Action: Collins, NRR
Cys: Travers
Knapp
Miraglia
Norry
Blaha
Meyer, ADM
Shelton, CIO
Roecklein, NRR
Paperiello, NMSS
Lohaus, SP
Borchardt, OE
Schroll, SECY

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

SECRETARY

IN RESPONSE, PLEASE REFER TO: M990910

September 10, 1999

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

John F. Cordes, Acting Director
Office of Commission Appellate Adjudication

FROM: Annette Vietti-Cook, Secretary

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 11:30 A.M., FRIDAY, SEPTEMBER 10, 1999, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

I. SECY-99-207 -- Final Rule: Respiratory Protection and Controls to Restrict Internal Exposures, 10 CFR Part 20

The Commission approved a final rule which amends 10 CFR Part 20, subject to the changes noted in attachment 1, to 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) regulations, reduce licensee burden without reducing worker safety, and are consistent with the Commission's intent to promulgate performance-based rules.

Following incorporation of these changes, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

~~(EDO)~~- (NRR) (SECY Suspense: 10/1/99) 199700194

The staff should issue revised Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection," in final concurrent with the issuance of this final rule on respiratory protection.

In future rulemaking packages where the staff recommends partially adopting a voluntary consensus standard, the staff should explicitly identify to the Commission all portions of the consensus standard that are not being adopted, and provide a justification why those portions of the technical standard are inconsistent with applicable law or otherwise impractical.

The Occupational Safety and Health Administration allows a licensed health care professional to determine whether the user is medically fit to use respiratory protection equipment, as the paper indicates, but ANSI Z88.2-1992 specifies that a physician shall make the determination. On the next revision to the ANSI standard, the staff should encourage the ANSI Subcommittee to consider whether licensed health care professionals, such as occupational health nurses, are qualified to make medical fitness determinations.

II. SECY-99-216 -- Yankee Atomic Electric Company (Yankee Nuclear Power Station), Docket No. 50-029-LA, Yankee Atomic's Motion for Leave to Withdraw Appeal of LBP-99-14

The Commission approved a Memorandum and Order which grants Yankee Atomic Electric Company's May 26, 1999 motion to dismiss without prejudice its appeal of a Board order admitting four contentions and vacating both LBP-99-14 and LBP-99-17.

(Subsequently, on September 10, 1999, the Secretary signed the Memorandum and Order.)

Attachment: 1) Comments and Changes to Rulemaking Package in SECY-99-207
2) Changes to be Incorporated in the Memorandum and Order in SECY-99-216

cc: Chairman Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
EDO
OGC
CIO
CFO
OCAA
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance
DCS - P1-17

Attachment 1

Comments and Changes to Rulemaking Package in SECY-99-207

General Comments

1. The staff should revise the Federal Register Notice (FRN) and all attachments to avoid the implication that NRC is adopting the voluntary consensus standard in full.

Changes to the Federal Register Notice

2. On page 1, in the *Summary*, line 6, spell out OSHA (Occupational Safety and Health Administration) in the first paragraph.

3. On page 5, paragraph 2, line 1, delete 'unique'. In line 2 delete the comma.

4. On page 5, paragraph 3, revise the last line to read ' ... rather than adopt ~~rely on~~ OSHA regulations.'

5. On page 7, paragraph 1, delete the last sentence (There is little ... at greater risk.)

6. On Page 7, paragraph 2 incorrectly assumes that all regulatory guidance use by licensees is unenforceable. For most materials (non-reactor) licensees, incorporation of regulatory guides into their licenses as amendments is routine. This paragraph needs to be expanded and revised to reflect that in those cases, licensee commitments to use specific regulatory guidance are enforceable when incorporated in the license.

7. On page 7, the staff should enhance the discussion that addresses why NRC is retaining the Table in Appendix A in the rule rather than in guidance, including providing additional justification for the decision.

8. On page 8, paragraph 2, revise the last sentence to read 'Other program elements such as minimal training on ~~the~~ limitations of ~~these~~ devices and correct methods of use are required ~~would be considered essential~~.'

9. On page 10, revise line 4 from the top to read ' ... requests a respirator that will ~~, or if the respirator is~~ not be used ....'

10. On page 13, 2nd full paragraph, revise the last line to read ' ... user seal check on filtering facepiece respirators in the positive ....'

11. On page 13, last paragraph, line 6, spell out IDLH (Immediately Dangerous to Life or Health).

12. On page 16, paragraph 3, line 3, insert quotation marks after '(PAPR)'.

13. On page 18, 1st full paragraph, revise the last sentence to read ' ... or valve function, and that are ~~the presence or absence of which is~~ under the control of the respirator wearer, are ~~, may be~~ present ....'

14. On page 19, paragraph 3, revise line 5 to read ' ... is aware that most radionuclides ....'

15. On page 19, last paragraph and continuing to page 20, the staff should strengthen the justification that addresses why a physician, as opposed to a licensed health care professional, must determine whether the user is medically fit to use respiratory protection equipment. The Occupational Safety and Health Administration allows a licensed health care professional to make the determination, as the paper indicates, but ANSI Z88.2-1992 specifies that a physician shall make the determination.

16. On page 20, top paragraph, the last sentence should be ended after 'respirator'.

17. On page 21, last paragraph, revise line 2 to read ' ... persons must be immediately available to ....'

18. On page 22, paragraph 1, delete the last 3 sentences (Other differences are minor ... measurements of intake.)

19. On page 29, paragraph 2, revise line 4 to read '~~AIH~~ Licensees who ....' Revise line 5 to read ' ... program are expected ~~required~~ to submit a program ....'

20. On page 38, 1st full paragraph, delete the 4th sentence (In the NRC's view ... questionable.)

21. On page 51, revise the last line to read ' ... initial fitting of a face sealing ....'

Changes to the Regulatory Analysis

22. On page 1, line 4, delete the apostrophe in 'its'. Revise line 8 to read ' ... 10 CFR Part 20 and revisions to ....' Revise line 21 to read ' ... are not practical ~~practicable~~.' Revise lines 23-24 to read ' ... use of respirators in many ~~most~~ circumstances ....'

23. On page 3, paragraph number (5), revise line 3 to read ' ... physiological impact, and ....' In line 5, replace the comma with a semicolon.

24. On page 5, line 2 from the top, move the apostrophe in 'licensees' to the end of the word. In line 3, the end of the sentence appears incomplete or missing something and needs to be corrected.

25. On page 8, 2nd full paragraph, revise line 9 to read 'Therefore, under the new rule ....'

26. On page 9, line 5 from the top, insert the missing multiplication sign.

27. On page 10, 1st full paragraph, line 11, insert a comma after 'current'.

Changes to the Environmental Assessment

28. On page 1, next to the last line, delete the 's' at the end of 'revises'.

Changes to Congressional letters

29. In paragraph 2, revise line 1 to read ' ... are based in part on guidance ....' In line 5, move the apostrophe in 'workers' to the end of the word.

