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

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

William T. Russell, Director
Office of Nuclear Reactor Regulation

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

Richard L. Bangart, Director
Office of State Programs

James Lieberman, Director
Office of Enforcement

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

SUBJECT: RULEMAKING PLAN: RESPIRATORY PROTECTION (SUBPART H AND APPENDIX A TO PART 20)

Your concurrence is requested on the attached rulemaking plan. During the revision of 10 CFR Part 20 in late 1980s, the staff was aware that certain provisions of Subpart H and Appendix A to Part 20 were out of date and that new guidance was under development by the American National Standards Institute (ANSI). This ANSI standard, "American National Standard for Respiratory Protection," (ANSI Z88.2-1992) was published by ANSI in August 1992.

Subsequently, RES staff begun working on a proposed rulemaking to amend Subpart H and Appendix A (prior to the development of MD 6.3, "The Rulemaking Process" and the requirement for a rulemaking plan). With the assistance from cognizant individuals of the program offices, a draft Federal Register notice and a draft revision to Regulatory Guide 8.15 have been completed. The drafts are based on Option 2 of the rulemaking plan (i.e., amend Subpart H and Appendix A and keep both in Part 20). In this rulemaking plan, however, RES is suggesting Option 3 (i.e., keep Subpart H in Part 20 but move Appendix A to RG 8.15) to be the preferred option.

The following is a summary of this request:

1. Title: Respiratory Protection.

2. RES Task Leader: Alan K. Roecklein (415-6223).

3. Cognizant Individual: NMSS - Sami S. Sherbini
NRR - James E. Wigginton
OSP - Dennis M. Sollenberger
OGC - Kathryn L. Winsberg
OE - Joseph R. DelMedico

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4. Compatibility for Agreement States: Yes.

5. Requested Action: review and concur.

6. Requested Completion Date: 3 weeks after the date of this memorandum.

7. Resources and Coordination: Estimated resources to develop this rule, a regulatory guide, and NUREG-0041 are 1.5 FTE. Contractor support is fully funded. A copy of this concurrence package has been forwarded to the Offices of the Controller for coordination of resource issues and to the IG for information.

Attachment:
Rulemaking Plan

cc w/attachment:
R. Scroggins, OC
L. J. Norton, IG
G. Cranford, IRM
S. Sherbini, NMSS
J. Wigginton, NRR
D. Sollenberger, OSP
S. Treby, OGC
A. C. Thadani, NRR

3. Cognizant Individual: NMSS - Sami S. Sherbini
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JEGlenn/RPHEB rf
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FCostanzi
ATse
PDR Yes/No

*See previous concurrences

Offc:	RPHEB:DRA	RPHEB:DRA	D:DRA:RES	D:RES
Name:	ARoecklein*	JGlenn*	BMorris	DMorrison
Date:	3/25/96	6/14/96	/ /96	/ /96
Dist:	Yes/No	Yes/No	Yes/No	Yes/No

OFFICIAL RECORD COPY

(File Code No.)_____

RULEMAKING PLAN FOR

PROPOSED AMENDMENTS
"RESPIRATORY PROTECTION AND CONTROLS TO
RESTRICT INTERNAL EXPOSURES"
(10 CFR PART 20)

Lead Office: Office of Nuclear Regulatory Research

Staff Contact: Alan K. Roecklein, RPHEB/DRA

Concurrences:

D. Morrison, RES Date

C. Paperiello, NMSS Date

W. Russell, NRR Date

R. Bangart, OSP Date

J. Lieberman, OE Date

W. Olmstead, OGC Date

Approval:

J. Taylor Date

Rulemaking Plan

Respiratory Protection and Controls To Restrict Internal Exposure

(10 CFR Part 20)

Regulatory Issue

The regulatory issue is that the current Subpart H and Appendix A to 10 CFR Part 20 are out of date and do not reflect new technology in respiratory protection. Some of the respirator designs listed in Appendix A are now known to be less effective, other new devices known to be more effective need to be listed, and some of the protection factors need to be revised based on new information and guidance. Respiratory protection equipment may be used by licensees to limit intakes of airborne radioactive material to workers when it is impracticable to apply process or other engineering controls to further reduce concentrations of radioactive materials in air and the specified protection factors are used by licensees in the selection of respirators and for estimating worker exposure. Subpart H and Appendix A contain the requirements related to the selection, use, maintenance, and training for use, etc., of the respiratory protection equipment.

