→ Cindy. RAD

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

April 2, 1999

MEMORANDUM TO: David B. Mathews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

FROM: Valeria H. Wilson, Director
Division of Administrative Services
Office of Administration

SUBJECT: OFFICE CONCURRENCE ON THE FINAL RULE ENTITLED "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES"

The Office of Administration (ADM) concurs on the final rule that amends the regulations governing respiratory protection and provides controls to restrict internal exposures. We have attached a marked copy of the proposed rule package that presents our comments.

The National Technology Transfer and Advancement Act of 1995 establishes additional requirements relating to the use of consensus standards in rulemaking. Please instruct your staff to contact the NRC Standards Executive, John Craig (D:DET/RES), for assistance in complying with the Act.

When your staff prepares the list of documents relevant to this final rule that is required by NRC's regulatory history procedures, please instruct them to place the designator "AF81-2" in the upper right-hand corner of each document concerning the final rule that is forwarded to the Nuclear Documents System.

If you have any questions concerning this matter, please have a member of your staff contact David L. Meyer, Chief, Rules and Directives Branch, at 415-7162 (DLM1) or Michael T. Lesar, ADM, at 415-7163 (MTL).

Attachment: As stated

cc: G. Millman, RES

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

April 7, 1999

MEMORANDUM TO: David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

FROM: Paul H. Lohaus, Director
Office of State Programs

SUBJECT: OSP COMMENTS ON FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20," AND REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION"

We have reviewed and concur in the final rulemaking package including the Federal Register notice for the amendment to Subpart H (respiratory protection rule) of Part 20 and the final revision of Regulatory Guide 8.15. As a result of our review, we suggest the changes noted below.

1. In paragraphs two and six of the Commission Paper, change "1.5 million per year" to read "1.5 million dollars per year."

2. In section IV, Issues of Compatibility for Agreement States, of the Federal Register notice, our suggested changes are indicated in the following redline/strikeout format.

> In accordance with the ~~new~~ Policy Statement on Adequacy and Compatibility of Agreement State Programs ~~policy~~ published September 3, 1997(62 FR 46517) and implementing procedures, ~~approved by the Commission on June 30, 1997~~, the proposed modifications to § 20.1701 through § 20.1703 (except 20.1703(c)(4)), ~~and § 20.1705~~ have health and safety significance and Agreement States should adopt the essential objectives of these rule modifications. ~~in order to maintain an adequate program~~. Therefore, these provisions are assigned to the "Health and Safety (H&S)" category. The proposed definitions (added to § 20.1003), of Air Purifying respirator, Atmosphere-supplying respirator, Assigned Protection Factor (APF), Demand respirator, Disposable respirator, Fit factor, Fit test, Filtering facepiece (dust mask), Helmet, Hood, Loose-fitting facepiece, Negative pressure respirator, Positive pressure respirator, Powered air-purifying respirator, Pressure demand respirator, Qualitative fit test, Quantitative fit test, Self-contained breathing apparatus, Supplied-air respirator, Tight-fitting facepiece, and User seal check (fit check), because of ~~its~~ their precise operational meanings, ~~is~~ are designated as compatibility category ~~C~~ B to help insure effective communication and to promote a common understanding for licensees who operate in multiple jurisdictions. Therefore, Agreement States should adopt definitions that are essentially identical to those of NRC. ~~should adopt the essential objectives of this provision to avoid conflicts, duplication or gaps~~. ~~The proposed definitions of, Fit check, Fit factor and Fit test, are stated in general terms and are therefore~~

~~designated as compatibility category D, not required for purposes of compatibility~~. ~~Flexibility is also provided to States regarding~~ § 20.1703(c)(4) and § 20.1704, which address ~~in how they handle~~ requirements for written procedures, and imposition of additional restrictions on the use of respiratory protection, respectively, ~~Therefore, provisions~~ are designated as compatibility category D.

Appendix A to 10 CFR Part 20, and § 20.1705 which permits applying for the use of higher APFs on a case by case basis, are ~~is~~ designated as compatibility category B. ~~because assigned protection factors (APFs) provide acceptable levels of protection to be afforded by respirators. Additionally, although § 20.1705 permits applying for the use of higher APFs on a case by case basis~~, Consistency is required in APFs that are established as acceptable in NRC and Agreement State regulations to reduce impacts on licensees who may operate in multiple jurisdictions.

3. In section 7.3 of the Regulatory Guide, reference is made to NRC's staff position that the respirator fit test may be as long as three years. This appears contrary to the rule requirement of an annual fit test (which was changed from three years in the proposed rule due to public comments). Section 7.3 should be revised to indicate a one year requirement.

