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

December 31, 1996

MEMORANDUM TO: Bill M. Morris, Director
Division of Regulatory Applications
Office of Nuclear Regulatory Research

THRU: Cheryl A. Trottier, Acting Chief
Radiation Protection and Health Effects Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

FROM: Alan K. Roecklein
Health Physics Section
Radiation Protection and Health Effects Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

SUBJECT: RESPIRATORY PROTECTION RULEMAKING

Following a meeting with Division Directors and Staff of the user offices to discuss the subject rulemaking, you raised three questions. They were:

1. Could the staff find any official authorization to work on the rule from the Commission or the EDO?

2. Can we estimate the frequency of changes to types of approved respirators or Assigned Protection Factors?

3. What is OGC's view regarding whether licensees can use disposable respirators under current rule?

Regarding question 1 , Attachment A is an Initiation of Rulemaking submitted by C. Raddatz on January 1, 1992 and concurred in through the Branch Chief, D. Cool. The package was submitted to N. Costanzi on January 17, 1992. At that time, I believe the burden reduction rulemaking on reducing frequency of medical examination was separated out from the subject Subpart H Rulemaking and the Initiation of Rulemaking was presumably held at the division level pending completion of the frequency of exam rulemaking.

Attachment B is an excerpt from the National Performance Assessment Report, SECY-95-123, concurred in by the EDO on May 15, 1995 and submitted to the Commission. The report recommends updating Subpart H and associated guidance. However, in SECY-96-176, the proposed rulemaking activity plan lists Revision of Respiratory Protection Requirements as Category III, Rules being Planned, even though the staff had been working on the rule and Regulatory Guide (RG) since 1992, and a draft rulemaking package and revised Regulatory Guide had been submitted to the Branch Chief in March of 1996.

There is no record of EDO or Commission specific approval of completing the Subpart H Revision. There is ample record of staff assignments to C. Raddatz and later A. Roecklein to develop a proposed rule, a revised RG 8.15 and NUREG-0041.

Regarding question 2, In the meeting, you asked about the frequency of new changes in respiratory types and/or APFs. This frequency might determine whether or not Appendix A should remain in the regulations or be placed in RG 8.15. If designs or APFs are changed frequently, then Appendix A should be in RG 8.15 to reduce costs of changes.

- When ANSI Z-88.2 was published in 1992, Appendix A information had been in effect for 16 years. The availability of RG 8.15 including a table of approved respiratory protection devices and associated protection factors was noticed in the Federal Register in 1976. Appendix A information was incorporated by reference into the regulations as part of RG 8.15 in 1981 and then put into the regulations as Appendix A in 1982.

- ANSI Standards are reviewed every 5 years, but often not changed as a result of the review. Assuming that every other review might result in need for change, and that a revision takes about 3 years to complete, we would expect the frequency of revision to be from 10 to 15 years.

- A wide range of reasonably priced respirator types is currently available utilizing the latest materials and designs. Currently recommended APFs are reliable under field conditions and are conservative. Thus, there would not seem to be a need for major changes in types or APFs in the immediate future.

- The use of respirators has decreased in recent years because of the TEDE/ALARA requirement. Thus, there is less need or incentive to produce new, unapproved design.

Regarding question 3, Attachment C is a response to the question from S. Treby to B. Morris, dated December 23, 1996. OGC view is that because certain procedural requirements (field test and fit test) needed in order to currently use respirators to limit intake cannot be done with disposables then licensees cannot currently use them.

Attachments: A. Memo to J. Taylor, no date
B. Regulation Review, SECY 95-123
dtd, May 15, 1995
C. Memo to B. Morris, dtd December 23, 1996

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OFFICE:	DRA/RPHEB*		DRA/RPHEB		D/DRA/RES			
NAME:	AKRoecklin;nb		CTrottier		BMorris			
DATE:	12/31/96		12/31/96		1/ /97			

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- When ANSI Z-88.2 was published in 1992, Appendix A information had been in effect for 16 years. The availability of RG 8.15 including a table of approved respiratory protection devices and associated protection factors was noticed in the Federal Register in 1976. Appendix A information was incorporated by reference into the regulations as part of RG 8.15 in 1981 and then put into the regulations as Appendix A in 1982.