During the revision of 10 CFR Part 20 in late 1980s, the staff was aware that certain provisions of Subpart H and Appendix A to Part 20 were out of date and that new guidance was under development by the American National Standards Institute (ANSI). This ANSI standard, "American National Standard for Respiratory Protection" (ANSI Z88.2-1992) was published by ANSI in August 1992.

Of major concern are the updated protection factors associated with certain types of respirators. The protection factor for a respirator is a measure of how effective the device is in removing contaminant from breathing air, and thus, it is a necessary input for estimating the internal dose received by the worker. Based on current technical knowledge, it is now believed that the effectiveness of some respirators has changed from those listed in the existing Appendix A. Most new protection factors have been reduced from those listed in Appendix A, however, some are increased and others remain unchanged. Without changing the protection factors, the licensee could underestimate the internal dose for those types of respirators with reduced protection factors.

Specifically, the ANSI Committee concluded that several respirator designs in the field are less protective than indicated by the protection factors listed in the current Appendix A. Reduced protection factors include the half-mask, air purifying respirator operating in the positive pressure mode; both the full and half-face, air-line respirators operating in the demand mode, and the SCBA device when operated in the demand and demand recirculating modes. Retaining assigned protection factors higher than the current consensus values is inappropriate for radiation protection.

The ANSI Committee concluded that several respirator designs not currently listed in Appendix A and prohibited from use by prior NRC policy statements, are effective in protecting against airborne radioactive material. The staff would propose adding these devices to the approved list with assigned

protection factors recommended by ANSI. These include air purifying devices with loose-fitting facepieces (APF=25), single use and reusable disposables, a half-mask, air-line device operating on pressure demand (APF=50) and a loose-fitting facepiece air-line device operating under continuous flow (APF=25).

Furthermore, the existing regulations contain requirements that may be unnecessarily prescriptive. The regulation could be made more performance based and less burdensome by deleting or moving these redundant or unimportant to safety requirements to a regulatory guide. For example, two recordkeeping requirements in the current rule, a requirement to write a respiratory protection policy statement, and a requirement to notify the regional office 30 days before respiratory protection is first used, are proposed for deletion. In the first case the written policy statement addresses program elements that are also required to be in the written program procedures and is thus considered redundant. In the second case, any major change in the status of respiratory protection use would be picked up by routine inspection, license renewal or amendment, and this requirement is no longer considered important.

Certain new "good practices" considered important to worker protection could be incorporated into the guidance. These include: the recommended "fit factors" to be achieved during fit testing to provide assurance that respirator fit is adequate to support the assigned protection factors; adding "decontamination" to the list of engineering controls to be used to limit airborne radioactive material before use of respirators is considered; deleting a suggestion that face-fitting respirators can be used for protection against facial contamination because this use is no longer considered to contribute to ALARA; requiring consideration of special designs needed for low temperature working conditions because exhalation values have been known to freeze-up.

Current Rule Requirement

The current regulations in Subpart H and Appendix A are consistent with the philosophy and science underlying the new Part 20. They already require that the practice of as low as is reasonably achievable (ALARA) apply to the sum of internal and external dose, permit correction of both high and low initial intake estimates if subsequent bioassay results so indicate, and require a respiratory protection program consistent with Subpart H whenever respirators are used to limit intakes.

Appendix A provides protection factors for specific types of respirators. It also references 30 CFR Part 11 for testing and certification by National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

Regulatory Problem to be Resolved

The current regulations and guidance should be revised as follows:

1. Update protection factors recommended by the ANSI standard and make future updates easier;

2. Recognize additional types of respiratory protection equipment recommended by the ANSI standard and make future inclusions easier;

3. Eliminate unnecessary prescriptive requirements, including certain reporting and recordkeeping requirements;

4. Make the regulation more performance based; and

5. Simplify and clarify the regulatory text.

The staff has considered other regulatory actions to accomplish the same goals. It was concluded that processes such as issuing generic letters, regulatory guides, information notices, and licensing actions would not be able to override the specific language, which is out of date, in current Subpart H and Appendix A.