Thank you for the opportunity to comment on the rulemaking package. If you have any questions, please contact me or Tom O'Brien of my staff at 415-2308.

From: Karen Olive
To: Alan Roecklein
Date: Tue, Mar 30, 1999 4:02 PM
Subject: Re: OCFO REVIEW OF FINAL RULE: RESPIRATORY PROTECTON AND CONTROLS ....

Alan:

I presume you agreed with my FTE savings estimate based on 31.9 hours - was that correct? If so, OCFO concurrence is provided. Thanks!

Karen
>>> Alan Roecklein 03/30 3:26 PM >>>
Karen,
I have made the change to the Resource paragraph as you suggested. Thank you.
I have agreement from the offices in NRR regarding the rule.
The Reg Analysis was prepared several years ago, by a contractor to RES. The numbers used were acceptable to RES at that time.

AKR@NRC.GOV

>>> Karen Olive 03/30 3:10 PM >>>
Alan:

I've been assigned the OCFO review of the subject rulemaking SECY. I haven't read the paper in detail yet but I wanted to make sure that it has been thru the NRR budget staff - Ron Villafranco.

Depending on whether or not Ron's staff have any changes that affect resources, I am prepared to provide OCFO concurrence based on my quick read. I suggest, however, that the Resource paragraph/sentence (page 4 of the SECY) be revised to read: "Resources to complete this rulemaking are budgeted. No additional resources are required for implementation; in fact, minimal NRR resource savings are expected (<0.5 FTE)."

I do have a question about the reg analysis (Attachment 3). OCFO does not typically get involved in the preparation of the reg analysis but I did skim it. I'm curious as to the basis for the NRC labor cost of $70/hour - please advise. I quickly added up the NRC hours saved and I get a whopping 31.9 hours or $2,237 (unless I missed something). Thus, savings are expected to be minimal. Thanks!

Karen, x6027

CC: Ron Villafranco, Thomas Dietz

From: Thomas Dietz
To: Alan Roecklein, Karen Olive
Date: Wed, Mar 31, 1999 4:07 PM
Subject: Re: OCFO REVIEW OF FINAL RULE: RESPIRATORY PROTECTON AND CONTROLS ....

Karen and Alan, received copy of the final rule and the analysis. Hard to judge in such a short time whether this is accurate. Did note the package. Couple of minor questions since this was done by Res several years ago. Although the impact would be slight, why use 100 licensees as opposed to our present actual which I believe is 103. Also the analysis refers to 150 non-power licensees. Presume this number has some meaning greater than the 50 non-power licensees that NRR is involved with. Given the rise in costs over several years I would presume savings would increase by the rate of inflation over the period. Otherwise package noted and CFO has concurred.

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CC: Ron Villafranco

From: Karen Olive
To: Alan Roecklein, Thomas Dietz
Date: Wed, Mar 31, 1999 4:36 PM
Subject: Re: OCFO REVIEW OF FINAL RULE: RESPIRATORY PROTECTON AND CONTROLS ....

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CC: Ron Villafranco

From: Alan Roecklein
To: Karen Olive, Thomas Dietz
Date: Thu, Apr 1, 1999 7:09 AM
Subject: Re: OCFO REVIEW OF FINAL RULE: RESPIRATORY PROTECTON AND CONTROLS ....

The 150 non-reactor licensees is an NMSS estimate of their licensees that use respirators. The reg analysis is at best an estimate so the contractor choose to round off to 100 power plants.

AKR@NRC.GOV

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CC: Ron Villafranco

→ Cindy

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

April 2, 1999

MEMORANDUM TO: David B. Matthews, Director
Division of Regulatory
Improvement Programs, NRR

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

SUBJECT: FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20", AND REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION."

The staff of the Office of Nuclear Material Safety and Safeguards (NMSS) has reviewed the final rule on Respiratory Protection, Subpart H in 10 CFR Part 20, and NMSS concurs without comment. However, although the staff reviewed Regulatory Guide 8.15, attached to your memorandum transmitting the final rule, we choose not to comment on it at the present time. It is our understanding that the guide is still being revised, and the final version will be provided to our office for review at a later date under a separate memorandum. In the meantime, the NMSS member of the respiratory protection working group will be reviewing the guide as it is developed and will provide informal comments on behalf of this office.

Please call the technical contact if you would like additional information regarding our review.

