

From: Kathryn Winsberg
To: TWD2.TWP9(AKR)
Date: 2/12/98 10:50am
Subject: Respiratory Protection -Reply

Alan, the Office of the General Counsel indicates "no legal objection" to the respiratory protection package, subject to the attached edits. In addition to the edits in the discussion of the Environmental Assessment, please note 2 small typos (indicated in redline/strikeout in attachment): 1) correct spelling of "NIOSH" on pg 6; and 2) eliminate extra space in "210, _205" [?] in the Paperwork Reduction Act section estimate of total annual hours on pg 22.

Thank you in advance for sending me the corrected version to attach to my memo to K. Cyr.

>>> Alan Roecklein 01/21/98 08:33am >>>

I am resending the correct Federal Register Notice of Proposed rulemaking , DG-8022(RG8.15), and the Commission paper. Again, I need final concurrence from OGC and NMSS and assurance from the rest of the working group that there are no further problems. Sorry for the confusion.

In § 20.1703(a)(2), (proposed § 20.1703(b)), licensees are permitted to apply for authorization to use equipment that has not been tested or certified by NIOSH and "has not had certification extended by NIOSH/MSHA." The words "has not had certification extended by NIOSH/MSHA" would be deleted because all these extensions have expired and no new extensions will be granted. The words "to the NRC" are added to make it clear that applications for authorized use of respiratory equipment are to be submitted to the Commission.

In § 20.1703(a)(3), (proposed § 20.1703(c)), paragraphs (c)(1) through (5) are retained as presently codified with the exception of some minor editing and that paragraph (c)(4) would be reworded to improve clarity, reorder priorities, and bring together in one paragraph all of the elements of the required written procedures. Paragraph (5) would be revised to clarify that the worker's medical evaluation for using non-face sealing respirators occurs prior to first field use rather than prior to first fitting (as required for tight fitting respirators) because fit testing is not needed for these types.

A new § 20.1703(c)(6) would be added to require fit testing prior to first field use of tight fitting, face sealing respirators and periodically thereafter. This proposed change would clarify when and how often fit testing is required. The licensee is to specify a frequency of retest in the procedures, not to exceed 3 years. This differs from the ANSI recommendation of annual fit testing. The NRC believes that if a licensee is alert to physiological changes that might affect an individual's ability to wear a respirator safely, annual fit testing is an excessive burden. This requirement is currently in the footnotes to Appendix A to Part 20 and would be moved to the body of the rule. Several general programmatic requirements currently found in footnotes to Appendix A to Part 20 would be moved to the text of the rule where they more appropriately belong and to ensure that they are not overlooked by licensees.

Agreement State regulations to reduce impacts on licensees who may operate in multiple jurisdictions.

These proposed amendments were provided to the Agreement States during the NRC staff review process via the use of the NRC rulemaking bulletin board and notification to the States of its availability.

IV. Finding of No Significant Environmental Impact Availability

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 proposed amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

The proposed amendment addresses technical and procedural improvements in the use of respiratory protection devices to maintain total occupational dose as low as is reasonably achievable. None of the impacts associated with this rulemaking have any effect on any places or entities outside of a licensed site. The net effect of this proposed 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. 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.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. ~~However, the general public should note that the NRC welcomes public participation. The NRC has also committed~~ Therefore, in accord with its commitment to complying with Executive Order 12898 - Federal Actions to Address

Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994, in all its actions. Therefore, the NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. In the letter and spirit of E.O. 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule but somehow were not addressed. The NRC uses the following working definition of "environmental justice": the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of the environmental assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

The draft environmental assessment is available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Single copies of this document are available as indicated in the ADDRESSES heading.

V. Paperwork Reduction Act Statement

This proposed rule contains amendments to reduce the information collection requirements contained in 10 CFR Part 20 that are considered to be insignificant, (250 hours annually) when compared with the overall requirements of the CFR Part (210,-205 hours annually). NRC does not consider this reduction in the burden to be significant enough to trigger the requirements of the Paperwork Reduction Act of 1995 (44. U.S.C. 3501 et seq.).



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

February 9, 1998

MEMORANDUM TO: Cheryl A. Trottier, Chief
Radiation Protection and Health Effects Branch
Division of Regulatory Applications, RES

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS 

SUBJECT: CONCURRENCE ON PROPOSED RESPIRATORY
PROTECTION RULE

IMNS concurred on the attached proposed rule.

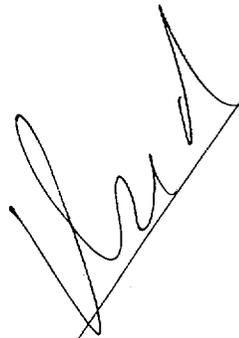
CONTACT: Sami Sherbini, NMSS/IMNS
(301) 415-7902

ADMIN/OMB

From: Herbert Parcover
To: TWD2.TWP6.DLM1
Date: 12/17/97 10:54am
Subject: PR, RESPIRATORY PROTECTION AND CONTROL, 10 CFR 20

The rule can be published with a change to the "Paperwork Reduction Act Statement" as noted in an earlier e-mail this date.

