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

November 20, 1996

MEMORANDUM TO: David L. Morrison, Director
Office of Nuclear Regulatory Research

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

Carl J Paperiello

SUBJECT: RULEMAKING PLAN: RESPIRATORY PROTECTION
(SUBPART H AND APPENDIX A TO PART 20)

The Office of Nuclear Material Safety and Safeguards has reviewed the proposed rulemaking plan for revising Subpart H of 10 CFR Part 20, and does not concur with the plan as detailed in the following comments:

1. Subpart H should be revised to update it to reflect current state-of-the art described partly in ANSI Z88.2-1992. We also agree that Subpart H should be revised to remove some requirements that have become unnecessary, and in some instances cumbersome, in view of current radiation protection practices.

   We would note that these changes have already been extensively discussed by my staff with staff from your office and that of Nuclear Reactor Regulation, and that a consensus has been reached on the changes that should be made. A consensus has also been reached on the material, currently in Subpart H, that should more appropriately be included in Regulatory Guide 8.15 or NUREG-0041. These changes were designed to make the proposed Subpart H substantially more performance based than the version currently in Part 20.

2. We do not agree with the removal of Appendix A from 10 CFR Part 20. It is not clear why such an action would make the regulations more performance based. The protection factors (PF) listed in Appendix A represent the means by which licensees convert measured air concentrations to intakes, and therefore to doses received. These factors are not measured in the field, but are assigned by expert consensus using the best available data. State-of-the art does not permit licensees to reliably establish such factors for their facilities on an objectively defensible basis. It is therefore necessary that NRC set these factors, and it is important that all our licensees use the same values of PFs for given types of respirators. The only means to ensure that this in fact is the case is to include these factors in the regulations.

Contact: Sami Sherbini, NMSS
(301) 415-7902

We do agree that it may be somewhat easier to change the PFs, in the future, if they were in a regulatory guide than in the regulations. However, incorporation of the PFs in the guides would leave NRC no means to ensure that the factors used by a licensee are appropriate, and are also comparable to those used by other licensees. This is especially the case because licensees currently rarely commit themselves to adhere to specific regulatory guides in their licensing documents. We would also like to point out that PFs do not change rapidly, and that the last time significant changes were made to PFs was approximately 20-years ago. Of course, this does not guarantee that future changes will not occur more frequently, but it does point to the fact that they are not rapidly changing parameters.

3. We do not believe that an information notice is a viable option at this time. The purpose of the information notice would be to notify licensees of changes in the PFs of some respirator types. However, licensees are required to use the PFs listed in Appendix A of 10 CFR Part 20, and would therefore not be permitted to use the information provided in the notice. The affected respirators are not of the types frequently used by our licensees, and we expect that the changes may affect very few, if any, licensees.

   In view of the above, and rather than issue an information notice, we recommend that the rulemaking be expedited to provide the revised information to our licensees as quickly as possible. To that end, we recommend that the draft materials developed to date by our staffs and NRR staff be used to expedite this process. In the meantime, we are not averse to issuing a short notice alerting licensees of the reductions in some PFs and informing them that the relevant sections of Part 20 will be revised shortly to permit use of updated guidance.

4. We do not agree with your interpretation that respirators with a PF of 1, "do not limit intakes," and are therefore not subject to the requirements in Subpart H. Our interpretation of Subpart H is that the only purpose respirators are worn is in fact to limit intakes. That, by definition, is their function, and the statement "to limit intakes" in the rule is, in this context, redundant. Subpart H is clearly divided into two sections: §20.1703(a), which applies to any use of a respirator, regardless of the degree of protection provided, and §20.1703(b), which specifies additional requirements to be met if the licensee wishes to take credit for the protection provided by the respirator.

   Section 20.1703(a) addresses the concern that respirators are potentially hazardous equipment, to be used only by those individuals who are trained to use them, who have been certified to be medically fit for such use, and the use of which is under the supervision of personnel who understand the hazards involved in the use of respirators and the requirements to keep them in proper operating condition. These are safety requirements that are unrelated to the protection provided by the respirators against airborne radioactive materials, and therefore are

independent of the PF assigned to the respirator. Section 20.1703(a) is largely an industrial safety provision, and the term "to limit intakes" inserted at the beginning of Subpart H is intended to limit its applicability to those uses involving radioactive materials, rather than any industrial use of respirators.

5. We believe that disposable/reusable respirators, with an assigned PF of 1, should be included in the table in Appendix A. Failure to include these respirators in the Appendix would permit licensees to use PF other than 1, such as the higher PF recommended in ANSI Z88.2-1992. The NRC believes that a PF higher than 1 is unjustified at this time for these devices.

   We would like to note that assigning a PF of 1 for respiratory protection devices is not a new practice, and has been in use for years for some devices, mainly iodine cartridges. These devices have been used extensively by licensees, but NRC has not permitted a PF above 1 except with specific approval. There were technical reasons for adopting this position, and the system has worked well. Licensees are also provided avenues for realizing the benefits offered by such devices, even though the protection factor is 1. This is accomplished by permitting licensees to base their intake assessments on bioassay results if they choose to do so. Licensees have availed themselves of this option in situations involving significant potential intakes, and may continue to do so with the disposable/reusable respirators.

6. We do not agree that the current rule would permit licensees to use disposable/reusable respirators if they are not listed in Appendix A. Section 20.1703 currently requires that personnel be fit-tested on all respirators they intend to use, even if no credit for protection is to be taken. They also require testing the respirators for operability immediately prior to each use.

   Fit testing of disposable/reusable respirators would constitute an unnecessary burden on licensees. In addition, testing these respirators for operability immediately prior to use is not possible because of the manner in which these respirators are constructed. The effect would be to disqualify their use without specific exemptions. The staff had considered this problem and decided that the best approach would be to list these respirators in Appendix A, with a PF of 1, and specifically exempt them, in the Appendix, from the fit testing and testing immediately before use requirements in Subpart H.

In view of the above considerations, we support Option 2 as the rulemaking option that addresses our needs most closely. Specifically, the following is recommended:

1. Amend Subpart H to: make it consistent with the latest technical guidance in the field; remove requirements that are no longer necessary in view of current radiation protection practices; and simplify the requirements by removing any items in the current regulations that are

of the nature of guidance. Such items would be included in a revised Regulatory Guide 8.15 or a revised NUREG-0041.

2. Revise Appendix A to 10 CFR Part 20 to update the PFs, add or remove approved respirator types as necessary, and transfer any guidance items to Regulatory Guide 8.15 or NUREG-0041.

3. Rewrite Regulatory Guide 8.15 to include items transferred from Subpart H, and to update the guidance information.

4. Rewrite NUREG-0041 to update the review of the state-of-the art in respiratory protection.

We strongly suggest that the consensus arrived at by our respective staffs to date on many of these matters be incorporated into this effort.