SECY-99-207

August 5, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

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

PURPOSE:

To obtain the Commission's approval to publish a final rule in the Federal Register that amends 10 CFR Part 20. The amendments recognize new respiratory protection devices and procedures that have been proven effective, adopt new national consensus standards from the American National Standards Institute (ANSI), conform NRC requirements to new Occupational Safety and Health Administration (OSHA EXIT) regulations, reduce licensee burden without reducing worker safety, and are consistent with the Commission's intent to promulgate performance-based rules.

BACKGROUND:

On May 21, 1991 (56 FR 23360), the Nuclear Regulatory Commission (NRC), published a major revision of 10 CFR Part 20 that included 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 has not made substantive changes to its regulation for 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," became available and provided the primary technical basis for the proposed rulemaking published for public comment in July of 1998.

Eighteen letters of public comment were received on the proposed rule and eight letters of comment on the draft revision of Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." Section II of the attached Federal Register Notice discusses how the public comments were resolved by the NRC staff.

DISCUSSION:

This revision to the respiratory protection requirements contained in Part 20 reaffirms the Commission's intent 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 final 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 and to conform to new regulations publishing by OSHA. The changes are believed by the staff to be a reduction of unnecessary regulatory burden that may save NRC licensees an estimated 1.5 million dollars per year. The rule is considerably less prescriptive while the staff believes that it will result in a reduction in risk to worker health and safety.

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

1. The rule clarifies 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 rule makes extensive changes to Appendix A to 10 CFR Part 20. Appendix A lists the respirator types considered acceptable by the NRC and lists the Assigned Protection Factors (APFs) (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 APFs 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 National Institute of Occupational Safety and Health (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 APFs are revised to be consistent with the new ANSI guidance.

3. The rule specifies the "fit factors" that licensees need to achieve in fit tests in order to apply the APFs specified for different types of devices pursuant to ANSI guidance and to be consistent with OSHA. The rule also specifies the frequency of fit testing. The NRC staff is retaining a requirement for a retest frequency not to exceed 1 year. The proposed rule had specified a retest frequency not to exceed 3 years. Several public commenters had objected to this proposal and recent OSHA regulations retained the one year retest frequency. The NRC staff decided not to change the currently required annual retest.

4. The rule deletes the current requirement for licensees to issue a written policy statement on respiratory protection because the staff believes that all of the essential elements addressed by a policy statement are already addressed in required written licensee procedures. This change results in some reduction of unnecessary burden.

5. The rule deletes 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 results in a minor reduction of unnecessary burden.

The NRC staff believes that the 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 are clearer and better organized and thus easier to implement, and when implemented, will make worker protection more effective.

A Regulatory Analysis (Attachment 2) 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 1.5 million dollars per year will result from the rule changes. The cost savings are found to result from 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 3) was performed and concluded that the 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.

Although the net effect of the rule amendments is a reduction in burden, changes in licensee procedures would be required, constituting a backfit. However, because the rule amendments incorporate national consensus standard (ANSI) recommendations that are worker safety related, the NRC staff believes that this rulemaking is justified as a cost-beneficial safety enhancement.

RESOURCES:

Resources to complete this rulemaking are included in the current budget. No additional resources are required for implementation; in fact, minimal NRC resource savings are expected (<0.5 FTE per fiscal year).

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 final rule for information technology and information management implications and concurs in it. The Office of Information Resources Management has determined that the 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. The Advisory Committee on Reactor Safeguards has no objection to issuing this rule for industry use.

RECOMMENDATION:

That the Commission:

1. Approve the notice of final 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 to become effective 120 days after publication;

    2. A Regulatory Analysis will be available in the Public Document Room (Attachment 2);

    3. An Environmental Assessment and a finding of no significant impact have been prepared (Attachment 3);

    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 4);

6. A press release will be issued (Attachment 6); and

7. Copies of the Federal Register notice of final rulemaking and the Regulatory Guide revision 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.

William D. Travers
Executive Director for Operations

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

Attachments:
1. Federal Register Notice
2. Regulatory Analysis
3. Environmental Assessment
4. Congressional Letters
5. Congressional Review Act Forms
6. Press Release

ATTACHMENT 3

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT ON AMENDMENTS OF 10 CFR PART 20, SECTION 20.1003, 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

February, 1999

I. The Action

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

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

II. Need for the Rulemaking Action

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

III. Alternatives Considered

The following alternatives to rulemaking have been considered.

