatory flexibility certification. The NRC is particularly seeking comment from small entities as defined under the NRC's size standards published on November 6, 1991 (56 FR 56672), as to how the regulations will affect them and how the regulations may be tired 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. ATTN: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

VIII. Backfit Analysis

Although the staff has concluded that the net effect of the changes being proposed is a reduction in burden, the implementation of the changes will require changes in licensee procedures constituting a potential backfit under 10 CFR § 50.109(a)(1). Under 10 CFR § 50.109(a)(2), a backfit analysis is required unless the proposed rule meets one of the exceptions listed in 10 CFR § 50.109(a)(4). As described below, this proposed rule meets the exception at 10 CFR § 50.109(a)(4)(iii) in that it is redefining the level of adequate safety as regards the use of respirators for radiological protection.

Section II. Summary of the Proposed Changes, in this Federal Register notice, summarizes all of the changes being proposed to Subpart H of 10 CFR Part 20 entitled "Respiratory Protection and Controls to Restrict Internal

Exposure." The reasons for making these changes are also provided. The changes proposed in this rulemaking are considered by the NRC staff to constitute a redefinition of adequate level of protection in that they adopt and endorse 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 which 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 minor procedural improvements that have been developed and proven by respiratory practitioners.

The staff believes that the sum of changes proposed to the rule constitutes 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 protection required for workers who use respiratory protection and are, therefore, the type of change for which a backfit analysis is not required under 10 CFR § 50.109(a)(4)(iii).

IX. List of Subjects

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.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 is revised 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 20.1701 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, ventilation) to control the concentration of radioactive material in air.

3. Section 20.1703 is revised to read as follows:

§ 20.1703 Use of individual respiratory protection equipment.

(a) If the licensee assigns or permits the use of respiratory protection equipment to limit intake,

(1) The licensee shall use, only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH), or

(2) 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, and except as provided in this part, the licensee shall submit an application to the Commission for authorized use of this equipment. The

application shall include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This shall be demonstrated either by licensee testing, or on the basis of reliable test information.

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

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

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

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

(iv) Written procedures regarding monitoring, including air sampling and bioassays; training of respirator users; fit testing; 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;

(v) Determination by a physician prior to the initial fitting of face sealing respirators, prior to 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;

(vi) Fit testing, with fit factor ≥ 10 times the APF for negative pressure devices, and a fit factor ≥ 100 for any positive pressure and pressure demand devices, prior to first field use of tight fitting, face sealing respirators and periodically thereafter.

(4) 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.

(5) 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 (below 32° F) and the concurrent use of other safety or radiological protection equipment in such a way as to not interfere with the proper operation of the respirator.

(6) 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. These persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards, shall observe or otherwise be in direct communication with such workers, and shall be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons shall be available to effectively assist all users of this type of equipment.

(7) Whenever atmosphere-supplying respirators are used, they must be supplied with respirable air of the minimum quantity and quality specified in the Code of Federal Regulations that describe NIOSH approval requirements.

(8) 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.

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

(1) The licensee selects respiratory protection equipment that provides an assigned protection factor (see Appendix A to §§ 20.1001-20.2402) greater than the multiple by which ~~peak concentrations~~ *Average?* of airborne radioactive materials in the working area are expected to exceed the values specified in Column 3 of table 1 in Appendix B to §§ 20.1001-20.2402. If the selection of a respiratory protection device with an assigned protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in § 20.1702 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA *or other conditions (pg 7)! 20.1703(f)(5)* *!!*

(2) The concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air 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.

(3) The licensee shall obtain authorization from the Commission before using assigned protection factors in excess of those specified in Appendix A to §§ 20.1001-20.2402. The Commission may authorize a licensee to use higher assigned protection factors on receipt of an application that -

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

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

4. 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 §§ 20.1001-20.2402 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.