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- When ANSI Z-88.2 was published in 1992, Appendix A information had been in effect for 16 years. The availability of RG 8.15 including a table of approved respiratory protection devices and associated protection factors was noticed in the Federal Register in 1976. Appendix A information was incorporated by reference into the regulations as part of RG 8.15 in 1981 and then put into the regulations as Appendix A in 1982.

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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.

AGENCY CONTACT:
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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.

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.

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Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

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

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*See previous concurrences

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SECY-95-123
May 15, 1995

REGULATION REVIEWED

10 CFR Part 20, Standards for Protection Against Radiation

FINDINGS:

Part 20 defines the basic radiation protection standards for all licensees. It provides the basis for consistency in evaluating and documenting exposures for workers who work for licensees and DOE and DOE prime contractors and serves as a model for State regulation of radioactive materials not covered by the Atomic Energy Act (AEA). Limits for occupational exposures and exposures of members of the public and requirements for activities to ensure compliance with the limits and maintaining doses and releases as low as reasonably achievable (ALARA) are established.

Part 20 is a mixture of performance and prescriptive requirements. For the basic standards, licensees may use prescriptive (Tables) or performance (i.e. dose limit) based requirements. Other aspects may be performance based or prescriptive (e.g., adequate surveys to... versus prescriptive reporting requirements.) Based on a recent regulatory impact survey of fuel cycle and materials licensees and feedback from the utilities, the revised Part 20 is not unnecessarily burdensome, overly prescriptive, or inefficient. The improvements in safety, consistency with international standards, and flexibility were mentioned by licensees. Some individuals and licensee categories disagreed. Increased safety benefits were considered to outweigh the increased burden by the majority of respondents.

Part 20 was revised in its entirety in May 1991. At that time, the following areas were identified in the final rule notice as issues being resolved separately: de minimis dose levels, residual contamination levels for decommissioning, localized skin doses due to hot particles, incident notification, and large irradiators. Also, the more detailed aspects of Subpart H on respiratory protection were not updated, in part due to new industry standards under development.

In addition, because the May 1991 revision of Part 20 was so basic and extensive, a number of clarifying rulemakings have been completed, identified, planned as resources permit, or are underway. These include two actions to clarify relationships to 10 CFR Part 35, wrong patient rule and patient release and amended definitions.

Attachment B

RECOMMENDATION:

To further update and clarify Part 20, the following new rulemakings are recommended:

(a) Relegation of Appendix B to guidance should be examined. Appendix B, is the longest and most prescriptive provision of Part 20 and involves calculations where the state-of-the-art is continually evolving. Relegation to Regulatory Guide status would provide more flexibility to reflect current science with no loss in safety; however, codification provides stability and these competing factors would have to be assessed. Appendix B is convenient for small or less experienced licensees. Only use of Table 3 for sewer releases is mandatory. (Use of Tables 1 and 2 are one of two ways of demonstrating compliance with the occupational and public dose limits, respectively.)

(b) In section 20.2104, paragraphs (a)(2), (c)(2), (d) and (f) require licensees to make best efforts to determine prior occupational dose and use NRC Form 4, to record prior doses for all workers for whom monitoring is required. Determination of prior dose is clearly warranted for cases of Planned Special Exposures and use of NRC Form 4 is useful for this determination, but requiring determination of prior doses for all workers on Form 4 is a burden that could be examined as a potential relief.

(c) Revision of Subpart H will clarify and correct 17 provisions, eliminate 11 provisions (3 of which duplicate other agency rules), add 3 provisions to reflect current industry standards, and add flexibility to reflect state-of-the-art equipment.

