

April 13, 1998

FOR: The Commissioners

FROM: L. Joseph Callan, Executive Director for Operations /s/

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

PURPOSE:

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

BACKGROUND:

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

DISCUSSION:

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

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

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

The proposed amendments include the following:

1. The proposed revision would clarify that a respiratory protection program is required if a licensee issues respiratory protection equipment to limit the intake of radioactive material. Some licensees have misunderstood the intent of the existing rule and believe that a respiratory protection program is needed only if the licensee "takes credit" for the use of respirators in estimating dose.
2. The proposed rule would make extensive changes to Appendix A to 10 CFR Part 20. Appendix A lists the respirator types considered acceptable by the NRC and lists the Protection Factors (PFs) (i.e. approved measures of respirator effectiveness). The current list is out of date, some new and effective devices are not recognized in the Appendix, and many of the PFs are no longer correct. The major changes to Appendix A, discussed in more detail in the Federal Register notice, are listed here.
 - Several footnotes that contain general programmatic requirements are moved to the body of the rule. Several are deleted because they are considered to be redundant with the NIOSH certification requirement.
 - Several devices, such as single-use disposable and air-supplied suits, are now recognized as being useful in respiratory protection and are listed with no APFs to provide licensees with greater flexibility in selecting respirators when limiting the intake of radioactive material is not the primary concern.
 - Several Protection Factors (PFs) are revised to be consistent with the new ANSI guidance.
3. The proposed rule would specify the "fit factors" that licensees need to achieve in fit tests in order to apply the "assigned protection factors" specified for different types of devices pursuant to ANSI guidance. The proposed rule would also specify the frequency of fit testing. The NRC staff is proposing a retest frequency not to exceed 3 years. This differs from the ANSI recommendation for annual fit testing. The staff believes that the relaxation of the frequency of fit testing would contribute a significant cost savings with no reduction in worker health and safety. The regulatory guide accompanying this rulemaking will elaborate on the physiological changes such as weight loss, facial changes, and other conditions in certain individuals that might suggest that more frequent fit testing should be done.
4. The proposed revision would delete the current requirement for licensees to issue a written policy statement on respiratory protection because the staff believes that all of the essential elements currently addressed by a policy statement are already addressed in required written licensee procedures. This change would result in some burden reduction.
5. The proposed revision would delete a requirement that a licensee notify in writing the director of the NRC Regional Office 30 days before the date that respiratory protection is first used. The only purpose of this notification was to alert inspectors of the need to look at a licensee's respiratory

protection program. This requirement contributes little to worker safety. This change would result in a minor burden reduction.

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

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

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

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

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

RESOURCES:

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

COORDINATION:

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

RECOMMENDATION:

That the Commission:

1. Approve the notice of proposed rulemaking for publication ([Attachment 1](#)).
2. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. NOTE:
 1. The rulemaking would be published in the Federal Register for a 75-day public comment period;
 2. A draft Regulatory Analysis will be available in the Public Document Room ([Attachment 3](#));
 3. A draft Environmental Assessment and a finding of no significant impact have been prepared ([Attachment 4](#));
 4. 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;
 5. The appropriate Congressional committees will be informed ([Attachment 5](#));
 6. A public announcement will be issued ([Attachment 6](#)); and
 7. Copies of the Federal Register notice of proposed rulemaking and the draft Regulatory Guide will be distributed to all Commission licensees likely to use respiratory protection and each Agreement State. The notice will be sent to other interested parties upon request.

L. Joseph Callan
Executive Director for Operations

Attachments:

1. [Federal Register Notice](#)
2. [Regulatory Guide 8.15](#)

3. Regulatory Analysis
4. Environmental Assessment
5. Congressional Letters
6. Public Announcement

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

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

ATTACHMENT 5

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

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a Public Announcement and a proposed amendment to 10 CFR Part 20 dealing with respiratory protection and other controls to restrict internal exposure of workers. The proposed amendment will be published in the Federal Register for a 75-day public comment period.

These amendments are based on guidance developed by the American National Standards Institute. These amendments will provide greater assurances that recent technological advances in respiratory protection equipment and procedures are reflected in NRC regulations, and that worker's exposures will be maintained as low as is reasonably achievable.

The proposed rules redefine the level of adequate protection, establish a less prescriptive framework and are estimated to reduce licensee burden by about \$2 million per year with no reduction in worker health or safety.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Federal Register Notice

cc: Representative Ralph Hall

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

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Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Federal Register Notice

cc: Senator Bob Graham