5. Appendix A to §§ 20.1001 - 20.2402 is revised to read:

APPENDIX A TO §§ 20.1001-20.2402

ASSIGNED PROTECTION FACTORS FOR RESPIRATORS^a

Description	Modes ^b	Assigned Protection Factors	
		Particulates ^c	Gases and vapors ^d
I. AIR PURIFYING RESPIRATORS			
Single-use disposable *	NP	1	1
Facepiece, halfmask ^f	NP	10	1
Facepiece, full	NP	100	1
Facepiece, half mask	PP	50	1
Facepiece, full	PP	1000	1
Helmet/hood	PP	1000	1
Facepiece, loose-fitting	PP	25	1
II. ATMOSPHERE SUPPLYING RESPIRATORS			
1. Air-line respirator			
Facepiece, half-mask	D	1	1
Facepiece, half-mask	CF	50	50
Facepiece, half-mask	PD	50	50
Facepiece, full	D	1	1
Facepiece, full	CF	1000	1,000
Facepiece, full	PD	21000	1,000
Helmet/hood	CF	1000	1,000
Facepiece, loose-fitting	CF	25	25
Suit	CF	1 ^a	1 ^a
2. Self-contained breathing apparatus (SCBA)			
Facepiece, full	D		1
Facepiece, full	PD		10,000 ^h
Facepiece, full	RD		1
Facepiece, full	RP		10,000 ^h
III. COMBINATION RESPIRATORS		Assigned protection factor for type and mode of operation as listed above	
Any combination of air-purifying and atmosphere-supplying respirators			

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 1910.134 and other sections.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to §§ 20.1001-20.2402 of this part are based on internal dose due to inhalation may, in addition, present external

exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

- b. The mode symbols are defined as follows:
 - NP = negative pressure (air-purifying respirator)
 - PP = positive pressure (air-purifying respirator)
 - CF = continuous flow (atmosphere-supplying respirator)
 - D = demand (supplied-air respirator)
 - PD = pressure demand (open circuit, atmosphere-supplying respirator)
 - RD = demand, recirculating (closed circuit SCBA)
 - RP = positive pressure, recirculating (closed circuit SCBA).
- c. Air purifying respirators must be equipped with particulate filters that are at least 99 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 less than 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. If the assigned protection factor for a device is 10, the effective assigned protection factor for tritium is about 2.5; for devices with assigned protection factors of 100, the effective assigned protection factor is about 2.9; for devices with assigned protection factors of 1000 or more, the effective assigned protection factor is about 2.99. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations. No credit (i.e., APF = 1) may be taken for the use of sorbents against airborne radioactive gases and/or 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. It is also recognized that it is not possible to perform an effective pre-use fit check on this type of device. All other respiratory protection program requirements listed in § 20.1703(a) apply.
- f. Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece. Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the filter medium is at least 99 percent efficient and all other requirements of this part are met.
- g. No NIOSH approval schedule is currently available for this equipment. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements are met [i.e., § 20.1703(a)], except for the NIOSH approval.

- h. 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 _____, 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

ATTACHMENT 3
Draft Regulatory Analysis

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

DRAFT FOR COMMENT

February 22, 1996

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1. STATEMENT OF THE PROBLEM

The Nuclear Regulatory Commission (NRC) has not made substantive technical changes in its regulation of the use of respiratory protection by its licensees in several decades. In the interim, the NRC has substantially revised regulation 10 CFR Part 20 to reflect new radiation protection recommendations with regard to primary dose limits and dosimetric models. The NRC staff 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. Situations where respirators might also be used include:

- 1) non-radioactive nuisance dust exists 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) use of certain respiratory protection devices to reduce heat stress on workers, or
- 4) use as contamination control devices in high contamination but relatively low airborne radioactivity areas with the potential for significant resuspension, or
- 5) 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 guidance on respiratory protection programs at licensee operations, and 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 change. 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).

Retaining the current rule represents the "NO ACTION ALTERNATIVE," which the NRC finds unacceptable because of the need to redefine acceptable levels of respiratory protection to be consistent with new guidance, continuing problems identified by licensees, or because the current rule is too inflexible for good health physics practice, or because the current rule is out of date with current practice. 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 provide for vision correction and consideration of communication, clarify existing requirements for visual capability (to include vision correction) and communications (currently required to be adequate for work), and provide added safety to workers using respirators at low temperatures.

In order to meet these requirements, 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 is considered to be an unacceptable degradation of personnel safety by NRC.