(d) Corrections related to recordkeeping and notification. These corrections will 1) restore mistakenly deleted recordkeeping requirements for documents needed for decomissioning and 2) eliminate duplicate reporting to Regional Offices and the Operations Center.

IMPLEMENTATION:

Updating Subpart H on respiratory protection is a minor rulemaking, but involves updating guidance also (two year goal). Appendix B revision or deletion, package procedures, and FORM 4 would each likely be minor also, depending on comments. Changes to recordkeeping and notification will take 2 years.

POLICY ISSUE

(NEGATIVE CONSENT)

SECY-96-176

August 8, 1996

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING ACTIVITY PLAN

PURPOSE:

The purpose of this Commission paper is to provide for Commission review the staff's proposed Rulemaking Activity Plan (RAP), (Attachment 2). The RAP includes descriptions of rules under the direction of the EDO that are currently actively being conducted and those that are being considered for future action. This process is intended to assure that the staff incorporates Commission policy input to contemplated rulemakings at an early stage of rule plan development, before significant resources are expended. It further will provide a mechanism to determine whether previously initiated rules should continue, be redirected or be terminated. Finally, the "Rulemaking Activity Plan" includes priorities for all ongoing and planned rules to allow effective allocation of resources in a manner consistent with Commission policy.

BACKGROUND:

In a Commission Staff Requirement Memorandum (SRM) of April 7, 1995, on the status of ongoing regulatory reform initiatives, the Commission directed the staff to (1) establish a process to review and prioritize rulemaking efforts on a continuing basis and (2) pay particular attention to how rulemaking efforts receive staff approval for initiation. The Commission asked that the staff identify all rulemakings currently under development or being contemplated and, based on safety benefit and cost, make a recommendation on the need for continuing the rulemaking process, and to submit this information

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

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the procedural process, approved by the Commission's SRM dated June 11, 1996, that would be followed when processing a rulemaking action that could affect Agreement States.

Regulatory Improvement In Granting Generic Exemptions From Regulations

A Commission paper on "Planning For Pursuing Regulatory Improvement In The Area Of Exemptions Granted To Regulations," was sent to the Commission, SECY-96-147, for approval on July 2, 1996 and was approved in an SRM dated August 1, 1996. This paper identified eleven rulemaking actions that will reduce the need for granting recurring exemptions. These rulemakings have now been incorporated into the current "Rulemaking Activity Plan" (ten were incorporated as new rulemakings and one was incorporated into an ongoing rulemaking action).

Potential Rulemaking Actions Still Under Review

The staff submitted the results of the "National Performance Review Phase II" regulations review study to the Commission in SECY-95-123, dated May 15, 1995. In this Commission paper, the staff provided information on 16 new candidate rulemakings (see Attachment 3) that resulted from the regulations review. For four of these rulemakings, legislative action will be necessary before the rulemakings can be initiated. OGC has the lead for the development of proposals for the needed legislation and will forward an appropriate proposal to the Commission for submission to the next Congress. Five of the 16 rulemakings have previously been included in the plan and four others have been included in this RAP as new rulemakings. For the three remaining potential rulemakings, the staff is continuing to determine whether these can effectively be combined with previously identified rulemaking actions already contained in the plan.

Finally, activities currently underway that could have an impact on our rulemaking planning are the results from the NAS report, "Radiation In Medicine: A Need for Regulatory Reform" and the NMSS effort on Business Process Reengineering and will be reflected in future plan updates as appropriate.

CATEGORY II- TECHNICAL BASIS UNDER DEVELOPMENT

HIGHER PRIORITY

MEDIUM PRIORITY

LOWER PRIORITY

CATEGORY III, RULES AND PETITIONS BEING PLANNED

HIGHER PRIORITY

CATEGORY III- RULES BEING PLANNED

RULES (INCLUDING PETITIONS) THAT ARE JUDGED TO BE NEEDED BASED ON PRELIMINARY ASSESSMENT BY USER OFFICE BUT MUST BE PROCESSED THROUGH NEW PLANNING PROCESS (MANAGEMENT DIRECTIVE 6.3) FOR EDO REVIEW AND APPROVAL.

