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

MEMORANDUM FOR: James M. Taylor
Executive Director For Operations

FROM: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

SUBJECT: INITIATION OF RULEMAKING - RESPIRATORY PROTECTION TO CONTROL INTERNAL EXPOSURE

Respiratory protection has formed an integral part of radiation protection for many years. Previously, control and prevention of all intakes through the use of respirators was emphasized without consideration of the external dose. With the revision of 10 CFR Part 20, the emphasis is on optimization of total effective dose equivalent with no bias towards internal or external sources.

When the revision to 10 CFR Part 20 was published in the Federal Register in May of 1991, only relatively minor changes that were necessary to remain consistent with the balance of the rule were made to Subpart H, RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS, and to Appendix A to 10 CFR Part 20. Under the provisions of the revised 10 CFR Part 20, many practices which are a part of good respiratory protection programs are not required in the revised regulation. ALARA is not the impetus behind respirator selection. Respirators are still required to reduce airborne radioactivity levels to below one derived air concentration.

At the meeting with the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) held on September 23 and 24, 1991, NUMARC presented a prepared statement on regulatory guides for the revised 10 CFR Part 20. They requested that a high priority be given to the development of additional guidance in the area of respiratory protection.

There have been significant developments in the area of respirator design. Improvements in fit testing, elasto-polymeric seal materials, etc. have increased the overall efficiency of respirators. Furthermore, at the time the revision to 10 CFR Part 20 was being drafted, a significant amount of research into workplace protection factors of commonly used respiratory protective equipment was nearing completion. For example, the American National Standards Institute (ANSI) has now published its revision to the respiratory protection standards (ANSI Z 88.2) and respiratory fit testing standards (ANSI Z 88.10). The National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Association (MSHA) have completed a major revision to their respiratory protection rules (42 CFR Part 84). The staff intends to incorporate these standards, as appropriate, into this rulemaking and to the revision of associated guidance documents.

Attachment A

This rulemaking should result in lower overall doses through minimization of the total effective dose equivalent, and lower cost to licensees and reduced equipment down time due to reduced dependence on respirators and the use of new, more efficient equipment and techniques.

The proposed rule will amend 10 CFR Part 20 §§ 20.1701 through 20.1703 and Appendix A to 10 CFR Part 20 §§ 20.1001 through 20.2401. It will include requirements for use of process or other engineering controls where practicable as well as the use of respiratory protective equipment in all controlled and restricted areas of licensed facilities. This rulemaking will require specific procedures and programs to be implemented by licensees governing approved equipment, user requirements, safety and ALARA. However, the rulemaking is not simply procedural in nature. The revision would modify the philosophy underlying respirator use, permit use of specific equipment and protection factors that are currently not allowed, and strengthen the overall use of ALARA as a function of both internal and external exposure.

The proposed rule will affect all NRC licensees that use respiratory protection equipment in the control of internal exposure to radiological contaminants. As a part of the effort to revise the regulations, the staff plans to carefully examine the relationship between the regulation, regulatory guides and technical information (including NUREG's) which are available, and to modify the regulations and guidance documents as a package to assure a proper relationship and approach. This rulemaking will be handled as a high priority effort.

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosures:
1. Regulatory Agenda Entry
2. Justification for Rulemaking

REGULATORY AGENDA ENTRY

TITLE: REVISION OF RESPIRATORY PROTECTION TO CONTROL INTERNAL EXPOSURES

CFR CITATION 10 CFR 20 SUBPART H AND APPENDIX A TO 10 CFR PART 20 §§ 20.1001 THROUGH 20.2401

ABSTRACT:

Respiratory protection has formed an integral part of radiation protection for many years. Previously, control and prevention of all intakes through the use of respirators was emphasized without consideration of the external dose. With the revision of 10 CFR Part 20, the emphasis is on minimization of total effective dose equivalent with no bias towards internal or external sources. In the meantime, there have been significant developments in the area of respirator design. Improvements in fit testing, elasto-polymeric seal materials, etc. have increased the overall efficiency of respirators. As a result, requirements contained in 10 CFR Part 20 Subpart H specify are no longer appropriate from the standpoint of reducing exposures to levels which are as low as reasonably achievable.