The proposed changes should also 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 rule change 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 come in to NRC under §20.1703(a)(2). In addition, the licensee will have to provide training for use of nose cups. While such 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 staff has concluded that, with the exception of events which could change an individual's respirator fit (e.g., weight loss or gain, surgery, etc.), that fit tests for tight fitting, face sealing respirators need not be conducted for a period not to exceed 3 years. This position is substantially different from the recommendations of the ANSI Z88-1992 standard for respiratory protection. Currently, some NRC licensees perform annual fit testing, and very few perform fit tests of workers only once during their employment. Records of fit tests at one licensee facility are transferable to other licensee operations. For normal circumstances, the NRC staff feels a fit test every 1 to 3 years is acceptable and will not result in any loss of worker protection. The special cases which NRC feels would require a fit test prior to next respirator use would be those which might reasonably degrade respirator fit include:

- 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 staff 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 (dust masks) to the proposed Appendix A recognizes the utility of disposables and formally permits their use with no protective credit (APF = 1). 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 they may provide some protection against intake. In addition, they may contribute to ALARA efforts. Although 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 acknowledgement of new developments in half-mask respiratory devices, and the potential for increasing use of these devices by licensees, and the declining use of traditional respiratory protection by NRC licensees who are required to use engineered controls or other means to minimize the potential for inhalation of radioactive materials in the workplace. Reusable, reusable-disposable, or maintenance-free respiratory devices with ratings 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. These devices are acceptable to the NRC staff 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 gradually replace more expensive respirators (primarily full facepiece respirators) whose condition has deteriorated to the point where it is no longer cost effective to repair them, their use has the potential for reducing the costs of the licensee's respiratory protection programs. 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 decreased effectiveness of these devices (PF = 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 APF for half and full facepiece air-line respirators in demand mode from APF = 5 to APF = 1. It is the NRC staff position that supplied air respirators operating in the demand mode should not be used 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 these more protective devices. The change may cause some increase in the overall regulatory burden and is addressed below in the value/impact analysis.

11) 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.

12) 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, and is consistent with ANSI recommendations. This is discussed further in the value/impact analysis.

13) 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 is not expected to result in a significant increase in regulatory burden. That is because of the unlikely need for an APF of 2,000, as opposed to 1,000, a desire to simplify the estimation of exposure in the field, and because 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.

14) 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. This is addressed below in the regulatory value/impact analysis.

15) The proposed addition of air-line suits with an APF = 1 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 allows licensees 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.

16) The proposed reduction of the APF for self-contained breathing apparatus (SCBA) from 50 to 1 for demand and demand recirculating mode in Appendix A could increase the regulatory burden for some licensees by requiring them to replace existing equipment with other alternatives. However, the chance of facepiece leakage under negative pressure is considered by the NRC staff to be

too high, especially for devices that may be used in emergency situations, and the NRC wishes to discourage the further use of these devices whose performance and reliability do not justify an APF of 50. These issues will be addressed further in the value/impact analysis.

17) The proposed exclusion of noble gases from respiratory protection considerations in footnote d of the proposed Appendix A would result 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 based respirator assignments on 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 assumed that the existing respiratory protection rules 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 all 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 staff labor cost is \$52/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 NP respirator, full mask PP respirator or powered air-purifying respirator (PAPR), and full mask pressure demand SCBA; no more than 10 percent currently use half-mask devices

These assumptions are made based on NRC data and on information obtained from industry experts on respiratory protection, licensees, and the Nuclear Energy Institute located in Washington, DC. The estimates and specific rationale used are presented below item by item following the same sequential order as

the discussion in Section 4. A summary of the overall value and impact is presented at the end of this section.

1) *Elimination of Policy Statements*

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

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

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

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

For 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:

$$\$52/\text{hr} \times 0.1 \text{ hr}/\text{review} \times 250 \text{ reviews}/\text{year} = \$1,300/\text{year}$$

In addition, the three new policy statements prepared for NRC per year take NRC staff 0.5 hour each for review; at \$52 per hour it will cost about \$80/yr.

$$\text{Total cost savings} = \$10,355/\text{year}$$

2) *Provision for Low-Temperature Usage*

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

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

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

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

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

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

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

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

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 every 2 or 3 years for most workers versus the current industry practice of about once each year for workers requiring respiratory protection, and transferring fit test records between licensees (e.g., for refueling operations). As discussed below in item 6), it is estimated that it takes about 1 hour for training and fit testing new workers. It is assumed that about half of that time is involved with fit testing (0.5 hr/worker). NUREG-0713, Vol. 15 (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. If it 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) would currently require fit testing each year. The cost of annual fit testing would be about:

$$\text{\$145/hr} \times 0.5 \text{ hr/worker-year} \times 20,000 \text{ workers} = \text{\$1,450,000/year}$$