HIGHER PRIORITY

RES-C3HP-04 Amend Certification of Compliance NO.72-1007 For The VSC-24 Dry Spent Fuel Storage Cask, Part 72.214--RM#390

OBJECTIVE-- The proposed rulemaking would revise the Commission regulations to add the modified VSC-24 dry spent fuel storage cask to Part 72.214 so that holders of operating power reactors can use this cask under a general license. Otherwise holders of power reactor operating licenses would have to obtain a specific license in order to use this cask. The modified cask will store spent fuel with control components. The currently approved VSC-24 cask cannot store spent fuel with control components.

TYPE-- BURDEN REDUCTION/REGULATORY REFORM/ADDS FLEXIBILITY

COST/BENEFIT-- The net benefit of the rule to the NRC is that the modified cask would have to be approved only once for use by a number of licensees. If a specific license would be required, the NRC would have to review each license application. For licensees, the rule would provide another option for the storage of spent fuel under the provisions of a general license.

Recommendation to Proceed-- Yes Pending approval using Management Directive 6.3 process, the staff believes that the rulemaking should proceed. The certification process for dry spent fuel storage cask designs has been codified under Part 72 pursuant to the Waste Policy Act. Accordingly it is expected that this rulemaking amendment will proceed because it will further streamline the cask licensing process.

RES-C3HP-05 Revision of Respiratory Protection Requirements, Part 20--RM#269

OBJECTIVE-- The proposed rulemaking would update the Commission regulations by permitting the use of the most current technology to provide respiratory protection. In particular, Appendix A to Part 20, which lists protection factors and certified equipment, does not reflect the current technology or the best practice. The elimination of outdated prescriptive requirements will not introduce new requirements but will reduce licensees burden by providing greater flexibility.

TYPE-- BURDEN REDUCTION/REGULATORY REFORM/ADDS FLEXIBILITY

COST/BENEFIT-- To be provided using Management Directive 6.3 process.

Recommendation to Proceed-- Yes Pending approval using Management Directive 6.3 process, the staff believes that the rulemaking should proceed.

RES-C3HP-06 Extremity Dosimetry--RM#146--W#870013

OBJECTIVE-- Commission SRM on SECY-86-360 dated 01/21/87 approved rulemaking to amend 10 CFR Part 20 to require the use of Accredited Personnel Dosimetry Processors (for whole body dosimeters). The Commission also agreed that the rule should be applied to extremity monitors as soon as a suitable performance standard became available.

Whole body dosimetry processing is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP), operated by the National Institute of Standards and Technology (NIST) formerly (NBS), and has been in official operation since February 1988. The testing laboratory utilized by NIST for this work is Battelle Pacific Northwest Laboratories (PNL) at Richland, Washington.

A draft performance standard for extremity dosimeters (HPSSC P/N 13.32) was prepared in June, 1986 by the Health Physics Society at the request of the NRC and has been used for performance testing of extremity dosimeters at PNL under contracts issued by the NRC. As a result of this testing, documented in NRC publications NUREG/CR-4959 (1987), NUREG/CR-5540 (1990) and NUREG/CR-5989 (1993), modifications were made to the draft standard, and a final standard ANSI N13.32 is expected to be published in fiscal year 1996. A final rule will be published approximately two years after its publication.