TIMETABLE:

ACTION	ELAPSED TIME FROM EDO APPROVAL OF RULEMAKING:
Proposed Rule for Division Comment	3 months
Proposed Rule for Office Review	6 months
Proposed Rule to EDO	9 months
Proposed Rule to Commission	10 months
Proposed Rule Published	12 months
Public Comment Period Complete	15 months
Final Rule to EDO	19 months
Final Rule to Commission	21 months
Final Rule Published	24 months

LEGAL AUTHORITY:
To be determined

EFFECTS ON SMALL BUSINESS AND OTHER ENTITIES:
The effects on small businesses is minimal as the philosophy of optimizing internal and external exposure is already part of the new Part 20. Overall, the change should reduce the overall cost of a respiratory protection program by reducing the actual dependence on respirators.

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JUSTIFICATION FOR RULEMAKING

REVISION TO 10 CFR 20.1701 - 20.1703
RESPIRATORY PROTECTION TO CONTROL INTERNAL EXPOSURES

THE ISSUE TO BE ADDRESSED BY THE RULEMAKING

Respiratory protection has formed an integral part of radiation protection for many years. Previously, control and prevention of all intakes through the use of respirators was emphasized without consideration of the external dose. With the revision of 10 CFR Part 20, the emphasis is on minimization of total effective dose equivalent with no bias towards internal or external sources. In the meantime, there have been significant developments in the area of respirator design. Improvements in fit testing, elasto-polymeric seal materials, etc. have increased the overall efficiency of respirators. As a result, requirements contained in 10 CFR Part 20 Subpart H specify are no longer appropriate from the standpoint of reducing exposures to levels which are as low as reasonably achievable.

In 1989, the Occupational Safety and Health Administration (OSHA) published a Notice of Proposed Rulemaking of 29 CFR 1910.134, "Respiratory Protection -- General Industry", and 29 CFR 1926.103, "Respiratory Protection -- Construction Industry", to modify existing standards on respiratory protection. Also in 1989, the National Institute for Occupational Safety and Health (NIOSH) published a Second Notice of Proposed Rulemaking for 42 CFR 84, "Certification of Respiratory Devices." In 1990, the American National Standards Institute (ANSI) published ANSI Z88.2-1990 which has since been revised as ANSI Z88.2-1991 "Practices for Respiratory Protection" which sets forth acceptable practices for respiratory protection programs based on the current state of knowledge in the field. The revision to 10 CFR 20, "Standards for Protection Against Radiation", has been published and will become effective by January of 1993. The changes to these standards were not addressed during the revision of 10 CFR Part 20 since these new standards were not available at the time the revision was drafted. In order to protect the health and safety of persons using respiratory protection equipment to control internal exposures at NRC licensees, revision of the current rule is necessary.

THE NECESSITY AND URGENCY OF ADDRESSING THE ISSUE

Current practices in respiratory protection involve the use of respirators to limit all intakes of radioactive material. In some cases, respirators are used solely to prevent facial contamination. No consideration is given to the potential increase in external exposures due to the reduced efficiency of the worker when respirators are used.

The use of the effective dose equivalent by the NRC implies that a rem of exposure resulting from intakes of radioactive material carries the same risk as a rem of exposure from external sources. The recent revision to Subpart H, as a part of the revision to the 10 CFR Part 20, begins the process of changing the philosophy of respiratory protection. This proposed revision would go even further to elaborate on that philosophy. As with the present rule and guidance documents, the proposed rule will require specific policy statements, procedures and programs to ensure that health of the individual is

properly protected and that external exposure is not sacrificed to prevent internal exposure.

In addition, the proposed revision and associated guidance documents will phase out the use of some outdated equipment which is of limited value and will allow new respiratory devices not available when the current rule was written. The proposed rule will codify the requirements for medical evaluation, fit testing, optimizing the sum of internal and external dose, and Quality Assurance to ensure the health and safety of respirator users. Finally, the proposed revision will update the terminology used in respiratory protection to conform with NIOSH/MSHA, OSHA and ANSI regulations and standards.

