My name is Wesley J. Kenneweg. I am employed as a Product Manager for National Mine Service Company. We would like to express our comments to the proposed changes to the federal certification and testing program for respirators as noted by NIOSH in the announcement for this meeting:

1. ALTERNATIVES TO THE EXISTING PROGRAM

It is our belief that the existing program should be revised but the testing and certification should be done jointly by NIOSH and MSHA as is now the case. MSHA (and previously MESA and the USBM) has a long history of involvement in the approval and more importantly the actual use and applications of respiratory protective equipment in underground mines. Their contributions to the approval process are, therefore, necessary and desired.

2. PERFORMANCE SPECIFICATIONS

We have no objection to upgrading the performance specifications for testing of respiratory protective equipment provided that these specifications are in fact realistic and established through the rulemaking process. One change that should be considered is a greater emphasis on machine testing which will give the applicant and user a more precise guideline for actual performance requirements set forth for each respirator.

3. QUALITY CONTROL

It is agreed that an "in depth" review of an applicants quality control plan is not necessary providing that the applicant does certify that an acceptable QC plan is in place and is adequate to insure product quality based on the criteria set by NIOSH. There is also no objection to a field audit program assuming that NIOSH will consider all the ramifications of such a program once implemented. One possible area of concern is the testing of respiratory protection equipment obtained in the field against existing performance criteria. Is NIOSH suggesting that, with each change enacted to the performance criteria by NIOSH, the manufacturer must:
A. Recall all of his respiratory products and modify them if necessary to meet these new criteria.

B. Resubmit all of his respiratory products for reapproval under the new criteria.

C. In the case of used equipment, be accountable for the misuse and poor maintenance of his products by the enduser. This misuse and lack of maintenance could be cause for failure during testing rather than the actual design of the certified products.

4. ENGINEERING DRAWINGS

If NIOSH is not in fact reviewing and approving tolerance drawings in the present program, then we feel an elimination of the submission of these drawings with approval applications would be welcome as it would help eliminate some of the red tape involved in the long drawn out approval process. The requirement for detailed engineering design (failure mode) analysis for each respirator submitted may be acceptable to us, but the parameters of such an analysis need to be carefully reviewed and discussed further after NIOSH has provided the manufacturers with a clear definition of what this analysis is to encompass.

5. CHANGES TO APPROVED DEVICES

We have no objection to eliminating the requirement that all changes made to a respiratory protection device be submitted to NIOSH as a request for extension of approval. NIOSH's comment that such an indiscriminate system in the case of insignificant changes can place a burden on the applicant with no positive impact on the enduser is well taken. Under the suggested plan, however, NIOSH must define the terms "significantly revised or redesigned" since a cosmetic change which does not affect the function of the respirator could be considered "significant" by one person and not another.

6. WITNESSING OF APPROVAL TESTS

It first should be noted that NIOSH's suggestion to bar the applicants from viewing the approval tests is in direct contradiction to NIOSH's letter of June 20, 1980 (attached herewith) which outlines the procedures by which an applicant can view the tests and comment on the test results. It is duly noted in this notice of June 20, 1980 that NIOSH based these new procedures on a thorough analysis of the issue. Allowing the applicant to view the testing is essential and desired if the test results are to be substantiated. This is particularly important if the results are negative. In this instance, the applicant can more easily determine the exact cause for the failure. NIOSH/MSHA control of test proceedings should be adequate to insure that the witnesses do not interfere with the testing, and if the testing criteria is conducted properly, the test personnel should not feel pressured by the presence of the applicant.
We, therefore, would like to go on record as being in agreement with NIOSH's letter of June 20, 1980 concerning this matter.