TYPE-- SAFETY ENHANCEMENT

COST/BENEFIT-- Implementation of the final rule will begin within six months of publication. Essentially all licensees subject to NVLAP accreditation of extremity dosimeters will be from among the group of licensees that are now subject to NVLAP accreditation for whole body dosimeters. At present 72 licensees are participating in the whole body program and it is estimated that approximately 30 of these will enter the extremity dosimetry program as soon as it becomes available. Based on an estimated participation in 3 of the 4 categories offered, there will be a biennial cost of approximately $3.2K per licensee for the extremity dosimeter testing and administrative fees, plus an additional one-time inspection and assessment fee of $2K for those licensees who choose to initiate the extremity accreditation at a time other than that scheduled for their biennial whole body NVLAP inspection and assessment. This latter fee will not be assessed on those licensees that merge their extremity testing program into the same time frame used for the whole body testing program.

LIST OF CANDIDATE RULEMAKINGS IDENTIFIED BY THE NPR REVIEW

1. Statement of Organization and General Information, Part 1 (legislation Needed)
2. Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders, Part 2
3. Standards for Protection Against Radiation, Part 20
4. Fitness-for-Duty Programs, Part 26
5. General Domestic Licenses for Byproduct Material, Part 31
6. Specific Domestic Licenses to Manufacture and Transfer Certain Items Containing Byproduct Material
7. Medical Use of Byproduct Material, Part 35
8. Domestic Licensing of Source Material, Part 40
9. Information requested by the Attorney General for Antitrust Review, Part 50 (§50.33a) (legislation Needed)
10. Additional TMI-Related Requirements, Part (§50.34(f))
11. Appendices M, N, O and Q, Part 50
12. Criteria and procedures for Determining the Adequacy of Available Spent Nuclear Fuel Storage Capacity, Part 53
13. Operators' Licenses, part 55
14. Physical Protection of Plants and Materials, Part 73
15. Continued Commission Authority Pertaining to Byproduct Material, Part 150 (legislation Needed)
16. 10 CFR Parts 170 and 171 (legislation Needed)

ATTACHMENT 3

Action: Morrison, RES

OFFICE OF THE
SECRETARY

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

October 9, 1996

Cys: Taylor
Milhoan
Thompson
Blaha
Paperiello, NMSS
Miraglia, NRR
Norry, ADM
Riana, RES

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-96-176 - PROPOSED RULEMAKING ACTIVITY PLAN

This is to advise you that the Commission has not objected to the staff continuing with implementation of the Rulemaking Activity Plan as provided in Attachment 2 to the subject paper except as noted below.

9500048

While the Commission does not object to moving forward with the rulemaking plan to shorten or eliminate the 30-day period in loading spent fuel after preoperational testing (RES-C3HP-10), it was noted that continued vigilance is needed in the development of staff and industry guidance in the area of dry cask storage. Specific emphasis should be placed on assuring that loading and unloading procedures for both normal and abnormal occurrences are in place and appropriate.

Since the Commission has approved the final rule changes to 10 CFR Part 35 involving, among other things, radiation therapy patient confinement (SECY-96-100), the NRC should be in a position to address PRM-20-24 without further delay. The staff should modify the Proposed Rulemaking Activity Plan with regard to PRM-20-24 and proceed to act on that petition for rulemaking.

In regard to the dry cask storage issue, the staff should continue to provide extensive oversight presence during preoperational testing to examine acceptance criteria and test results in real time.

SECY NOTE: THIS SRM AND SECY-96-176 WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

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

OFFICE OF THE
GENERAL COUNSEL

December 23, 1996

MEMORANDUM TO: Bill A. Morris, Director
Division of Regulatory Applications
Office of Research

FROM: Stuart A. Treby
Assistant General Counsel for
Rulemaking and Fuel Cycle

SUBJECT: REQUESTED INTERPRETATION WHETHER PART 20 PERMITS LICENSEES TO ISSUE DISPOSABLE OR REUSABLE/DISPOSABLE RESPIRATORY PROTECTION DEVICES

You have requested an OGC interpretation[1] concerning whether 10 C.F.R. Part 20 regulations would permit NRC licensees to use disposable respiratory or reusable/disposable respiratory protection devices. However, our analysis cannot reach a definitive conclusion by pure legal interpretation, but depends also upon input from knowledgeable NRC technical staff regarding actual practical performance of the equipment in question in order to reach a conclusion. Using the information we have received from the technical staff about the actual performance of this equipment, we would conclude that the use of disposable respiratory protection equipment would not be permitted by current regulations, as explained below.