Changes to the Press Release

30. On page 1, paragraph 3, line 2, the staff should verify the revision date of 1992. The revision was published on May 21, 1991.

Attachment 2

Changes to be Incorporated in the Memorandum and Order in SECY-99-216

1. On page 2, 1st full paragraph, at the end of line 7, insert the following footnote: 'The Commission is also declining to take review sua sponte of the Licensing Board's Memorandum and Order (LBP-99-27) terminating, without prejudice or conditions, all portions of the proceedings except for the instant appeal of LBP-99-14.'

2. On page 3, line 4 from the top, after the period, insert a new sentence as follows: 'The admitted contentions were focused on alleged deficiencies and inadequacies of the withdrawn LTP.' Revise the next sentence to read 'Moreover, ~~In any subsequent proceeding,~~ the intervenors ....'

3. On page 3, revise line 5 from the top to read ' ...same position in any subsequent proceeding as if they had ....'

4. On page 3, delete the sentence in lines 8 to 11 from the top (Similarly, the termination of this ... before the Commission.)

5. On page 3, in the 1st full paragraph, revise line 1 to read 'For ~~both~~ these reasons, we decline ....'

6. On page 4, insert the following sentence as a new second paragraph under 'CONCLUSION': 'Therefore, the proceeding is terminated.'

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

SECRETARY

September 10, 1999

COMMISSION VOTING RECORD

DECISION ITEM: SECY-99-207

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

The Commission (with all Commissioners agreeing) approved the subject paper as noted in the Affirmation Session and recorded in the Affirmation Session Staff Requirements Memorandum (SRM) of September 10, 1999.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission, and the Affirmation Session SRM of September 10, 1999.

Annette Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets
3. Final SRM

cc: Chairman Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR
DCS

VOTING SUMMARY - SECY-99-207

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DICUS	X				X	8/20/99
COMR. DIAZ	X				X	8/21/99
COMR. McGAFFIGAN	X				X	9/2/99
COMR. MERRIFIELD	X					8/18/99

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and some provided additional comments. Subsequently, the comments of the Commission were incorporated in the final rule as reflected in the Affirmation Session SRM issued on September 10, 1999.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN DICUS

SUBJECT: **SECY-99-207 - FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20"**

Approved _x_ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

1. Federal Register Notice, Page 7, second paragraph. This paragraph incorrectly assumes that all regulatory guidance use by licensees is unenforceable. For most materials (non-reactor) licensees, incorporation of regulatory guides into their licenses as amendments is routine, therefore this paragraph needs to be expanded and revised to reflect that in those cases, licensee commitments to use specific regulatory guidance are enforceable when incorporated in the license.

2. Although the revisions to Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection," were not forwarded to the Commission for consideration with this final rule package, staff should issue the revised Regulatory Guide in final concurrent with the issuance of the final rule on respiratory protection.

Greta Joy Dicus
SIGNATURE

August 20, 1999
DATE

Entered on "AS" Yes _x_ No ____

Specific Editorial Comments on SECY 99-207

1. FRN, page 1, *Summary*. Spell out OSHA (Occupational Safety and Health Administration) in the first paragraph.

2. FRN, page 13, last paragraph. Spell out IDLH (Immediately Dangerous to Life or Health).

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-99-207 - FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20"**

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

The staff should enhance the discussion on page 7 of the FRN that addresses why NRC is retaining the Table in Appendix A in the rule rather than in guidance, including providing additional justification for the decision.

The last sentence of the second paragraph on page 8 of the FRN should be modified to read "Other program elements such as minimal training on limitations of the devices and correct methods of use are required."

SIGNATURE

8/21/99

DATE

Entered on "AS" Yes XX No ____

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-99-207 - FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20"**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

Edward McGaffigan, Jr.
SIGNATURE

September 2, 1999
DATE

Entered on "AS" Yes X No ____

Commissioner McGaffigan's Comments on SECY-99-207

I approve publication of the final rule amending the 10 CFR Part 20 respiratory protection requirements, subject to the following comments and edits.

The staff's statements throughout SECY-99-207 and its attachments that NRC is adopting the American National Standards Institute's ANSI Standard Z88.2-1992, "American National Standard Practice for Respiratory Protection," are inexact. In fact, many of the provisions of ANSI Z88.2-1992 are being incorporated in the regulations or regulatory guide, but not all. The staff should revise the Federal Register Notice (FRN) and all attachments to avoid the implication that NRC is adopting the voluntary consensus standard in full.

In future rulemaking packages where the staff recommends partially adopting a voluntary consensus standard, the staff should explicitly identify to the Commission all portions of the consensus standard that are not being adopted, and provide a justification why those portions of the technical standard are inconsistent with applicable law or otherwise impractical.

The staff should strengthen the justification on pages 19-20 of the FRN that addresses why a physician, as opposed to a licensed health care professional, must determine whether the user is medically fit to use respiratory protection equipment. The Occupational Safety and Health Administration allows a licensed health care professional to make the determination, as the paper indicates, but ANSI Z88.2-1992 specifies that a physician shall make the determination. Our final rule should follow the voluntary consensus standard. However, on the next revision to the ANSI standard, the staff should encourage the ANSI Subcommittee to consider whether licensed health care professionals, such as occupational health nurses, are qualified to make medical fitness determinations.

The final rule now contains assigned protection factors (APFs) that are identical to ANSI's APFs, except for filtering facepiece disposables (e.g., dust masks) and suits. Thus, the staff should delete the text on page 22 of the FRN regarding differences between NRC's and ANSI's APFs (the third through fifth sentences in the top paragraph of page 22).

Additional edits to the FRN and all attachments are shown on the attached pages. I concur with Chairman Dicus' comments and suggested edits to the FRN. I also concur with Commissioner Diaz' comments.

Edw

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 published 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.

In addition, the NRC regulation includes the Assigned Protection Factors (APFs) recommended by the American National Standards Institute (ANSI) with some modifications. Because, in radiological applications, using APFs to generate an estimate of intake of radioactive materials is an acceptable method to demonstrate compliance with NRC dose limits, APFs must be included in the regulation. However, OSHA rules do not specify APFs because this section of the OSHA rules is still under development.

The NRC regulations include dose limitation for radiation exposure with the unique concept of keeping total dose As Low As Is Reasonably Achievable (ALARA). OSHA does not address radiation hazards and does not include the ALARA concept.

Finally NRC requirements do make it clear that if an NRC licensee is using respiratory protection to protect workers against non-radiological hazards, the OSHA requirements apply. If the NRC has jurisdiction and is responsible for inspection, the MOU specifies that NRC will inform the licensee and OSHA if the NRC observes an unsafe condition relative to non-radiological hazards. For all of these reasons, NRC believes it must have respiratory protection regulations in place, rather than rely on OSHA regulations.