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

$$\text{\$145/hr} \times 0.5 \text{ hr/2.5 worker-year} \times 20,000 \text{ workers} = \text{\$580,000/year}$$

Therefore, the potential savings could be on the order of about $\text{\$870,000/year}$ 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 staff. For most current licensees, such notifications have already been made. However, to permit potential new licensees or decontamination and decommissioning efforts to begin in the future, it was assumed that two licensees per year (one reactor and one non-reactor licensee) would prepare notifications at 0.5 hour per notification, the annual cost savings would be:

$$(\$145/\text{hr} \times 1 \text{ licensee/year} \times 0.5 \text{ hr/licensee}) + (\$116/\text{hr} \times 1 \text{ licensee/year} \times 0.5 \text{ hr/licensee}) = \$261/\text{year}$$

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

$$\$52/\text{hr} \times 0.2 \text{ hr/licensee} \times 2 \text{ licensees/year} = \$20/\text{year}$$

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

$$\$52/\text{hr} \times 2.5 \text{ hr/licensee} \times 2 \text{ licensees/year} = \$260/\text{year}$$

Total savings would be about \$546/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 the 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 increases 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, since 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 APF of 1

This change will formally acknowledge the current practice of providing disposable dust masks to employees who request such equipment in the workplace where respiratory protection against airborne radioactive material is not needed based on ALARA considerations. This practice has resulted from state/OSHA requirements for providing respirators to workers when they ask for them. Under the current rule, if an employee (e.g., maintenance or operations workers) 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.

However, if such a respirator is provided, the employee must be included in the approved respirator program which calls for a medical examination, fit testing, training, and other requirements. 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).

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). Since 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 (APF = 1.0), such as 3M model 8710 (i.e., no allowed protection factor). Under the proposed rule, a maximum of about 90,000 traditional respirator uses could be avoided each year. Assuming 40 percent of all uses are replaced by disposable respirators (40,000 per year, averaged over several years), the proposed rule would replace an equal number of 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 sneezes 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 $50,000 \text{ respirators} / 7.5 \text{ years} = 6,670 \text{ respirators per year}$. If these respirators were replaced by traditional respirators, the cost for half-mask (\$25 each) and full-face mask (\$150 each) respirators would be:

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

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

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

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

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

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

For traditional respirator uses, if 5 percent of the worker 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:

$$\begin{aligned} & \$145/\text{worker} \times 1,000 \text{ workers} = \$145,000/\text{year} \\ & \text{(i.e., a net savings of only about } \$13,000/\text{year)} \end{aligned}$$

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

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

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

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

Thus, the total cost for traditional respirators would be about \$8.762-million dollars/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:

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

Thus, the potential savings might be on the order of $(\$917\text{K} + \$145\text{K} + \$480\text{K} + \$280\text{K}) - (\$32\text{K} + \$232\text{K} + \$6.0\text{K}) = \$1,272\text{K}$ or \$1.3-million.

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), because current NRC rules basically discourage the use of such devices as part of licensed activities since 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, but would not be required to perform irritant smoke tests each time those devices were 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 respirators without requiring irritant smoke tests for each use (only a

simple physical check, such as a negative and/or positive pressure fit check would be required). Half-mask devices also offer greater ease of use for workers wearing optical glasses.

One of the newest type 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. These newer half-face mask devices would be acceptable to NRC staff as long as they are made of high efficiency filters (greater than 99 percent particulate removal), and can be checked for fit (not necessarily with irritant smoke) each time they are donned. Acceptance of the use of these new devices would formalize the NRC staff acceptance of their use by licensees. Since 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 actual initial costs. 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 (as they wear out) should also be considered under the proposed rule.

