I am Earle P. Shoub, Consultant to the American Optical Corporation. Accompanying me are Mr. William A. Carruth, Quality Assurance Manager, and Dr. David Dreifus, Safety Technology, R&D Director. We are all pleased to have the opportunity to be here today to present this statement.

The American Optical Corporation, which is vitally interested in the subject of this meeting and the committee report upon which it is based, has been manufacturing certified air-purifying and air-supplying respirators from the time of the earliest approval schedules promulgated by the Bureau of Mines. Presently, AO is among the largest respirator manufacturers in the United States. All of its respirators for industrial use are jointly certified by NIOSH and MSHA. AO speaks from this base of long experience and total participation in the certification program.

An open appraisal of the respirator certification program is a commendable, timely undertaking. The topics discussed in the committee report and set forth in the Federal Register of June 18, 1980, are generally germane to the laudable desire to effect improvements in the procedures and program for the certification of respirators. In many instances, however, the discussions and conclusions require tempering in the light of Congressional wisdom, limited statutory authority, due process, and the realities of the work place.

The report of the committee appointed by the Director of NIOSH contains a review of the agency's statutory authority to engage in any program to certify or approve respirators. This statutory authority appears to envision a program jointly managed by MSHA and NIOSH. It is important to note that the statutory

authority includes stringent requirements for rule making and that in ordinary circumstances there is no provision for ignoring due process.

AO is aware that NIOSH has adopted and regularly uses variations upon and additions to the published testing procedures based on "notices to respirator manufacturers", which have not been published in the regulations. In some cases, all the manufacturers did not receive the notice involved. These arbitrarily made changes may have been necessary temporary measures, but since some are as much as three to four years old and older, publication, public comment, and proper rule making could easily have been accomplished by now. AO submits that the rule making procedures of the Act should be followed until such time as other legislation is actually enacted.

Moreover, while AO is in favor of periodic reappraisal and improvement in any program, it believes that a meaningful reappraisal can be conducted only if all involved parties are fully informed about the situation which exists at the time of reappraisal. It, therefore, urges NIOSH to collect all its unofficial and official requirements which are not presently contained in Part 11 and to proceed to amend that regulation so as to include every requirement, testing procedure, interpretation, performance standard, administrative procedure or process, which is de facto in place so that the regulation will become a full disclosure of the status quo. In this manner all interested parties will be on an equal footing in commenting on any proposed new or revised regulations.

AO is convinced that this procedure would serve the best interests of labor and management as well as respirator manufacturers and potential manufacturers. The

ultimate respirator user and his or her representatives would, it is believed, receive the greatest benefit.

Turning now to the specific topics which appear in the notice of this meeting contained in the Federal Register of June 18, 1980, the American Optical Corporation would like to offer the following comments:

1. Performance Specifications: The institution of performance specifications may be desirable and provide certification requirements more amenable to revision through the public rule making procedure upon which NIOSH promises to rely. There are, however, some features not addressed under this topic which require consideration. Among these features are:

   a. What effect will a modification of a standard have on existing approvals? This is a difficult issue which does not lend itself to a universal, pre-determined result. AO believes it would be desirable for NIOSH to utilize the same rule making procedure to expire existing approvals as it indicates it will use to modify a performance standard.

   b. Determination of compliance with a performance standard will frequently depend on the selection of the method of measurement. The procedure for determining performance should be completely spelled out in the regulations and should be precisely the same as the procedures used by NIOSH to verify compliance in field surveys. This comment would increase in importance if the certification program moves from a series of go- no go tests to ones with quantitative measurements indicating the level of quality. It would become almost inescapable

if there should be more than one source of certification or field audit.

c. Because they are amenable to use to grade or rate the quality of the product being examined, performance standards should be designed to apply equally to all the purposes, places, and industries in which the product may be used. Also, for this reason, all such requirements for certification should be measurable in a graded, reliable fashion so that the total respirator may be rated.