Several commenters suggested endorsing ANSI guidance in the regulations such as ANSI Z88.2-1992, "American National Standard for Respiratory Protection." The ANSI standards are viewed by the NRC staff as comprehensive guidelines that if implemented would contribute to an acceptable program. The NRC staff participated in development of the standards. However, the ANSI standard does not specifically address radiological protection. In addition, the ANSI recommendations for general respirator usage are too prescriptive to be incorporated as regulatory requirements given the Commission's intent to promulgate risk-informed and performance-based rules.

With changes to the proposed rule discussed here, 10 CFR Part 20, Subpart H will be consistent in almost all respects with ANSI guidance. The final Regulatory Guide 8.15,

Three respirator types operating in demand or in demand, recirculating mode were given APFs of 5 in the proposed rule. This was in an effort to discourage their use by mistake in high concentration areas. ANSI gives these devices APFs equal to 100. Consistent with ANSI and in response to public comment, the NRC staff has changed these APFs to 100. ~~There is little practical difference between a 5 and a 100, and, because a higher fit factor will then be required for their use, workers will not be put at greater risk.~~

It was suggested that Appendix A could be put into Regulatory Guide 8.15 so that changes could be made more easily as ANSI revised APFs. This suggestion is not accepted by the NRC staff because APFs may be used to generate estimates of dose of record from the intake of radioactive material and as such should be regulatory requirements. Regulatory Guides provide descriptions of acceptable programs, are guidance only, and cannot be enforced.

Several commenters suggested that the NRC terms and definitions should be consistent with those used by OSHA. The NRC staff agrees. Several OSHA terms and definitions have been added to 10 CFR Part 20 in this final rule and several proposed NRC definitions have been amended to be more consistent with OSHA terms.

A commenter observed that § 20.1703(c)(3) requires that respirators be tested for operability prior to each use but that such tests (user seal checks) are not quantitative and there is no requirement to document the check. It was suggested that this requirement be deleted. The NRC staff does not intend that user seal checks (fit checks) be quantitative nor that they be documented. User seal checks have been required by the NRC since 1979 and are well known to the industry. Licensee training programs describe the procedures and the procedures are subject to periodic licensee and NRC audits. The need to perform a user seal check (fit check) prior to each use is considered an essential safety procedure, consistent with industry practice and ANSI guidance. This requirement is retained.

intake." In effect, if a licensee determines that respiratory protection is not required to limit intake of radioactive material and a respirator is used for some other reason, then the § 20.1703 conditions are not applicable. However, in this case, other regulations would govern the use of respirators. For example, if a worker requests a respirator that will be ~~, or if the respirator is~~ not used to limit intakes of radioactive material, then OSHA or State requirements would come into play. For example, OSHA requirements for the voluntary use of disposable filtering facepieces (dust masks) would be little more than brief instruction on the limitations of the device and correct methods of use. NRC, as well as OSHA requirements for the use of tight-fitting, half or full-facepiece respirators are more extensive, including medical evaluation.

A suggestion was made that § 20.1703(d) should include instructing a worker that a respirator could be removed in any situation where the user judges that his or her health is at risk due to physical or psychological stress caused by use of the respirator. The NRC staff believes the present language in this section and guidance in Reg. Guide 8.15, is adequate to assure that a worker knows when and how to secure relief from respirator-induced stress.

A commenter requested that provisions be added to allow the use of combination full facepiece, pressure demand, supplied air respirators with auxiliary self-contained air supply for use during emergency entry into an unassessed environment. The NRC staff intends that Appendix A Section III, Combination Respirators, include any devices or combinations of devices as approved by NIOSH in 42 CFR Part 84.70. Regulatory Guide 8.15 provides further guidance on the use of combination respirators. The NRC staff does not believe that any change is needed in the regulation to permit (and continue to allow) the use of these approved devices.

A commenter questioned the statement in footnote e of Appendix A that "...no distinction is made ... between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the face piece (e.g., disposable or reusable

provision clearly modifies information in Appendix A. The NRC staff believes it should remain in the footnotes. With the restructuring of Appendix A, this information is found in new footnotes c and f. More detailed discussion of the criteria for approval of sorbent cartridges against gases and vapors has been added to Regulatory Guide 8.15.

A commentor suggested deleting proposed footnote e because the initial statement to the effect that filtering facepieces may be used without medical screening or fit testing applies to all tight fitting respirators. That is not the case. Fit testing and medical screening are required for any respirator that is assigned a protection factor (APF). Only disposable, filtering facepieces without elastomeric sealing surface and adjustable straps that do not have an APF can be used without medical screening. If the devices are fit tested in order to use an APF, then medical screening would also be required.

This commentor suggested that the caution in the proposed footnote e to the effect that it is difficult to perform positive or negative pressure user seal checks on filtering facepiece respirators is not based on technical information. The statement is based on cumulative experience in the industry and inspection by the NRC staff of a large number of filtering facepiece respirators that do not have elastomeric sealing surfaces and adjustable straps. In most cases, it was very difficult for highly experienced respirator users to effectively perform a user seal check in the negative or positive pressure mode.

on filtering facepiece respirators

A commentor proposed deleting the last sentence in the final footnote i that warns against using SCBA in pressure demand or recirculating positive pressure modes if any outward leakage of breathing gas is perceived. This is an important warning for use of these devices in emergencies or unassessed situations because leakage could significantly reduce the expected duration of the air supply and thus stay time. Premature exhaustion of the air supply could result in serious injury or death of a worker in an IDLH area. This warning appropriately modifies the assigned protection factor for this type of device.

spell out

The commentor questioned the wording in § 20.1703(c)(3) that would exempt respirators with no APFs from user seal checks for tight fitting respirators and functional or operability checks for others such as atmosphere supplied suits. The NRC staff agrees that if a device is capable of being fit checked or operability checked then these checks should be performed each time the device is used whether or not a APF is used. The words "...with APFs..." are removed from § 20.1703(c)(3).

It was observed that § 20.1703(c)(6) does not specify that fit testing measures face seal rather than equipment operation and therefore must always be performed with the facepiece operating in the negative pressure mode. This provision has been changed to be consistent with ANSI. Also, the proposed requirement to fit test any tight-fitting, positive pressure, continuous flow and pressure demand devices to a fit factor ≥ 100 is inconsistent with the OSHA specification of 500. This difference could result in workers using different masks depending on whether the respirator was used for protection against radiological or non-radiological hazards. It was further stated that a fit factor of 100 may be too low for full-face tight- fitting masks because it in fact would represent a relatively poor fit. The NRC staff believes that the OSHA recommended fit factor of 500 is not difficult to achieve and provides an additional increment of safety. The final rule reflects this change.