CC: TWD2.TWP9.AKR

A handwritten signature in cursive script, appearing to read "Parcover", is written across the lower portion of the document. A long, thin diagonal line is drawn from the top right corner towards the bottom left corner, passing through the signature.



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

November 28, 1997

cc: Murphy
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NG, JR.

MEMORANDUM TO: ~~Malcolm R. Knapp, Acting Director~~
Office of Nuclear Regulatory Research

FROM: Jack W. Roe, Director *JWR*
Division of Reactor Program Management
Office of Nuclear Reactor Regulation

SUBJECT: NRR REVIEW OF PROPOSED REVISIONS OF
RESPIRATORY RULE AND STAFF GUIDANCE:
AMENDMENTS TO 10 CFR PART 20, SUBPART H AND
REVISION OF REGULATORY GUIDE 8.15

NRR has reviewed the subject package, as requested by your November 13, 1997 memorandum, and has provided minor, technical and editorial comments informally to your Task Leader for his consideration. NRR supports and concurs on the proposed rule changes and revision of the companion regulatory guide, subject to the resolution of the following comment. The latest proposed change to Appendix A, Assigned Protection Factors for Respirators, needs revision to better clarify the staff's proposal to allow use (but no credit for protection) of certain respirators. *done*

NRR's Emergency Preparedness and Radiation Protection Branch has already started working with the Task Leader to resolve our comments. NRR has kept the Regions informed of the key points of this respiratory protection rule/guide revision, so seeking Regional comments at this point is not necessary. If you have any questions concerning our comments, please contact Jim Wigginton.

cc: S. Sherbini, NMSS
K. Winsberg, OGC
T. O'Brien, OSP
R. DelMedico, OE
A. Roecklein, RES



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 24, 1997

C10

MEMORANDUM TO: Alan K. Roecklein, Task Leader
Division of Regulatory Application
Office of Nuclear Regulatory Research

FROM: *Brenda J. Shelton*
Brenda Jo Shelton, Chief
Information and Records Management Branch
Information Management Division
Office of the Chief Information Officer

SUBJECT: OFFICE REVIEW AND CONCURRENCE: PROPOSED AMENDMENTS TO
SECTION 20.1003, SUBPART H "RESPIRATORY PROTECTION AND
CONTROLS TO RESTRICT INTERNAL EXPOSURES" AND APPENDIX A, OF
10 CFR PART 20, AND PROPOSED REVISION 1 TO REGULATORY GUIDE
8.15, "ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION"

The Office of the Chief Information Officer concurs in the subject proposed rule and regulatory guide. However, because the proposed rule will modify information collection requirements, Office of Management and Budget (OMB) review and approval is required. Accordingly, modify the "Coordination" statement in the Commission Paper to include the Office of the Chief Information Officer concurrence as follows: "The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it. However, the proposed rule impacts information collection requirements that must be submitted to OMB for review and approval."

Please change the "Paperwork Reduction Act Statement" to Attachment 1. Also note that an OMB clearance package must be prepared for this rulemaking and must be submitted to OMB at the same time the proposed rule is submitted to the Federal Register for publication. Should you have any questions, please contact Herbert Parcover at 415-7226 or e-mail HMP.

Attachment: As stated
cc: D. Meyer, ADM



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

cc: Murphy
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OE

NG, JR.

November 26, 1997

MEMORANDUM TO: Malcom R. Knapp, Acting Director
Office of Nuclear Regulatory Research

FROM: James Lieberman, Director
Office of Enforcement

JL

SUBJECT: OFFICE REVIEW AND CONCURRENCE: PROPOSED AMENDMENTS
TO SECTION 20.1003, SUBPART H "RESPIRATORY PROTECTION
AND CONTROLS TO RESTRICT INTERNAL EXPOSURES" AND
APPENDIX A, OF 10 CFR PART 20, AND PROPOSED REVISION 1 TO
REGULATORY GUIDE 8.15, "ACCEPTABLE PROGRAMS FOR
RESPIRATORY PROTECTION."

The Office of Enforcement (OE) has reviewed this proposed rulemaking and concurs, with the following changes:

✓ *FR Notice, page 29, 20.1703(c)(6)* - Fit testing. . . prior to first field use of tight fitting, face sealing respirators and periodically thereafter **at a frequency specified by the licensee in the fit test procedures.**

✓ *Reg. Guide, Page 10, 4.1 NIOSH-Approved Equipment, 3rd sentence* - In addition, **the NIOSH approval is valid only if** the licensee uses, maintains, and stores these devices in such a manner that they are in like-new condition at the time of issue. . .