7. DURATION OF APPROVAL

NIOSH's efforts to streamline the approvals program for the applicants and ultimately the enduser would not be enhanced by a 5 year reapproval program. If, as noted previously, there are no significant revisions to the respiratory device as determined by NIOSH through their field audit program, there is no reason for the equipment to be resubmitted for approval after 5 years. This resubmittal with the stipulation that the device and its component parts can not be sold until reapproval is granted, could very easily result in an increased hazard to the enduser simply due to the fact that he will not be able to obtain the necessary respiratory protection products or its component parts during this reapproval process. At best, he may be forced to purchase alternate equipment during this time even though the equipment in his possession is designed according to the specifications under which NIOSH/MSHA granted the original certification. This reapproval would also have the affect of further extending the time required for approval testing at NIOSH since NIOSH would eventually be involved in a continuous program of reapproving devices as well as processing the new approval applications that are submitted to them on a regular basis. Thus, we feel this suggested change would not be a beneficial one.

8. TESTING OF PROTO-TYPE RESPIRATORS

Proto-type testing is important as noted by NIOSH under the points of discussion for this meeting. However, we feel it is equally important for NIOSH to be willing to discuss the results of these tests with the manufacturer. By refusing to review the test results with the manufacturer, NIOSH is negating a good portion of the positive benefits that can be derived from such testing. Another point for discussion here is the viewing of such testing by the manufacturer. Here again, we feel that this is an important and necessary part of the testing process.

9. APPROVAL TESTS, GROUP TESTING

Group testing of specific types of respirators sounds like an ideal situation if everyone were working on the same type of respirator at the same time. However, by forcing the manufacturer to either speed up his engineering of the product to meet a specified NIOSH test date or to wait until the next call-up for the particular respirator involved, NIOSH is again putting an unfair burden on the manufacturer and ultimately the enduser of the device. Unless NIOSH is planning to staff the approvals branch with additional people to handle the group tests and the submittals that arrive outside the designated acceptance period, we must go on record as being against this suggested change.
10. PUBLICATION OF TEST DATA

The publishing of failing test data should not be considered as a major factor in encouraging the manufacturer to be more careful in designing his products. The fact that he has taken the time and expense to engineer a respiratory product according to NIOSH's and MSHA's performance criteria should not be forgotten nor taken lightly. The publishing of test data may generate a long lasting but unfounded negative attitude toward the product involved or other respiratory products manufactured by the applicant or even other manufacturers. Thus, negative aspects of such a policy change by NIOSH would seem to outweigh any foreseeable positive affects for NIOSH, the manufacturer, or the enduser.

This concludes our statement. We thank you for giving us the opportunity to express our views relative to this matter.

Wesley J. Kenneweg
During the past several years, various manufacturers and trade associations have requested that NIOSH implement a formal appeals procedure applicable to the respirator testing and certification program jointly conducted by NIOSH and the Mine Safety and Health Administration (MSHA) under 30 CFR Part 11. Based on a thorough analysis of the issue, NIOSH agrees that a formal appeals procedure should be incorporated into the program. Accordingly, effective July 1, 1980, the following appeals procedure will be implemented:

1. Upon written request, the applicant or his agent will be informed of the test date(s) pertaining to the applicant’s equipment. NIOSH will provide the applicant or his agent with a minimum of five working days (i.e., excluding Saturdays and Sundays) advance notice of the scheduled test date(s);

2. Applicant or his agent will be permitted to witness the test(s) but will not be allowed to interfere with or otherwise interrupt the test(s);

3. Applicant or his agent may appeal the test results based on one or more of the following three reasons:
   a. Conducted the wrong test.
   b. Performed the right test incorrectly.
   c. Misinterpreted the test results;

4. A written appeal must be submitted to the Director, Division of Safety Research (DSR), within two working days of the test completion in the cases of 3a. and 3b. and within three working days of receipt of the test results in the case of 3c;

5. When an appeal is received, the Director, DSR, will designate a senior, experienced NIOSH engineer or scientist not assigned to the Division of Safety Research to serve as an appeal arbiter;

6. An informal hearing will be held within 7 working days of receipt of an appeal. The appeal arbiter will provide the Director, DSR, with a written decision within five working days of the hearing. The hearing arbiter will either uphold the test results, reverse the test results, or order retesting.

Sincerely yours,

James A. Oppold, Ph.D., PE, CSP
Director
Division of Safety Research

June 20, 1980