A commentor observed that Appendix A lists a positive pressure (PP) operational mode for some air purifying respirator types. This designation refers to "powered air purifying respirators (PAPR)" and should be so designated. The NRC staff agrees and has made this change.

A commentor suggested the use of "intake" or "dose from internal radioactive material," instead of "internal exposures," because there is some confusion regarding the meaning of that term. The NRC staff has reviewed the final rule and, whenever appropriate, more precise terminology has been used as suggested.

standby person to be in a high radiation area or otherwise be exposed to radiation or physiological stress. The NRC staff agrees and has changed this section to require the standby rescue person to "maintain continuous communication" with the workers. Acceptable communication methods are identified as, visual, voice, signal line, telephone, radio, or other suitable means.

The commentor stated that proposed § 20.1703(h) regarding materials or substances that might interfere with the seal of a respirator did not adequately reflect the discussion in the statement of considerations, and that, because the fit test proves the ability to properly maintain a seal, this restriction is not needed. The NRC staff observes that a fit test is not performed every time that a worker uses a respirator. A user seal check might work with some obstruction in the seal area but then break down in the work situation. To better reflect the scope and intent of this provision and to be consistent with OSHA, the NRC staff has added the underlined words as follows: (h) No objects, materials, or substances, such as facial hair, or any other conditions that interfere with the face - facepiece seal or valve function, ~~the presence or absence of which is~~ and that are under the control of the respirator wearer, ~~may be~~ are present....

A commentor suggested elimination of the planned revision of NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Material," because the document contains information that is found elsewhere and is redundant. The NRC staff agrees that it would not be useful to repeat information that is found elsewhere and one reason for updating and revising the NUREG is to eliminate and avoid redundancy. The document will be a technical source for NRC licensees setting up or operating respiratory protection programs that will include many references to ANSI, NIOSH, and other documents that describe acceptable programs. Only procedures unique to protection against airborne radioactive material will be addressed in detail if no other sources are available.

The commentor observed that waiving the medical screening requirement for the use of single-use disposable respirators is inconsistent with OSHA. In fact, OSHA waives the medical screening requirement for any voluntary use of filtering facepiece respirators. The assumption is that if a licensee determines that a respirator is not needed (meets ALARA considerations) but a worker requests one, then the least intrusive device should be used, such as a disposable, filtering facepiece with no APF that would be unlikely to expose the worker to physiological stress. The NRC position is consistent with that of OSHA.

Several commentors questioned the use of 15 percent loss of worker efficiency when using a respirator as a recommended, upper bound default value if a licensee is not able to justify a higher value. An EPRI study, for example, showed that loss of worker efficiency did not exceed 7 percent. Other measurements resulted in findings of 25 percent loss of efficiency under conditions requiring respiratory protection. With this range, a recommended default value of not more than 15 percent, as specified in Reg. Guide 8.15 seems reasonable. The guide provides suggestions for determining an efficiency loss factor that would be job and site specific.

A commentor questioned the need to apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine). The commentor stated that the NRC should specify the same APF listed for particulate filters for radioactive gases or vapors with good warning properties. The NRC staff is aware that most radionuclides (e.g., airborne radioiodines) have poor to no warning properties. For this reason, the NRC staff intends to continue requiring a specific case approval process with some demonstration of effectiveness before approval for use.

A commentor suggested permitting "a licensed health care professional," in addition to a physician, to determine that a person is medically fit to use a respirator, as is done by OSHA. The established NRC position, as described further in Reg. Guide 8.15, continues to be that a

Revise

Revise

licensed health care professional can administer a medical exam, but the program must be designed by, and be under the supervision of a physician. The NRC staff is aware that serious injury and death can occur if a person with certain medical conditions is permitted to use a respirator~~, and is not convinced that the importance of the medical evaluation should be reduced.~~

A commentor observed that ANSI Z88.2-1992, does not include APFs for SCBA used in the pressure-demand or positive pressure recirculating modes, because some workplace simulation tests showed that up to 5 percent of workers don't achieve protection factors that high. ANSI instead suggests that APFs up to 10,000 should be used only for emergency planning purposes. Footnote a to Appendix A in the NRC regulation makes it clear that the APFs apply only to airborne radiological hazards and not when chemical or other respiratory hazards exist.

A commentor suggested deletion of irritant smoke and isoamyl acetate as example of a user seal check because these are not checks that a user can perform without assistance. The NRC staff agrees but does not preclude the use of assistance in performing a user seal check. It is common for a technician to perform user seal checks on a work crew preparing for entry to a job site requiring respirators. If no assistance is available then clearly positive or negative pressure checks would be the available options.

It was suggested that more guidance be provided on functional check or testing for operability. The NRC staff agrees and Reg. Guide 8.15 will be expanded to provide more guidance on accepted techniques.

It was suggested that more specificity regarding actual procedures be put in the rule or the Reg. Guide and that requirements for addressing non-routine and emergency use of respirators should be added. The NRC staff does not agree because respiratory programs should be site and work specific and the intent of revising the rule was to make it more

performance based. Considerable guidance on acceptable methods exists and is referenced in Reg. Guide 8.15 or NUREG-0041.

A commentor said that NRC should require use of the OSHA medical check questionnaire, or its equivalent. The NRC staff agrees that the OSHA questionnaire is an acceptable way, along with appropriate medical oversight, to medically screen workers to use respirators safely, but that other methods are also acceptable. In the interest of maintaining a performance-based rule, the NRC will rely on review of a licensee's/physician's judgement regarding the best way to qualify workers. The OSHA questionnaire is referenced in Reg. Guide 8.15 for guidance.

It was suggested that provisions for vision, communication, and low temperature protection be made at no cost to the employee. The NRC staff believes that this issue is outside the scope of 10 CFR Part 20 and should be addressed between workers and licensee management.

A commentor suggested adding a definition for "Immediately Dangerous to Life or Health," IDLH. Subpart H of 10 CFR Part 20 provides program requirements for respiratory protection against airborne radioactive material. It would be extremely rare for airborne concentrations of radioactive material to reach IDLH levels. IDLH refers to industrial and toxic chemical hazards that NRC licensees must be alert to in compliance with OSHA regulations. It would be inappropriate for NRC to suggest that airborne radiological condition would require a definition of IDLH. OSHA defines IDLH as "...an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individuals' ability to escape from a dangerous atmosphere."

It was suggested that § 20.1703(f) state that a sufficient number of standby rescue persons must be immediately available to provide effective emergency rescue. The NRC staff agrees and these words have been added.