✓ *Reg. Guide, page 24, D. Implementation, last sentence* - . . . the method to be described in the active guide reflecting public comments will be used in the evaluation of applications for new licenses or license amendments. **Licensees may use the procedures in the guide to show compliance with Subpart H of 10 CFR Part 20.**

cc: A. Thadani, DEDE
D. Cool, NMSS
J. Roe, NRR
S. Treby, OGC
R. Bangart, OSP
A. Roecklein, RES



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

cc: Murphy
Trottier
Roecklein
File

OSP

January 24, 1998

NG, JR.

MEMORANDUM TO: Malcolm R. Knapp, Acting Director
Office of Nuclear Regulatory Research

FROM: Richard L. Bangart, Director
Office of State Programs *Richard L. Bangart*

SUBJECT: REVIEW OF RESPIRATORY PROTECTION RULE AND STAFF
GUIDANCE

We have reviewed the subject package as requested by Alan Rocklein's electronic mail transmittal to our office on January 21, 1998. We concur with the revisions to the proposed rule, draft regulatory guide, and Commission Paper.

Thank you for the opportunity to comment on the proposed rule, guidance, and Commission Paper. If you have any questions, please contact me or Tom O'Brien of my staff at 415-2308.



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

December 18, 1997

cc: Tse
Trottier
Roecklein
Murphy
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dm

MEMORANDUM TO: Malcolm R. Knapp, Acting Director
Office of Nuclear Regulatory Research

FROM: Richard L. Bangart, Director
Office of State Programs *Richard L. Bangart*

SUBJECT: OSP REVIEW OF PROPOSED REVISIONS OF RESPIRATORY
RULE AND STAFF GUIDANCE: AMENDMENTS TO 10 CFR
PART 20, SUBPART H, AND REVISION OF REGULATORY
GUIDE 8.15

OSP has reviewed the subject package as requested by your November 13, 1997 memorandum. We concur with the proposed rule changes and revisions to the draft regulatory guide. Technical and editorial modifications were informally discussed with, and accepted by, your Task Leader who indicated that the OSP and other program office modifications would be reflected in a mark-up draft to be routed at a later date.

Also, please note that the Agreement States have been notified of the availability of the subject package on the Technical Conferencing Forum and provided a 30 day period in which to submit comments to the RES Task Leader.

Thank you for the opportunity to comment on the proposed rule and guidance. If you have any questions, please contact Tom O'Brien (x2308) of my staff.

OCFO

From: Thomas Heavey
To: TWP9.AKR
Date: 11/21/97 3:44pm
Subject: COMMISSION PAPER: RESPIRATORY PROTECTION AND CONTROLS

Used

OCFO has reviewed the above Commission Paper and concurs, provided that the following adjustments are made:

Revise the RESOURCES: paragraph to state "Resources needed to conduct and implement this rulemaking are included in the current budget."

Revise the COORDINATION: paragraph to state that "The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections."

-Tom

CC: TWP8.SXS2, WND2.WNP5.JEW2, WND1.WNP9.TJO, WND1.WNP...



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

ADM
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November 28, 1997

NG, JR.

MEMORANDUM TO: Malcolm R. Knapp, Acting Director
Office of Nuclear Regulatory Research

FROM: Edward L. Halman, Director
Office of Administration *Edward L. Halman*

SUBJECT: OFFICE CONCURRENCE ON A DIRECT FINAL RULE ENTITLED
"RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT
INTERNAL EXPOSURES" (PART 20) *Michael Lesar*

The Office of Administration (ADM) concurs, subject to the comments provided, on the package that presents the proposed rule that would amend regulations concerning the use of respiratory protection and other controls to restrict internal exposure to radioactive material. We have attached a marked copy of the package that presents our comments.

We have suggested a shortened subject title for the document and amended the Summary statement to meet the publication requirements of the Office of the Federal Register (OFR). In addition, we have corrected the amendatory language and the presentation of codified text to meet OFR requirements.

We have provided the standard language to be used in the statement concerning the availability of the environmental assessment for the proposed rule that indicates compliance with the environmental justice and Agreement State review procedures adopted by the Commission.

To assist your staff in preparing the list of documents centrally relevant to this direct final rule that is required by NRC's regulatory history procedures, please instruct your staff to place the designator "AF81-1" in the upper right-hand corner of each document concerning the direct final rule that you forward 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, ADM, at 415-1762 (DLM1) or Michael T. Lesar, ADM, at 415-7163 (MTL).

Attachments:
As stated

AEOD
Concurrence

- g. A public announcement will be issued (Attachment 6); and
- h. 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. Draft Regulatory Guide 8.15
3. Draft Regulatory Analysis
4. Draft Environmental Assessment
5. Draft Congressional Letters
6. Draft Public Announcement
7. OMB Supporting Statement

RECORD NOTE: A draft copy of the proposed rule was sent to OIG for information on: _____
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*See previous concurrences

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NAME:	ARoecklein*	CTrottier*	AMurphy	CPaperiello	SCollins
DATE:	07/19/97	09/26/97	10/29/97	/ / 197	/ / 197
OFFICE:	D:OSP	D:OE	OGC	RDB:ADM	IRM
NAME:	RBangart	JDieberman	WOImstead	DMeyer	BJShelton
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