ALTERNATIVES TO RULEMAKING

1. Do nothing i.e., make a determination that the current rule adequately protects the health and safety of workers using respiratory protection equipment without undermining the ALARA principle.

    a. The protection factors in the existing Appendix A are overly conservative and their use might result in increased exposures to respirator users due to decreased stay times in radiation areas resulting in additional entries into radiation areas, increased man hours needed to complete the task and additional respiratory protective equipment and maintenance.

    b. Some licensee will continue to use respirators inappropriately i.e., to control facial contamination at the expense of increased total effective dose equivalent exposures.

    c. Respirators might be issued to users who are not trained, medically evaluated for respirator use or properly fit tested to determine that the rated protection factors are achievable.

The staff does not believe that this approach would continue to provide adequate and ALARA dose control.

2. Issue a regulatory guide which modifies the existing respiratory guidelines without revising the rule.

    a. While the issue of fit testing, training and medical evaluation can be addressed in a regulatory guide, the protection factors cannot be changed.

    b. The use of respirators to limit all intakes may continue with the resultant increase of external exposures due to longer stay times in radiation areas.

It is the view of the staff that a revision to the rule is called for in addition to modification to the regulatory guide.

HOW THE ISSUE WILL BE ADDRESSED THROUGH RULEMAKING

A revised 10 CFR Part 20 Subpart H and Appendix A will be developed. The new rule will include those measures now required in 10 CFR 20, and still appropriate, together with the latest developments in the area of respiratory protection.

1. Language within the rule will be updated to reflect current knowledge.

2. The order of the requirements in the rule will be changed to emphasize the relative importance of each. The licensee will be required to develop and issue policy statements; implement programs, including procedures and practices; and utilize approved equipment within specific guidelines.

3. Specific requirements such as medical evaluation, fit testing, training and bioassay will be codified.

4. Licensees will be required to comply with this rule any time respirators are used inside the restricted area, regardless of the airborne contaminant for which protection is needed.

5. Common terminology will be defined.

6. Requirements currently in the footnotes to Appendix A will be moved to the rule where they properly belong and elaborated on for clarity.

7. New approved equipment will be included in Appendix A.

8. Assigned protection factors will be changed to reflect the types of equipment in use by NRC licensees, and the actual performance of this equipment.

HOW THE PUBLIC, INDUSTRY, AND NRC WILL BE AFFECTED BY THE RULEMAKING INCLUDING BENEFITS, COSTS, OCCUPATIONAL EXPOSURE, AND RESOURCES

Benefit to individual members of the public will be minimal as the rule only deals with occupational use of respiratory protective equipment.

The chief benefit to industry should be to reduce overall occupational exposures. The industry will be permitted to optimize internal and external exposure by selecting respiratory protection devices only when their use will result in a reduction in total dose. Reduced respirator use in some circumstances will reduce the time required to effect repairs, thus reducing both maintenance down time and exposure.

The proposed rule will allow for the use of disposable high efficiency particulate air (HEPA) filter respirators and thus, a wider variety of respiratory protection devices will be available to the industry to provide more flexibility in their uses. This type of equipment usually has less impact on worker efficiency than full face particulate air respirators and could reduce the cost of respiratory equipment significantly.

Overall exposures (total effective dose equivalent) should be reduced as a result of this rulemaking. This will be due to the increased flexibility in the use of respirators. Furthermore, efficiency and costs of facility activities such as maintenance may be reduced through increased worker stay times and productivity. After the initial costs of revising programs have been absorbed, actual costs should be reduced. Respirator use will likely be reduced, thus reducing the cost of the respiratory protection program itself.

The chief benefit to the NRC will be the carrying out of the NRC mission. The NRC will experience rulemaking costs, inspection costs, and laboratory support costs. NRC exposures are expected to be unchanged. Resources needed to support this rulemaking are expected to be staff time and travel, contractor costs, and recordkeeping.

NRC STAFF RESOURCES AND TIMETABLE FOR THE RULEMAKING

It is estimated that 1.0 staff years of effort by RES over a 2-year period will be needed for the rulemaking.

Timetable:

Proposed rule for Office Review	Date of EDO approval + 6 months
Proposed rule to EDO	Date of EDO approval + 9 months
Final rule published	Date of EDO approval + 24 months
The priority of the rulemaking:	Routine.

This rulemaking should result in lower overall doses through minimization of the total effective dose equivalent, and lower cost to licensees and reduced equipment down time due to reduced dependence on respirators and the use of new, more efficient equipment and techniques.

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