Preliminary Regulatory Analysis

Background Information

It is estimated that about 250 licensees would be affected by the changes: 100 power reactor licensees and 150 other licensees. Approximately 200,000 workers at licensee sites (primarily power reactors) are currently monitored for radiation exposures; about 100,000 of them are exposed to a measurable dose; about 20,000 of them use respirators; and there are about 100,000 uses of respirators per year. The preliminary analysis indicated that, under current regulations, the estimated baseline cost for licensees to implement respiratory protection is about $26 million per year. The estimated reduction in costs attributed to Options 2 and 3 is $1.4 million per year. The estimate of burden reduction includes: deleting the requirements for a written policy statement and notification of use (~10,500); permitting the use of disposable respirators (~1.2 million); and permitting the use of reusable disposable masks (~100K).

Impact on Licensees

The following discussion focuses on the impacts of three options.

Options

1. No action.

2. Amend Subpart H and Appendix A to Part 20 to incorporate new protection factors, recognize additional respiratory protection equipment, etc., into the regulations.

3. Amend Part 20 to update, simplify, and clarify regulatory text in Subpart H and delete appendix A; in addition, move certain existing requirements in Appendix A that are needed as guidance to RG 8.15 and incorporate new protection factors and respiratory protection equipment, etc, recommended by ANSI into the RG 8.15.

Decision Criteria

Option 1:

This option would leave NRC regulations inconsistent with the new ANSI consensus guidance and current practice. If this option were adopted, the licensee may underestimate the internal dose received by a worker using a respirator whose protection factor has been, based on the ANSI standard, reduced (or overestimate the internal dose if the protection factor has been increased). Furthermore, the licensees would not be able to use additional types of respirators that are not currently listed in Appendix A without obtaining a license amendment from the NRC. This option is therefore deemed unacceptable.

Option 2:

This option would make NRC regulations on respiratory protection consistent with current technology. If this option were adopted, the licensee would be required, by regulation, to use up-to-date protection factors based on current knowledge. Furthermore, the licensees would be able to use several additional types of respirators that are not currently listed in Appendix A. However, this option would continue to maintain a prescriptive based regulation. If protection factors were revised or new equipment were available in the future, a rulemaking process would be necessary to change the regulations. This option is not recommended because the Commission encourages the adoption of performance based regulations and it would be more burdensome to incorporate future revisions of protection factors and new equipment through a rulemaking process. The preliminary analysis indicated that, under this option, the estimated savings to affected licensees would be about $1.4 million per year.

Option 3:

This option would make Subpart H of Part 20 consistent with current technology, become more performance based, and increase operational flexibility. This option would delete Appendix A from Part 20 and move the existing requirements in the appendix that are needed as guidance to RG 8.15. Furthermore, the new protection factors and respiratory equipment recommended by ANSI would be incorporated into RG 8.15. If this option were adopted, there would be no need for a rulemaking process to allow licensees to use new protection factors or new equipment in the future. However, this option might make enforcement of respiratory protection regulations more difficult and might permit non-uniformity of application of the regulatory guidance. The preliminary analysis indicated that, under this option, the estimated savings to affected licensees would be about $1.4 million per year.

Preferred Option

The preferred option is Option 3. The staff recommends rulemaking to update Subpart H of Part 20 and to delete Appendix A from Part 20. In addition, the staff recommends to move the existing requirements in Appendix A that are needed as guidance to RG 8.15, and to incorporate the up-to-date protection factors and new respiratory equipment into RG 8.15. The proposed rule would specifically solicit comment on the issue of providing Appendix A protection factors as guidance in RG 8.15.

OGC Legal Analysis

OGC does not expect to have legal objection to this rulemaking.

Backfit Analysis

Although the adoption of Option 3 would constitute a potential backfit under § 50.109(a)(1), this change meets the exception at § 50.109(a)(4)(iii) since it redefines the level of adequate protection as regards the use of respirators. Thus, a backfit analysis is not required.