A commentor observed that the APFs specified by NRC in Appendix A are not in complete agreement with those recommended by ANSI. The difference for disposable filtering facepieces (dust masks) has been discussed. ~~Other differences are minor, do not impose a burden on licensees, and are based on field experiences. The few changes made by the NRC staff are reductions to the APF assigned by ANSI and result in APFs still high enough to accommodate radiological conditions usually encountered. The reduced APFs are more conservative, are based on work place experience, and would result in estimates of intake that could be modified according to § 20.1703(i) by more precise measurements of intake.~~ DELETE (No longer accurate)

Eight comment letters were received regarding the draft Reg. Guide 8.15. All of the suggested changes derived from comments made on proposed Subpart H of 10 CFR Part 20. Reg. Guide 8.15 has been revised based on this analysis of comments submitted on the proposed rule and the changes that have been made to the rule as discussed in this section.

III. Summary of Changes

This final rule amends § 20.1003, "Definitions", §§ 20.1701 through 20.1704, adds § 20.1705, and amends Appendix A to Part 20.

In § 20.1003, the NRC is adding definitions for Air-purifying respirator, Assigned protection factor (APF), Atmosphere-supplying respirator, Demand respirator, Disposable respirator, Filtering facepiece (dust mask), Fit factor, Fit test, Helmet, Hood, Loose-fitting facepiece, Negative pressure respirator, Positive pressure respirator, Powered air-purifying respirator (PAPR), Pressure demand respirator, Qualitative fit test (QLFT), Quantitative fit test (QNFT), Self-contained breathing apparatus (SCBA), Supplied-air respirator (SAR) or airline respirator, Tight-fitting facepiece and User seal check. These added definitions clarify the new regulations at §§ 20.1701 through 20.1705.

Section 20.1703(c) is removed because it requires licensees to use only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH, as emergency devices. Because only equipment approved by NIOSH or NRC can be used in the respiratory protection program pursuant to § 20.1703(a) and (b), this provision is redundant. The revisions of Regulatory Guide 8.15 and NUREG-0041 discuss acceptable types of emergency and escape equipment .

Section 20.1703(d) is removed. This provision required a licensee to notify the director of the appropriate NRC Regional Office in writing at least 30 days before the date that respiratory protection equipment is first used so that the NRC staff could review the licensee program. All licensees who possess radioactive material in a form that requires a respiratory protection program are ~~required~~ expected to submit a program description during the license application, amendment, or renewal processes. Their programs would be reviewed during this process. A 30–day notification requirement imposes a needless administrative burden on licensees with no increase in worker health and safety. This change is considered to be a burden reduction.

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 protection equipment for the purpose of limiting exposures of individuals to airborne radioactive materials.

Appendix A to Part 20 - " Assigned Protection Factors for Respirators," is modified extensively. In general, new devices are recognized, APFs are revised to be consistent with current ANSI guidance and technical knowledge, and the footnotes to Appendix A are moved, deleted, revised, or adjusted so that only those necessary to explain the table remain. Footnotes that are instructive or that facilitate implementation of the rule are being moved to Regulatory Guide 8.15. Several footnotes are considered to be redundant in that they reiterate NIOSH certification criteria to be discussed in NUREG–0041 and are removed. Generic

accordance with § 20.1703(b). Requirements for standby rescue persons apply to operations where these devices are used (§ 20.1703(f)).

In Appendix A to Part 20, APFs for SCBA devices remain unchanged except for those operating in demand or demand recirculating modes. APFs for these two devices have been changed from 5 to 100 to be consistent with ANSI and in response to public comment. Use of SCBA in demand open circuit and demand recirculating mode requires considerable caution. ~~In the NRC's view, the performance level and reliability of these devices in the demand mode is questionable.~~ The chance of facepiece leakage when operating in the negative pressure mode is considerably higher than when operating in a positive pressure mode. This is especially critical for devices that could be mistakenly used in immediately dangerous to life and health (IDLH) areas during emergency situations. Although ANSI lists relatively high APFs for these devices, they are not recommended by the NRC for use and acceptable alternative devices are readily available. Footnote h requires that controls be implemented to assure that these devices are not used in IDLH areas.

A specific statement is added in footnote f, to exclude radioactive noble gases from consideration as an inhalation hazard and advising that external (submersion) dose considerations should be the basis for protective actions. DAC values are listed for each noble gas isotope. This has led some licensees to inappropriately base respirator assignments in whole or in part on the presence of these gases. The requirement for monitoring external dose can be found in 10 CFR 20.1502.

IV. Issue of Compatibility for Agreement States

In accordance with the Policy Statement on Adequacy and Compatibility of Agreement State Programs published September 3, 1997 (62 FR 46517) and implementing procedures,

application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) Surveys and bioassays, as necessary, to evaluate actual intakes;

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(4) Written procedures regarding

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician that the individual user is medically fit to use respiratory protection equipment; before

(i) The initial fitting of a face sealing respirator;

1. Statement of the Problem

With the exception of the May 1991 revision to 10 CFR Part 20 that, among other things, required licensees to maintain the sum of internal and external dose as low as is reasonably achievable (ALARA), the Nuclear Regulatory Commission (NRC) has not made substantive technical changes in its regulation on the use of respiratory protection by its licensees in several decades. In the interim, the NRC has substantially revised regulation 10 CFR Part 20 to reflect new radiation protection recommendations with regard to primary dose limits and dosimetric models. The NRC has now prepared amendments to Subpart H ("Respiratory Protection and Controls to Restrict Internal Exposure") of 10 CFR Part 20 revisions to Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." NUREG-0041 (Rev. 1), "Manual of Respiratory Protection Against Airborne Radioactive Materials" is expected to be published following the final rule. These changes reaffirm the Commission's intention to reduce the unnecessary use of respirators when their use does not optimize the sum of the Deep Dose Equivalent (DDE) and the Committed Effective Dose Equivalent (CEDE), or Total Effective Dose Equivalent (TEDE). Instead of relying on respiratory protection devices, licensees are required to consider the use of process and engineering controls, filtered ventilation systems, decontamination of work areas, control of access to radiological areas, limitation of exposure time, and use of other types of exposure controls. The new regulations and guidance generally endorse the use of ANSI standard Z88.2-1992, "American National Standard Practice for Respiratory Protection," with a few exceptions. This ANSI standard represents the most current industry guidance for the use of respiratory protection when other ALARA-based alternatives are not practicable. The new NRC standards are designed to be consistent with the new OSHA regulations at 29 CFR Parts 1910 and 1926. While licensees are required by Part 20 to use one or more of the alternative control practices discussed above (i.e., avoid use of respirators in most circumstances), respirator use would be permitted if the practice will help to optimize the TEDE. Respirators might also be used in situations where:

(1) non-radioactive nuisance dust is present in the work area, or
(2) workers and/or the health physics department are in a relatively short-term learning process or making a transition from routine use of respirators, or
(3) the use of certain respiratory protection devices reduces heat stress on workers, or
(4) they are used as contamination control devices in high contamination but relatively low airborne radioactivity areas with the potential for significant resuspension, or
(5) a worker requests a respirator when the licensee has determined that use of a respirator is not needed, or
(6) they serve as a precautionary measure in which there is a large uncertainty in the magnitude of the projected concentrations of airborne material to which workers might be exposed.