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

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

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

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

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

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

The cost of reusable/disposable respirators is on the order of \$7 (or less) each (e.g., 3M model 9970). It is assumed that they would also be used only once before disposal for each time an APF greater than one is required. Thus, annual costs of using these devices in place of traditional respirators would be:

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

Since there are no changes in training or procedures for this substitution, there are no additional costs and the potential annual savings would be about:

$$(\$16,650 + \$60,417 + \$35,000) - \$35,000 = \$77,067/\text{year}$$

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 the 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 APF from 5 to 1 for Air-line Demand Mode Respirator

This change will require a worker to use at least an air line demand respirator so that a continuous supply of air is provided to the facepiece and to achieve an APF of at least five, if there is no problem with an oxygen deficiency in the work space. Licensees may choose to use other types of air-line respirators or especially if such respirators are in their stock. However, available information indicates that there are currently few (if any) of these devices in use, so no demonstrable impacts would result from the formal recognition of present day industry practice.

11) 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). Since almost all licensees already have full mask 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.

12) 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.

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

This change is made to simplify the APF System and to reflect the fact that 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 on respiratory protection among licensees, no significant value/impact is expected.

14) 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. Since there is no currently allowed air-line respirator 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.

15) Addition of Air-line Suit with an APF of 1

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

16) Reduction of the APF from 50 to 1 for a SCBA in Demand and Demand Circulating Mode Due to Observed Failures in the Field

This change (which is designed to discourage further use of these out-dated devices) might appear to increase cost to a licensee since the choice of available respirators with an APF of 50 is further restricted. However, because most licensees will have in stock other respirators with APFs greater than 50, there should be no real or measurable impacts on almost all licensees. Further, few of these types of SCBA are still being used by NRC licensees, and no significant impacts are expected to result from this change.

17) Exclusion of Noble Gases from Respiratory Protection Considerations

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

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

A summary of the estimated annual value and impact for each major change is presented below. Total annual increase in value is estimated to be \$3,115,055 while the total added cost is estimated at \$1,181,576 for net annual savings of \$1,932,500.

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 present 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	\$10,355	\$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	560	0
5. Allowing half-mask for plutonium use	0	0
6. Disposable mask with APF = 1	1,542,000	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, 5 to 1. Air-line D Mode	0	0
11. 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
12. Half-mask Air-line PD. APF = 50	0	0
13. Reducing APF, 2,000 to 1,000. Full mask Air-line PD	0	0
14. Loose fitting Air-line. APF = 25	0	0
15. Air-line suits. APF = 1	0	0
16. Reducing SCBA D or DR. APF 50 to 1	0	0
17. Exclusion of Noble Gases from Subpart H	73	0
TOTAL VALUE/IMPACT	3,115,055	1,181,576

ATTACHMENT 4

Draft Environmental Assessment

ENVIRONMENTAL ASSESSMENT
AND FINDING OF NO SIGNIFICANT IMPACT ON
PROPOSED AMENDMENTS OF 10 CFR PART 20, SUBPART H -
"RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT
INTERNAL EXPOSURE," AND APPENDIX A
ALAN K. ROECKLEIN
OFFICE OF NUCLEAR REGULATORY RESEARCH
U.S. NUCLEAR REGULATORY COMMISSION
MARCH 1996

I. The Proposed Action

The Nuclear Regulatory Commission is proposing to amend its regulations regarding respiratory protection to make these regulations 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 are endorsed by NRC and are available to NRC licensees.

The proposed amendment is focused on technical and procedural improvement of the use of respiratory protection devices. It adds recognition of new devices that have been proven to be useful in protecting workers. It revises Assigned Protection Factors (APFs) which are used to estimate the degree of protection afforded workers based on ANSI determinations.

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. Although the NRC staff 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. At that time a major American National Standards Institute (ANSI) standard was in preparation that was intended to provide state-of-the-art guidance on acceptable respiratory protection devices and procedures. A decision was made to proceed with the Part 20 rulemaking and to address Subpart H when the ANSI guidance was complete.

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 provided an authoritative consensus on major elements of an acceptable respiratory protection program, including guidance on respiratory selection, training, fit testing, and assigned protection factors (APF). Based on the publication of ANSI Z88.2-1992 and a determination by the NRC staff that Subpart H of Part 20 can be less prescriptive without reducing public and worker health and safety, the NRC believes this rulemaking is necessary.

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 licensees to revise 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 endorsed 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 on 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 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. 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 are acknowledged for their contributions of technical information and data.