2. Quality Control: The thrust of this topic appears to be an assertion that the manufacturer shall be responsible for the quality of its product at the time of sale, while in distributors' and purchasers' stocks, and during and after use, including extended use. At the same time, NIOSH proposes to eliminate or reduce considerably the information concerning the manufacturer's quality control plan presently required as part of each application. Some comments immediately come to mind:

a. A quality control plan which provides assurance that the percent defective approved product will not exceed a predetermined limit would permit some saving in the quantity of copies and bulk of an application. The percent defective for each type of deficiency acceptable to NIOSH, however, should be spelled out in its regulations and be the same for all manufacturers.

b. Sampling by NIOSH from manufacturers', distributors' and purchasers' stores to verify compliance with the above limit is not greatly different from present requirements. Sampling devices in actual use is a doubtful

tool to help locate previously undetected inherent weaknesses in design and in maintenance programs. All the pertinent information on which to assign each piece of responsibility is unlikely to be uncovered. Penalty may too readily fall on the wrong shoulders.

c. As indicated, it does not appear to be appropriate to create a whipping boy. Before the results of an unsatisfactory field audit are permitted to be used adversely to a manufacturer, it should be established that the cause of dissatisfaction is within his control and that it does not involve deviation from any of the requirements for respirator design based on sound engineering and scientific principles, and evidence of good workmanship subject to and approved by NIOSH.

d. Except in instances of immediate urgency and severity, an adequate opportunity for adminstrative and other appeals should be available before action is required or adverse information published.

e. The proposal to publish the results of market and work place surveys is of doubtful value, may be misleading, and requires expansion to be made at all meaningful. Only test results about devices which have not been mishandled or excessively used should be recognized. Equally important is that field surveys must employ only established testing procedures and be completely isolated from the development and trial of new tests.

3. Engineering Drawings with Dimensional Tolerances: While it is tempting to embrace the proposal to eliminate these tedious detailed drawings except when a special need arises, one wonders how NIOSH would exercise its responsi-

bility to review applications "...for respirator design based on sound engineering and scientific principles, construction of suitable materials, and evidence of good workmanship..." without the details which would be included on some of these drawings.

4. Changes to Approved Devices: AO concurs that introducing nonsignificant changes without requiring obtaining an extension of approval should be permitted. It recommends that any regulation to this effect include an unambiguous definition of "nonsignificant change".

5. Witnessing of Approval Tests: The proper conduct of tests by NIOSH is of great concern to all interested parties. If NIOSH's concern is limited, as stated, to preventing unwarranted interference during the performance of tests, there should be no difficulty in specifying the role to be played by witnesses during tests. The proper conduct of tests, adherence to published procedures, and recording of results are obviously essential ingredients under the current regulations if all interested parties, including the ultimate user, are to be protected and made to have confidence in the system and the certification. Adding a rating or grading scale by way of publishing results of tests only increases the importance of the correctness of the collected data. In view of the potential consequences and essential nature of the tests performed by NIOSH, it is unthinkable that they should only be conducted in secrecy without professional scrutiny by those affected.

6. Duration of Approval: There is no discernable advantage to be derived from a system which requires periodic reapproval. It is more important to

establish a valid relationship with technological advances. When improved regulations are promulgated, they could readily include a termination date for prior approvals of devices which do not meet the latest requirements. Enough time should be allowed for NIOSH to process all applications for renewals.

7. Product Quality Requirements: No comment.

8. Unpublished Test Requirements: AO heartily concurs that there should be no unpublished test requirements. It has repeatedly made and emphasized this point. It would add, however, that there should also be no ambiguous test requirements.

9. Testing of Prototype Respirators: NIOSH cannot escape its role as the national reference laboratory for respirators. Prototype testing is one way in which laboratories, public and private, can verify their performance. Unduly delaying prototype testing would not work to the advantage of the respirator user who wishes to employ the most modern, certified device. Prototype testing should be given equal weight and attention with other testing.

10. Group Testing of Respirators: This approach subtly prevents respirator manufacturers from witnessing tests, since the products of various manufacturers would be tested simultaneously. At the same time, because it could delay testing field audit samples, it could conceivably delay extending protection to workers who are dependent on respiratory protection to help preserve their health.

11. User and Maintenance Manuals: Explicit, easily followed manuals should be helpful, provided they are put into service. It must be remembered that the persons in the work place will carry much of the burden.

12. NIOSH Systems Manual: Since many provisions of a manual of this type would impact on and influence regulations and procedures promulgated through public rule making, the NIOSH Systems Manual should be promulgated and revised as necessary by the same procedure.

13. Publication of Test Data: If data is to be published, the manufacturer affected should be able to ascertain whether it is correct and obtain any legitimate correction. Witnessing tests and equitable appeals procedures are two important rights which should not be denied.