In all cases, respirators should be selected to have the least possible impact on worker function (e.g., stress from heat, breathing resistance, ability to see and communicate). These and other options are permitted by the rule change, which also revises the current table of respirator assigned protection factors (APFs) to reflect the latest information and experience available.

§ 20.1703(b). While these changes may be justified on the basis of improved personnel safety under low temperature conditions, the potential impacts are addressed in the following section.

(3) The deletion of § 20.1703(d) removes the requirement to notify the NRC region in writing 30 days before the first use of respiratory protection. Removing a requirement for duplication of reporting is expected to result in a small reduction in regulatory burden for both the NRC and some licensees, and is addressed below in the value/impact analysis.

(4) The part of Footnote g to Table 1 of Appendix A which currently precludes the use of half mask facepiece air purifying respirators for protection against plutonium or other high-toxicity materials is deleted. Half-mask respirators, if properly fitted, maintained and worn, provide adequate protection against plutonium if used within the limitations stated in the NIOSH approval and in the rule. The NRC has not identified any current technical or scientific basis for such a prohibition, and deletion may result in some reduction in regulatory burden because the change should increase operational flexibility. This is evaluated further in the value/impact analysis.

(5) The addition of single use, disposable respiratory protection devices (e.g., dust masks) to the proposed Appendix A recognizes the utility of disposables and formally permits their use with no protective credit allowed. These devices have minimal physiological impact, and accommodate workers who request respirators (some States have OSHA rules which require providing respirators to workers who request them); NRC does not require fit testing or medical screening and although not quantifiable, they have been shown to provide some protection against intake. Although many of these devices cannot be tested for a measurable seal, licensees should train workers in their use and limitations. Use of such devices by persons desiring but not requiring respiratory protection (i.e., because of engineered control systems, or other factors) could result in substantial savings, and will be addressed further in the value/impact analysis.

(6) Permitting the use of "Reusable-Disposable" half-mask facepiece respirators, represents an acknowledgment of new developments in half-mask respiratory devices. This change permits increased use of these devices by licensees, and less use of more expensive respiratory protection by licensees. Reusable, reusable-disposable, or maintenance-free respiratory devices for use with radioactive material are relatively new variations on half-mask facepiece respirators. In these devices, the filter medium is an integral part of the facepiece and is not replaceable. The face-to-facepiece seal area is generally enhanced by the application of plastic or rubber. The devices have at least two adjustable suspension straps. These devices are acceptable to the NRC and are considered half masks as long as the following criteria are met: they are made of high efficiency filter media, they can be fit tested, and a fit check can be properly performed by the wearer upon donning. Since, under the proposed rule, these devices can replace more expensive respirators (primarily full facepiece respirators) their use has the potential for reducing the cost of the licensee's respiratory protection program. The use of such devices is addressed further in the value/impact analysis.

(7) The revision of Appendix A APF from 50 to 100 for air purifying, full face masks operating in negative pressure mode is consistent with ANSI Z88.2-1992 recommendations, and may result in increased flexibility (and reduced regulatory burden) for some licensees. This is addressed further in the value/impact analysis.

Missing something. Incomplete.

is known from dosimetry reports that the existing respiratory protection rules as implemented are effective in protecting licensee's employees from inhalation exposure to airborne radioactive materials, and that these rule changes constitute of respiratory protection. Although the changes marginally add to worker safety and health, there is no attempt to quantify added value or impact to employee health. Rather, the values and impacts of the changes are all related to potential saving or added cost in operating effective respirator programs at licensee sites. This analysis considers both power reactor licensees and materials licensees, and impacts and benefits of the new rules on respiratory protection programs are considered to be the same for both types of licensees. In making the estimates, the following general assumptions are made:

- There are about 250 licensees affected by the changes; 100 power reactor licensees and 150 nuclear materials licensees
- Labor cost is $145/hr for a power reactor licensee and $116/hr for other licensees
- NRC labor cost is estimated to be $70/hr
- Approximately 200,000 workers at licensee sites (primarily power reactors) are currently monitored for radiation exposure; about half of the monitored workers are exposed to a measurable dose; of those exposed to a measurable dose, about 10 percent/yr may use respirators (20,000)
- The most predominantly used respirators are the full mask negative pressure (NP) respirator, full mask positive pressure (PP) respirator or powered air-purifying respirator (PAPR), and full mask pressure demand (PD) Self Contained Breathing Apparatus (SCBA); no more than 10 percent currently use half-mask devices

These assumptions are made based on NRC data and on information obtained from industry experts on respiratory protection, licensees, and the Nuclear Energy Institute located in Washington, DC. The estimates and specific rationale used are presented below item by item following the same sequential order as the discussion in Section 4. A summary of the overall value and impact is presented at the end of this section.

(1) Elimination of Policy Statements

This change will save licensees the cost of preparing policy statements and also save NRC inspection staff from reviewing policy statements. It is assumed that about three licensees per year (one reactor licensee and two non-reactor licensees) would have prepared new policy statements in the future. Assuming that it would take 2.5 hours to prepare policy statements for a licensee, the cost saving per year would be:

($145/hr x 2.5 hr/licensee x 1 licensee) + ($116/hr x 2.5 hr/licensee x 2 licensees) ~ $1,000

Each licensee would also save the cost of an annual review of its policy statement. Assuming 0.25 hr for each review, for 250 licensees (100 reactor licensees and 150 non-reactor licensees), the annual saving would be:

could save substantial costs to licensees (especially power reactor licensees) with no reduction in worker safety.

Respirator programs currently cost about $245 per employee per year for a reactor licensee and $216 per employee per year for a non-reactor licensee (assuming 1 hour of training and fit testing plus $100 for medical examination). Because almost all respirator use among NRC licensees are for reactor operations, non-reactor licensees can be ignored in the approximation. This does not include the costs for respirators, replacement due to wear and tear, replacement of filters, or cleaning and maintenance.

Currently, it is estimated that there are about 1,000 respirator uses/reactor-year, primarily during maintenance and refueling, or about 100,000 uses per year in the U.S. This number has probably gone down considerably, but data on the change is not available. It is assumed that about 90 percent of all respirators with APFs greater than 1.0 are full-face piece respirators (APF = 50), with the remaining 10 percent, half-face mask respirators (APF = 10). It is further estimated that of all these applications, only about 10 percent require (based on ALARA considerations) use of respirators with APFs greater than one (but less than 10), while the remaining 90 percent of uses could be satisfied by a disposable respirator (no allowed protection factor). Therefore, under the new rule, about 90,000 traditional respirator uses could be replaced by disposables each year. Assuming 40 percent of all half or full facepiece respirator uses would be replaced by disposable respirators (40,000 per year, averaged over several years), the new rule would replace about 40,000 traditional respirator uses each year. Assuming the current industry maintains on the order of 500 respirators at each plant (50,000 respirators) which are used about 100,000 times per year, there would be about two uses per respirator per year.