Reducing AFPs for several devices such as the air purifying half-mask operating in positive pressure mode and the airline full-facepiece operating in demand, based on field observation that these devices are not as reliable as previously thought, constitutes a redefinition of adequate protection. These devices are not used widely in radiation work, and inexpensive, reliable substitutes are readily available so that reducing the APFs does not constitute a large burden. The redefinition of their ability to protect workers provides a small margin of assurance that their potential failure will not result in an overexposure.

Recognizing that single-use and reusable disposable respirators can be valuable options in a respiratory protection program is a redefinition of adequate protection. The NRC has previously said that these devices cannot be used in licensed operations. It is now believed that although these devices cannot be tested quantitatively to determine an APF other than 1, they do provide some protection in that at least contaminated dusts are filtered out of breathed air. The devices expose workers to minimal physiological stress and do not appear to slow work and thus contribute to reducing total effective dose equivalent consistent with the new ALARA policy. Most respirator uses are to protect against potential releases of radioactive material into the air when systems are opened for maintenance and the new disposables are an alternative "just-in-case" option to the more expensive and cumbersome full-face masks. Recognizing the use of these devices is considered to be a major cost/burden reduction because their cost is far less than the combined costs of purchase, maintenance, fittesting and medical exam required to use other more restrictive reusable respirators.

Several other changes proposed are considered to be redefinition of adequate protection. For example, deleting the requirements for written policy statements and notification of the NRC that new respiratory equipment will be

put into use, are no longer considered necessary by the NRC staff to assure worker protection. The retained requirement for written procedures and the requirement to use "approved" devices render these reporting requirements unimportant to safety and their deletion is a burden reduction.

The existing regulation includes numerous requirements to assure adequate conditions of respirator use such as air quality and filter efficiency that are already requirements for NIOSH approval. Because NIOSH approval is required in order to take credit for the use of a device, these regulations are considered redundant burdens on licensees that do not contribute to worker protection and may use protection resources that could be more effectively redirected.

Agreement State Implementation Issues

The staff believes that the proposed modifications to Subpart H and deletion of Appendix A to Part 20 should be Division 2 items of compatibility because these regulations are intended to help implement compliance with dose limits. However, the States would have the option to be more restrictive. This rulemaking plan will be provided to the Agreement States during the NRC staff review process. No Agreement State implementation problems are expected.

Supporting Documents Needed

The staff would revise RG 8.15, "Acceptable Programs for Respiratory Protection," and NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials."

Issuance By EDO or Commission

The staff is recommending Commission issuance.

Resources Needed to Complete Rulemaking

FTE: 1.5 FTE broken down as follows:

RES - 0.8 FTE (review and revise proposed rule, develop final rule, and manage contract support)
NMSS - 0.2 FTE (provide technical input, review draft documents)
NRR - 0.2 FTE (provide technical input, review draft documents)
OGC - 0.2 FTE (review draft documents, provide legal input)
OSP - 0.1 FTE (review draft documents, coordinate with Agreement States)

Contractor Resources: An existing contract in DRA is providing technical support for completing the draft revisions of regulatory guide 8.15 and NUREG-0041, thus, no additional contract funding is needed. These resources are already included in the Five-Year Plan.

Lead Office Staff and Staff From Supporting Offices

Staff Level Working Group		Concurring Official
RES:	Alan Roecklein	Bill M. Morris
NMSS:	Sami S. Sherbini	Donald A. Cool
NRR:	James E. Wigginton	Brian K. Grimes
OGC:	Kathryn L. Winsberg	Stuart A. Treby
OSP:	Dennis M. Sollenberger	Richard L. Bangart
OE:	Joseph R. DelMedico	James Lieberman

Management Steering Group

Not needed for this rulemaking.

Public Participation

There is no need for enhanced public participation for this rulemaking. The rulemaking documents will be placed on the NRC's electronic rulemaking bulletin board in addition to publication in the Federal Register. There will be early and substantive input sought from Agreement States.

Schedule

CRGR Review of Proposed Rule:	6 months after EDO approves the plan.
Proposed rule/draft RG to EDO:	9 months after EDO approves the plan.
Public comment period:	75 days.
Final rule/RG to EDO:	12 months after comment period closed.