

BRIEFING POINTS

10 CFR PART 20 - SUBPART H

**RESPIRATORY PROTECTION AND CONTROLS TO
RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS**

I. BACKGROUND:

- 1990: Changes to Subpart H were put on hold because ANSI Z88.2, the industry standard on respiratory protection, was being revised but had not been published. It was expected that the new standard would include guidance that would affect Subpart H as well as NRC guidance documents.
- 1992: ANSI Z88.2 was published. As anticipated, the standard contained changes in practices that called for corresponding changes in Subpart H as well as in the guidance documents, specifically Reg. Guide 8.15 and NUREG 0041.
- 1993: NRR requested that the effort to revise Subpart H should be revived in view of the publication of ANSI Z88.2.
- 1994: RES activates the effort to revise Subpart H and the guidance documents. A working group is formed for this purpose, which included one representative from each of NRR, NMSS, and RES. A contractor is hired to assist in drafting the revised rule and guidance documents.
- 1995: Work on the proposed revisions completed, and a consensus is reached on the form and content of the changes. A draft revised Reg. Guide 8.15 and NUREG 0041 are also prepared, and all are assembled into a rulemaking package.

March 1996:

The draft package is submitted to division managers for review and approval.

July 1996:

Director, DRA/RES does not approve of the package. The div. director disapproves of the following items, and states that the following changes be made:

- 1) Appendix A of 10 Part 20 (which specifies the assigned protection factors for respirators) should be moved out of Part 20 and placed in RG 8.15.
- 2) An information notice should be issued to alert industry to reductions in protection factors recommended in ANSI Z88.2.
- 3) Disposable respirators with a protection factor of 1 should not be included in Appendix A.

- 4) A rulemaking plan for revision of Subpart H had not been approved by the Commission, and a plan must be prepared and submitted for Commission approval.

September 1996:

Discussions between NRR, NMSS, and RES resulted in RES revising its position on items 2 and 3, especially after OGC provided a written interpretation supporting staff's position of including disposable respirators into Appendix A. RES insisted that items 1 and 4 were not negotiable.

October, 1996:

RES submits a rulemaking plan to the program offices for approval. The plan contains items that the program offices had already made clear they cannot accept, particularly removing Appendix A from Part 20. In addition, the plan contained estimated efforts for completion of the work that were excessive in view of the fact that the staff had completed most of the revision work at the time the plan was submitted. The program offices responded that they cannot concur on the proposed plan because it is flawed.

November 1996:

A meeting at the division director level between RES, NRR, and NMSS failed to resolve the disagreements.

February 1997:

RES downgrades the Subpart H revision project to "On Hold" in a proposed priority listing for ongoing work. NRR does not concur on the downgrade. Status then changed to "Medium Priority."

March 1997:

RES submits a revised rulemaking plan for concurrence by the program offices. The plan still contains the proposal to remove Appendix A from Part 20, despite continued and clear statements from both NRR and NMSS that this action would be unacceptable to both offices.

II. Major Issues of Disagreement:

1. Because most of the work required for revision of Subpart H and the guidance documents has already been completed, the program office staff believes that the work estimates in the proposed plan neither reflects nor acknowledges the extensive effort already expended by the staff of RES, NRR, and NMSS. NRR and NMSS would like the plan to indicate accurately the state of the revision effort and the balance of work that remains to be done.
2. Both NRR and NMSS agree that removal of Appendix A from Part 20 would take away NRC's ability to regulate important aspects of the use of respirators. Because protection factors for different respirators are assigned by consensus reached amongst experts in the

field, licensees would have no sound basis for selection of protection factors on a “performance” basis, nor would NRC have any basis to assess such “performance based” selections.

Protection factors are used both as a basis of selecting the appropriate type of respirator for a given situation, and are also used to calculate intakes for purposes of showing compliance with the occupational dose limits. The protection factor is the constant of proportionality between the air sampling data and the intake assigned to the worker. Protection factors cannot be measured in the field (except under research conditions using special equipment), and they are also not the same quantities as those measured during respirator fit testing of workers (the fit factors). They are akin to the quality factors used to convert absorbed dose to dose equivalent. The quality factors cannot be measured, and are assigned by cognizant experts in the field of radiation protection, and are incorporated into Part 20 as conversion constants that must be used by all licensees. Protection factors play much the same role in respirator use, and are assigned on much the same basis, by cognizant experts and, currently, are incorporated in Part 20 for use by all licensees.

^{NMSS}
NRR and ~~RES~~ have made repeated efforts to present and clarify these points to RES, and to emphasize that removal of Appendix A from Part 20 would make the protection factors nonenforceable, and would therefore in effect remove NRC’s ability to regulate the assessment of intakes by workers using respirators. These efforts have failed, and the proposed revisions are held up pending resolution of these items.

Note: This briefing coordinated with the corresponding briefing prepared by NRR.