ALTERNATIVE 1: NO ACTION

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

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

ALTERNATIVE 2: REVISE REGULATORY GUIDANCE ONLY
Regulatory guides are intended to assist licensees with complying with regulatory requirements. Several elements of a respiratory protection program are significant health and safety issues and as such need to be codified as requirements. Regulatory guides do not establish requirements.

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

IV. Environmental Impacts of the Proposed Action and the Alternatives

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

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

V. Finding of No Significant Environmental Impact

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments are not a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

The Commission believes that these amendments would result in benefits to workers, flexibility to licensees and would continue to adequately protect public health and safety. There will be no change in radiation exposure to the public or to the environment due to the proposed rule changes.

VI. List of Agencies and Persons Consulted

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

K. Paul Steinmeyer, Radiation Safety Associates, Inc.
Robert daRosa, Lawrence Livermore Laboratory, (Retired)

ATTACHMENT 4

The Honorable Joe L. Barton
Chairman, Subcommittee on Energy
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 Press Release and a final amendment to 10 CFR Part 20 dealing with respiratory protection and other controls to restrict internal exposure of radiation workers. The amendment will be published in the Federal Register. The new rules will become effective 120 days from the date of publication.

These amendments are based on guidance developed by the American National Standards Institute and are consistent with new respiratory protection regulations published recently by the Occupational Safety and Health Administration (OSHA). These amendments provide greater assurance 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 rules enhance worker protection, establish a less prescriptive framework and are estimated to reduce unnecessary licensee burden by about $1.5 million per year with no reduction in worker health or safety. The Commission's rule is consistent with the general mandate of the Technology Transfer and Advancement Act of 1995 (Public Law 104-113) to utilize consensus standards.

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

Enclosures: 1. Federal Register Notice

2. Press Release

cc: Representative Ralph M. 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
Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a Press Release and a final amendment to 10 CFR Part 20 dealing with respiratory protection and other controls to restrict internal exposure of radiation workers. The amendment will be published in the Federal Register. The new rules will become effective 120 days from the date of publication.

These amendments are based on guidance developed by the American National Standards Institute and are consistent with new respiratory protection regulations published recently by the Occupational Safety and Health Administration (OSHA). These amendments provide greater assurance 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.

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

Enclosures: 1. Federal Register Notice
2. Press Release

cc: Senator Bob Graham

ATTACHMENT 6

NRC ISSUES FINAL REVISIONS TO REGULATIONS ON RESPIRATORY PROTECTION

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

The revised rules provide greater assurance that workers' radiation exposures will be maintained as low as is reasonably achievable and approve for licensee use advances in respiratory protection equipment and procedures. The new rules are more performance based, more flexible and easier to implement. The NRC believes the new rules will save licensees about $1.5 million per year, with no reduction in worker health and safety.

When the Commission's overall radiation protection regulations were significantly revised in 1992, the rules for respiratory protection were not similarly revised because the American National Standards Institute (ANSI) was working on consensus guidance in this area. The ANSI guidance, "American National Standard Practice for Respiratory Protection," is now available and is essentially the technical basis for this rule. The Commission's rule is consistent with the general mandate of the Technology Transfer and Advancement Act of 1995 (Public Law 104-113) to utilize consensus standards. The new rules are also consistent with new respiratory protection regulations published recently by the Occupational Safety and Health Administration (OSHA).

The changes emphasize the use of process or engineering controls, decontamination of work areas, access controls, and other procedures instead of the use of respiratory protection devices, which tend to increase external radiation doses and worker stress.

The rules also recognize new respiratory protection devices that have been proven effective, discourage the use of other devices that are now considered less effective based on field tests, and revise requirements for respiratory protection procedures such as testing to evaluate the fit of a respirator on a particular individual.

The rules also revise the "assigned protection factors" --expected workplace levels of respiratory protection that would be provided to properly fitted and trained users by properly functioning respirators--to be consistent with ANSI evaluations.

Further details of the final rules are contained in a Federal Register notice to be published shortly.