K. Paul Steinmeyer, Radiation Safety Associates, Inc.

Robert daRosa, Lawrence Livermore Laboratory, (Retired)

James E. Wigginton, Office of Nuclear Reactor Regulation, NRC

Sami S. Sherbini, Office of Nuclear Material Safety and Safeguards, NRC

Roger L. Pederson, Office of Nuclear Reactor Regulation, NRC

Bradley W. Jones, Office of General Council, NRC

ATTACHMENT 5

Draft Congressional Letters



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

The Honorable Lauch Faircloth, 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.

Updating the Nuclear Regulatory Commission's (NRC) rules on respiratory protection has been awaiting completion of technical guidance from the American National Standards Institute (ANSI), which is now complete. The amendments track ANSI guidance by recognizing new devices that have proven to be effective, adapt new procedures such as fit testing that reflect recommended good practice and reaffirm the NRC's intent to minimize the sum of external and internal doses by questioning the automatic use of respirators.

The proposed rules redefine the level of adequate protection, establish a less prescriptive framework and are estimated to reduce licensee burden by about \$2,000,000 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

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

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Bob Graham

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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.

Updating the Nuclear Regulatory Commission's (NRC) rules on respiratory protection has been awaiting completion of technical guidance from the American National Standards Institute (ANSI), which is now complete. The amendments track ANSI guidance by recognizing new devices that have proven to be effective, adapt new procedures such as fit testing that reflect recommended good practice and reaffirm the NRC's intent to minimize the sum of external and internal doses by questioning the automatic use of respirators.

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Rep. Frank Pallone

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

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ATTACHMENT 6

Draft Public Announcement

DRAFT PUBLIC ANNOUNCEMENT

NRC Proposes Revisions to Regulations on Respiratory Protection and Controls Rules to Restrict Internal Exposure (10 CFR Part 20)

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

When 10 CFR Part 20 was significantly revised in 1992, the American Standards Institute (ANSI) was working on new consensus guidance on the use of respiratory protection. Consequently, Subpart H of 10 CFR Part 20 and Appendix A were not changed significantly. The ANSI guidance is now published and the proposed updating of the rules for respiratory protection has been published.

The proposed amendments would recognize new devices which have been proven to be effective, would revise Assigned Protection Factors (APF) to be consistent with the new test results on existing respirator and would revise certain procedures such as fit testing to be consistent with recommended good practice. The new rules would be performance based, prescriptive and easier to implement. The NRC staff estimates that the simplified rules would save the industry on the order of 2 million dollars per year without any reduction in worker health and safety.

Interested persons are invited to submit written comments on the proposed changes, which are to Part 20 of the Commission's regulations, by _____ (75 days after publication of a notice of proposed rulemaking in the Federal Register on _____).

The comments should be addressed to Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

ATTACHMENT 7
OMB Supporting Statement

**Supporting Statement for Amendment to
10 CFR Part 20, Subpart H and Appendix A**

**Respiratory Protection and Controls to Restrict
Internal Exposure, and Appendix A**

Description of the Information Collection

The Nuclear Regulatory Commission is proposing to delete from the regulations one recordkeeping requirement and one reporting requirement. They are:

- 1- § 20.1703(a)(4), paragraphs (i) through (iii) that require licensees to issue written policy statements on aspects of their respiratory protection program;
- 2- § 20.1703(d), that 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.

A. JUSTIFICATION

1. The NRC does not believe there is a need to retain these two information collection requirements. The notification requirement is often redundant with the license application, renewal and amendment process. Part 20 already requires that licensees use only respirators approved by NIOSH/MSHA and that their respiratory protection program be approved. The written policy statement to some extent duplicates written procedures for implementing the respiratory protection program which are available to NRC inspectors as part of a license. The policy items that a licensee would commit to in a policy statement: use of engineering controls; routine, nonroutine and emergency use; and periods of use and relief, are required elsewhere by the regulations. Thus there is no need for this additional record.
2. The NRC has no need for notification of use of respiratory protection equipment, or a written policy statement regarding elements of a respiratory protection program. If the licensee selects equipment that is tested and certified by NIOSH/MSHA and describes the respiratory protection program in the license, then there is no need for a special notification. If the licensee wishes to use equipment that is not tested and certified then the regulations require the licensee to submit an application to the NRC for authorization. The elements of a respiratory protection program currently required to be addressed in the licensees policy statement are required by existing regulations or addressed in the licensees procedures and these are subject to inspection.