Because of radiation protection concerns about contaminating the inside of respirators when they are removed after wear in contaminated environments, and worker's fears of breathing cold bacteria, or flu or AIDS viruses from used filters (some expired air will always exit through the filters and sneezing could spray a mist on them), industry generally uses each respirator only once before it is recycled for cleaning and filter replacement.

Further, assuming full face-piece and half-mask respirators last from 5 - 10 years (7.5 years on average) before being replaced, licensees would replace 50,000 respirators/7.5 years = 6,670 respirators per year. If these respirators were replaced by traditional respirators, the cost for half-mask ($25 each) and full-face mask ($150 each) respirators would be:

$$[(\$25 \times 0.1) + (\$150 \times 0.9)] \times 6{,}670 = \$917{,}125/\text{year}$$

The cost of replacing these traditional devices by disposable masks would be:

$$0.4 \times 100{,}000 \text{ masks/yr} \times \$0.8/\text{mask} = \$32{,}000/\text{year}$$

(i.e., the net savings would be about $885,125/year)

Assuming each worker uses a respirator two times per year, about 20,000 workers x 0.4 = 8,000 workers would be using disposable masks each year for the first time under the new rule. Assuming training on use of the new disposable respirators takes 0.2 hours/worker, the training costs would be:

$145/worker-hr x 0.2 hour x 8,000 workers/year = $232,000/year

For traditional respirator uses, if 5 percent of the work force is replaced each year, there would be about 1,000 new workers to train each year. Under the current regulations, that training cost would be:

$145/worker x 0.2 hours x 1,000 workers = $29,000/year

Maintenance costs for disposable masks would be zero. However, the maintenance costs for traditional respirators would be substantial for the 40,000 uses each year which could be avoided by using disposable masks. Assuming only 5 minutes per mask for cleaning and replacement of the filter(s) and bagging, the costs would be:

40,000 uses/year x 5/60 hr/use x $145/hr = $483,300/year

The cost of replacing the filter(s) on traditional masks would be:

40,000 uses/year x $7/use = $280,000/year

Thus, the total cost for traditional respirators would be about $1.7 million/year

New procedures would only be required if disposable masks were to be used, the cost for all operating reactors, assuming 2 hours of preparation per plant, would be:

2 hrs/plant x 100 plants x $145/hr = $29,000 **the first year only**
(or $6,000/year over a period of 5 years)

Cost Savings From Permitting Use of Disposables

Cost of Using Traditional Masks		Cost of Change to Disposables	
Replacing worn-out or damaged half or full-face respirators	917K	Cost of disposables	32K
Training new users of traditional masks	29K	Training on use of new disposables	232K
Respirator Maintenance	480K	Cost of writing new procedures	6K
Filter Replacement	280K		
Total	1706K	Total	270K

Thus the potential savings from permitting the use of disposables is about $1,436K.

(6) Permitting the Use of "Reusable-Disposable" Half-mask Facepiece Respirators

At the present time, essentially no power reactor licensees are using half–mask respirators in the NP mode (APF = 10). Current NRC guidance discourages the use of such devices as part

of licensed activities because they must be checked for fit with irritant smoke each time they are put on. Thus, licensees typically use a more expensive full facepiece respirator in the NP mode with an APF = 50, because they are not required to perform irritant smoke tests each time those devices are donned. Under the new rule change that requirement would be removed for half-masks, and licensees would have an opportunity to replace current full facepiece respirators with half-mask disposable or reusable-disposable respirators.

One of the newest types of half-face mask devices approved by NIOSH is the "reusable-disposable" half-mask respirator. These devices are substantially less costly than current half- or full-face masks and do not require any maintenance program, since they are simply discarded when wearers have completed their work. Thus, while less costly to purchase and maintain than full face-mask devices, the costs of new reusable-disposable facepiece respirators would mount up quickly under periods of heavy use. Thus, the value must be compared with the lifetime cost per use of the respiratory devices they might replace. Because the use of these half-mask respirators would require training and procedures comparable to current respirators, there are no expected cost reductions associated with their use except the initial purchase costs relative to the cost of maintaining and replacing worn-out half and full-face respirators. Because these respiratory devices will not be useful for as long as current, more expensive full-or half-mask facepiece respirators (with an accepted maintenance program), the cost of replacing some part of the currently used, more costly facepieces should also be considered in the cost analysis for the proposed rule.

It is assumed that about 10 percent of all traditional respirators in use are half-mask devices with an APF = 10; that means that about 0.1 x 50,000 = 5,000 of these devices might be used per year. If, as above, they are used about 20 times per year, cost $25 each, and last about 7.5 years on average, replacement costs are about:

$25/mask / 7.5 year x 5,000 uses/year = $16,650/year

Cleaning costs for these traditional respirators, using the same assumptions as in 6) above, would be:

5,000 uses/year x 5/60 hr/use x $145/hr = $60,417/year

Filter replacement costs at about $7 per mask would be about:

5,000 uses/year x $7/use = $35,000/year

The cost of reusable/disposable respirators is on the order of $7 (or less) each. It is assumed that they would also be used only once before disposal for each time an APF greater than one is required. Thus, annual costs of using these devices in place of traditional respirators would be:

5,000 uses/year x $7/device = $35,000/year

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.

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

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 in part 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 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

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.

Staff should check this year. The revision was actually published on 5/21/91. ✓

When the Commission's overall radiation protection regulations were significantly revised in ~~1992~~ 1991?, 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.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-99-207 - FINAL RULE: "RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURES, 10 CFR PART 20"**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

SIGNATURE

8/12/99

DATE

Entered on "AS" Yes ✓ No ____

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

IN RESPONSE, PLEASE
REFER TO: M990910

September 10, 1999

SECRETARY

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

John F. Cordes, Acting Director
Office of Commission Appellate Adjudication

FROM: Annette Vietti-Cook, Secretary

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 11:30 A.M., FRIDAY, SEPTEMBER 10, 1999, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

I. SECY-99-207 -- Final Rule: Respiratory Protection and Controls to Restrict Internal Exposures, 10 CFR Part 20

The Commission approved a final rule which amends 10 CFR Part 20, subject to the changes noted in attachment 1, to 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) regulations, reduce licensee burden without reducing worker safety, and are consistent with the Commission's intent to promulgate performance-based rules.

Following incorporation of these changes, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.
(EDO) (SECY Suspense: 10/1/99)

The staff should issue revised Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection," in final concurrent with the issuance of this final rule on respiratory protection.

In future rulemaking packages where the staff recommends partially adopting a voluntary consensus standard, the staff should explicitly identify to the Commission all portions of the consensus standard that are not being adopted, and provide a justification why those portions of the technical standard are inconsistent with applicable law or otherwise impractical.