CONTACT: Sami Sherbini, NMSS/IMNS
(301) 415-7902

→Cindy

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001
April 5, 1999

MEMORANDUM TO: David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

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

SUBJECT: FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20," AND REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION."

The Office of the General Counsel has no legal objection to the final rule package subject to the edits described in the attachment.

Attachment: As stated

cc: J. Funches
C. Paperiello
P. Lohaus
J. Lieberman
D. Meyer

COMMENTS OF THE OFFICE OF THE GENERAL COUNSEL ON FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20," AND REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION."

1) Commission paper, page 4, the first paragraph should be replaced with the following text:

> Although the net effect of the rule amendments is a reduction in burden, changes in licensee procedures would be required, potentially constituting a backfit. However, because the rule amendments are redefining the level of adequate safety regarding the use of respirators for radiation protection, this rulemaking meets one of the exceptions to the requirement for a backfit analysis listed in 10 CFR §§50.109(a)(4)(iii), 72.72(b), and 76.76(a)(4)(iii).;

2) Federal Register notice, page 4, edit first line to read: " . . .issues, this analysis will address all comments but specific commenters will not be identified.";

3) Federal Register notice, page 4, second full paragraph, second line, insert the word "radiological" after the word "worker", so that it reads " . . ., which includes worker radiological health and safety, . . .";

4) Federal Register notice, page 5, first paragraph, edit first line to read: "The NRC cannot meet its responsibility to protect worker and public radiological safety in these areas without a . . .";

5) Federal Register notice, page 5, fourth paragraph, delete 3rd sentence regarding "NRC staff position" on compliance with OSHA regulations because it is unnecessary for the topic of discussion.;

6) Federal Register notice, page 6, carryover paragraph, delete last sentence regarding incorporation by reference not being the preferred way to provide enforceable safety standards.;

7) Federal Register notice, page 6, first full paragraph, add at end of paragraph: "This is considered by NRC to be consistent with the National Technology Transfer and Advancement Act of 1995.

8) Federal Register notice, page 13, second and third full paragraph; page 14, first full paragraph; page 34, second, third and fourth paragraphs; and throughout FR notice, check designation of footnotes. Because of many changes between current Appendix A, proposed Appendix A, and final Appendix A, there is some confusion in referring to footnotes.;

9) Federal Register notice, page 24, carryover paragraph, line 5, delete "(2)", and edit last sentence of paragraph to read "The NRC has instead restructured the section to add

similar language to a new subparagraph 20.1702(b) in the text of the rule to facilitate clarification of this important provision.";

10) Federal Register notice, page 29, last paragraph carrying over to page 30, edit the sentence to read: "Section 20.1704(a) is revised to clarify that the Commission will use ALARA considerations in any additional restrictions imposed by the Commission on the use of respiratory equipment for the purpose of limiting exposures of individuals to airborne radioactive materials.";

11) Federal Register notice, page 39, "Issue of Compatibility for Agreement States", delete several references to "proposed" modifications or definitions, and confirm with the Office of State Programs that the compatibility designations are consistent with current criteria.;

12) Federal Register notice, page 40, first paragraph of section V., third line, change "will not be" to "are not.";

13) Federal Register notice, page 40, second paragraph of section V., first line, begin sentence: "The amendments make . . . ";

14) Federal Register notice, page 41, before last paragraph of section V., insert: "The NRC requested public comments and the views of the States on the environmental assessment for this rule. No comments were received which required any change to the environmental assessment.";

15) Federal Register notice, page 41, section VI., third sentence, insert the word "reduction" after "Because the burden";

16) Federal Register notice, page 42, section X., second sentence of first paragraph, delete "Under § 50.109(a)(2)," and begin sentence with remaining text. Also delete two occurrences of word "proposed" in this paragraph.

17) Federal Register notice, page 43, first full paragraph, first sentence, change "II" to "III."; and

18) Federal Register notice, page 52, first sentence of § 20.1704, change text back to agree with current or proposed rule language, "The Commission may impose restrictions in addition to those in § 20.1702, 20.1703, and appendix A to Part 20 in order to:" --or explain in section by section summary of changes why this change has been made.

→ Cindy

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

April 2, 1999

MEMORANDUM TO: David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

FROM: R. W. Borchardt, Deputy Director R.W. Borchardt
Office of Enforcement

SUBJECT: FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20," AND REVISION 1 TO REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION"

The Office of Enforcement has reviewed the subject final rule and concurs. No changes to the Enforcement Policy are deemed necessary as a result of the promulgation of this final rule.

cc: C. Paperiello, NMSS
P. Lohaus, SP
J. Gray, OGC