3. Deletion of these two information collection requirements is considered a reduction of licensee burden with no reduction of worker or public safety.
4. Both of the information collection requirements that are proposed for deletion partly duplicate existing requirements elsewhere that are adequate and justified. § 20.1703(a)(3)(iv) requires written procedures regarding selection of respirators and limitation on use and relief. § 20.1701 requires the licensee to use process or other engineering controls to limit intakes.
5. License applications, renewals and amendments including written procedures that are currently required by regulation, provide information regarding selection and use of respirators which is adequate for the Commission to assure worker protection. The 30-day notification of the use of respirators was thought to be needed when regulations on respiratory protection were first promulgated. With a mature industry and years of experience, the NRC staff no longer feels this advance notice is needed.
6. Deletion of these information collection requirements represent a reduction in small business burden to the extent that small businesses are using respiratory protection.
7. There are no health or safety consequences to the deletion of these information collection requirements.
8. The staff has discussed deletion of these two information collection requirements with contractors, selected licensees and the Agreement States. There is a consensus that the requirements are redundant and that deletion would not reduce public or worker health and safety.
9. The NRC staff estimates that there are approximately 500 NRC licensees that use respiratory protection devices to reduce intakes of airborne radioactive material. NRC inspectors review the currently required written policy statement once every 2 years, or 250 reviews per year. A review takes about 0.1 hours. Thus, about 25 hours of NRC inspector time is needed to assure existence and acceptability of licensee respirator policy statements. At about \$100 per hour, inspection of this requirement costs the government about \$2,500 per year.

The regions receive about 10 notifications of use of respiratory protection each year. These are reviewed and filed at a cost of about 0.2 hours per notification. Thus, 2 hours times \$100 per hour yields a cost of about \$200 in NRC staff time to review and process the required notification.

Deletion of these two information collection requirements would save the federal government about \$2,700 per year.

10. The burden on licensees for implementing these two information collection requirements is estimated as follows: All existing licensees with respiratory protection programs have policy statements in place. Approximately 10 licensees per year initiate respiratory protection programs and would be required to issue written policy statements on their program. Preparing and issuing a policy statement is estimated to require 10 hours. Total cost per year is thus 10 new programs times 10 hours times approximately \$100/hour, or \$10,000 per year.

Existing licensees would probably review their written policy statement annually. This review is estimated to require 0.5 hours per year times 500 licensees times approximately \$100 per hour, or \$25,000 per year. Licensees submit approximately 10 notifications of use of respirators to the regional offices per year. Preparation and submittal of these reports is estimated to require 2 hours. The cost of this reporting requirement to industry is 10 reports times 2 hours per report times \$100 per hour, or \$2,000 per year.

The total monetary burden to industry for complying with these two information collection requirements is estimated to be \$37,000 per year.

The NRC is proposing to delete the requirements for these information collections, with a resultant estimated savings of \$37,000 with no known impact on public or worker health and safety.

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C. Paperiello et al.

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3. Cognizant Individual:

NMSS - Sami S. Sherbini
 NRR - James E. Wigginton
 OSP - Dennis M. Sollenberger
 OGC - Stuart A. Treby

4. Requested Action: Review, comment and provide office concurrence.

5. Requested Completion Date:

6. Background: This proposed rule and associated draft regulatory guide revision were developed with considerable input and review by the cognizant individuals and an outside contractor, expert in current respiratory protection practice, Mr. Paul Steinmeyer. Because of the extensive involvement of staff from other offices, RES is assuming division concurrence. A revision of NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials" is ongoing and is expected to be ready for publication when the rule and regulatory guide revision are final. No additional NRC resources are anticipated to implement the rule. The draft regulatory analysis indicates an estimated reduction of licensee burden of about 2 million dollars per year.

Attachments: Rulemaking Package and
 Draft Regulatory Guide

cc: w/atts.
 R.M. Scroggins, OC
 L. J. Norton, IG
 W. Beecher, PA
 D. K. Rathbun, CA

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