The Occupational Safety and Health Administration allows a licensed health care professional to determine whether the user is medically fit to use respiratory protection equipment, as the paper indicates, but ANSI Z88.2-1992 specifies that a physician shall make the determination. On the next revision to the ANSI standard, the staff should encourage the ANSI Subcommittee to consider whether licensed health care professionals, such as occupational health nurses, are qualified to make medical fitness determinations.

II. SECY-99-216 -- Yankee Atomic Electric Company (Yankee Nuclear Power Station), Docket No. 50-029-LA, Yankee Atomic's Motion for Leave to Withdraw Appeal of LBP-99-14

The Commission approved a Memorandum and Order which grants Yankee Atomic Electric Company's May 26, 1999 motion to dismiss without prejudice its appeal of a Board order admitting four contentions and vacating both LBP-99-14 and LBP-99-17.

(Subsequently, on September 10, 1999, the Secretary signed the Memorandum and Order.)

Attachment: 1) Comments and Changes to Rulemaking Package in SECY-99-207
2) Changes to be Incorporated in the Memorandum and Order in SECY-99-216

cc: Chairman Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
EDO
OGC
CIO
CFO
OCAA
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance
DCS - P1-17

Attachment 1

Comments and Changes to Rulemaking Package in SECY-99-207

General Comments

1. The staff should revise the Federal Register Notice (FRN) and all attachments to avoid the implication that NRC is adopting the voluntary consensus standard in full.

Changes to the Federal Register Notice

2. On page 1, in the *Summary*, line 6, spell out OSHA (Occupational Safety and Health Administration) in the first paragraph.

3. On page 5, paragraph 2, line 1, delete 'unique'. In line 2 delete the comma.

4. On page 5, paragraph 3, revise the last line to read ' ... rather than adopt ~~rely on~~ OSHA regulations.'

5. On page 7, paragraph 1, delete the last sentence (There is little ... at greater risk.)

6. On Page 7, paragraph 2 incorrectly assumes that all regulatory guidance use by licensees is unenforceable. For most materials (non-reactor) licensees, incorporation of regulatory guides into their licenses as amendments is routine. This paragraph needs to be expanded and revised to reflect that in those cases, licensee commitments to use specific regulatory guidance are enforceable when incorporated in the license.

7. On page 7, the staff should enhance the discussion that addresses why NRC is retaining the Table in Appendix A in the rule rather than in guidance, including providing additional justification for the decision.

8. On page 8, paragraph 2, revise the last sentence to read 'Other program elements such as minimal training on ~~the~~ limitations of ~~these~~ devices and correct methods of use are required ~~would be considered essential~~.'

9. On page 10, revise line 4 from the top to read ' ... requests a respirator that will ~~, or if the respirator is~~ not be used ....'

10. On page 13, 2nd full paragraph, revise the last line to read ' ... user seal check on filtering facepiece respirators in the positive ....'

11. On page 13, last paragraph, line 6, spell out IDLH (Immediately Dangerous to Life or Health).

12. On page 16, paragraph 3, line 3, insert quotation marks after '(PAPR)'.

13. On page 18, 1st full paragraph, revise the last sentence to read ' ... or valve function, and that are ~~the presence or absence of which is~~ under the control of the respirator wearer, are ~~, may be~~ present ....'

14. On page 19, paragraph 3, revise line 5 to read ' ... is aware that most radionuclides ....'

15. On page 19, last paragraph and continuing to page 20, the staff should strengthen the justification that addresses why a physician, as opposed to a licensed health care professional, must determine whether the user is medically fit to use respiratory protection equipment. The Occupational Safety and Health Administration allows a licensed health care professional to make the determination, as the paper indicates, but ANSI Z88.2-1992 specifies that a physician shall make the determination.

16. On page 20, top paragraph, the last sentence should be ended after 'respirator'.

17. On page 21, last paragraph, revise line 2 to read ' ... persons must be immediately available to ....'

18. On page 22, paragraph 1, delete the last 3 sentences (Other differences are minor ... measurements of intake.)

19. On page 29, paragraph 2, revise line 4 to read '~~All~~ Licensees who ....' Revise line 5 to read ' ... program are expected ~~required~~ to submit a program ....'

20. On page 38, 1st full paragraph, delete the 4th sentence (In the NRC's view ... questionable.)

21. On page 51, revise the last line to read ' ... initial fitting of a face sealing ....'

Changes to the Regulatory Analysis

22. On page 1, line 4, delete the apostrophe in 'its'. Revise line 8 to read ' ... 10 CFR Part 20 and revisions to ....' Revise line 21 to read ' ... are not practical ~~practicable~~.' Revise lines 23-24 to read ' ... use of respirators in many ~~most~~ circumstances ....'

23. On page 3, paragraph number (5), revise line 3 to read ' ... physiological impact, and ....' In line 5, replace the comma with a semicolon.

24. On page 5, line 2 from the top, move the apostrophe in 'licensees' to the end of the word. In line 3, the end of the sentence appears incomplete or missing something and needs to be corrected.

25. On page 8, 2nd full paragraph, revise line 9 to read 'Therefore, under the new rule ....'

26. On page 9, line 5 from the top, insert the missing multiplication sign.

27. On page 10, 1st full paragraph, line 11, insert a comma after 'current'.

Changes to the Environmental Assessment

28. On page 1, next to the last line, delete the 's' at the end of 'revises'.

Changes to Congressional letters

29. In paragraph 2, revise line 1 to read ' ... are based in part on guidance ....' In line 5, move the apostrophe in 'workers' to the end of the word.

Changes to the Press Release

30. On page 1, paragraph 3, line 2, the staff should verify the revision date of 1992. The revision was published on May 21, 1991.

Attachment 2

Changes to be Incorporated in the Memorandum and Order in SECY-99-216

1. On page 2, 1st full paragraph, at the end of line 7, insert the following footnote: 'The Commission is also declining to take review sua sponte of the Licensing Board's Memorandum and Order (LBP-99-27) terminating, without prejudice or conditions, all portions of the proceedings except for the instant appeal of LBP-99-14.'

2. On page 3, line 4 from the top, after the period, insert a new sentence as follows: 'The admitted contentions were focused on alleged deficiencies and inadequacies of the withdrawn LTP.' Revise the next sentence to read 'Moreover, ~~In any subsequent proceeding,~~ the intervenors ....'

3. On page 3, revise line 5 from the top to read ' ...same position in any subsequent proceeding as if they had ....'

4. On page 3, delete the sentence in lines 8 to 11 from the top (Similarly, the termination of this ... before the Commission.)

5. On page 3, in the 1st full paragraph, revise line 1 to read 'For ~~both~~ these reasons, we decline ....'

6. On page 4, insert the following sentence as a new second paragraph under 'CONCLUSION': 'Therefore, the proceeding is terminated.'