The pertinent regulations are contained in Subpart H of 10 C.F.R. Part 20, entitled "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas". Section 20.1702 provides that if it is not practical to apply process or engineering controls

CONTACT: Kathryn Winsberg, OGC
415-1641

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[1] The Commission's regulations authorize the General Counsel to issue formal, written interpretations of laws, regulations, and other sources of authority or guidance, which are recognized as binding on the Commission. Following issuance, these interpretations are codified in 10 C.F.R. Part 8 of the Commission's regulations. However, the General Counsel exercises this authority very sparingly and only in instances involving major policy or legal questions. Accordingly, the views in this memorandum do not constitute a formal interpretation.

NOTE: ATTORNEY-CLIENT INFORMATION
LIMITED TO THE NRC UNLESS THE COMMISSION DETERMINES OTHERWISE

Attachment C.

to reduce concentration of radioactive materials below the limit defining an airborne radioactivity area, the licensee must maintain the total effective dose ALARA, increase monitoring, and limit intakes by methods that may include use of respiratory equipment.

Section 20.1703(a) further provides that if the licensee uses respiratory protection to limit intakes pursuant to § 20.1702, certain specified requirements apply. The statement of consideration for this rule clearly states that § 2.1703(a) is meant to apply when respiratory protection equipment is used to limit intakes of radioactive materials[2], regardless of whether the licensee intends to take credit for a respiratory protection factor in estimating exposure. Therefore, the fact that there is currently no assigned protection factor for disposable respiratory protection equipment would not by itself preclude either the use of disposable respiratory protection equipment or the applicability of the other requirements stated in § 2.1703(a).

Section 1703(a)(1) states that the licensee "shall only use respiratory protection equipment that is tested and certified, or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA). NRC technical staff inform us that the disposable respiratory equipment does meet this requirement. (Section 1703(a)(2), which provides an alternative method for submitting test information for equipment which has not been tested or certified by NIOSH/MSHA, therefore would not be necessary for this equipment).

Section 1703(a)(3) requires a licensee to implement a respiratory protection program including five specified elements: i) air sampling; ii) surveys and bioassays; iii) testing of equipment for operability immediately prior to each use; iv) written procedures regarding selection, fitting, issuance, maintenance and testing of respirators including testing for operability immediately prior to each use, supervision and training, monitoring and recordkeeping; v) determination by physician of physical fitness to use respiratory protection equipment. According to the technical staff, it is impossible for licensees to comply with requirements (iii) and (iv) regarding operability testing prior to each use and written procedures for such operability testing, with regard to disposable respiratory protection equipment. The nature of the design of this equipment does not allow the operability tests to be conducted. (For example, there may not be segregated outlet and inlet ports to be blocked to test the seal because the whole mask allows air in and out). Therefore, licensees would be in violation of this regulatory requirement if they used this disposable respiratory protection equipment and did not perform operability testing prior to each use, nor have a written procedure for such testing.

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[2] However, note that if the equipment is being used exclusively for non-radiological protection (where there are no airborne radiological hazards), this regulation would not be applicable to such use.

The technical staff has advised us that the use of disposable respiratory protection equipment would not be precluded by the requirement in § 20.1703(a)(4) for a written policy statement, the requirement in § 20.1703(a)(5) for advice to respirator users, or by the requirement in § 20.1703(a)(6) for use of equipment within limitations for type and mode of use.

In conclusion, as discussed above, we believe that the use of disposable respiratory equipment would not be permitted under the current regulations because of the inability to comply with the requirements of §§20.1703(a)(3)(iii) and (iv) for operability testing prior to each use.

cc: A. Roecklein
S. Sherbini
J. Wigginton