Department of
Health and Human Resources
Public Health Service

TRANSCRIPT

Title of Conference: NIOSH - Public Meeting on the Testing and Certification Program

Place: National Bureau of Standards, Gaithersburg, Maryland

Date: July 29, 1980 Starting Time: 9:00 a.m.

Contractor: _____

_____

_____

_____

Requisition Number: _____

List of Attendees:

DR. JON MAY

Chairperson

Hearing Assistant

ABL Associates, Inc.

I N D E X

P R O C E E D I N G S

My name is Richard M. Duffy. I am the Industrial Hygienist and Occupational Health and Safety Coordinator for the International Association of Fire Fighters, AFL-CIO, CLC and I am here this morning to present to you our concerns and views associated with the role of the National Institute for Occupational Safety and Health in the testing and certification of respiratory protective equipment. I am accompanied today by Bill Hoyle, President of our Washington, D.C. affiliate. We will both be available to answer questions at the conclusion of this testimony.

In order for NIOSH, as well as others in attendance here, to fully understand what the International Association of Fire Fighters is and what its interests are in the testing and certification of respiratory protective equipment, I will first offer some brief, preliminary background information about our organization.

The International Association of Fire Fighters is an international union affiliated with the AFL-CIO and the Canadian Labor Congress. We have been in existence since 1918 and our offices are located at 1750 New York Avenue, N.W., Washington, D.C.

At present we represent approximately 180,000 paid professional fire service employees in the United States and Canada. This total membership represents approximately 75% of the paid professional fire fighters in the United States and approximately 95% in Canada. The membership of the IAFF

works for various employers including the federal government, states, counties, municipalities, fire districts, airports, and industrial manufacturers. While our membership may be diverse in terms of geographical location, climate, fire ground tactics, apparatus, and equipment, one thing all our fire fighters have in common is that they utilize respiratory protective equipment, specifically self-contained breathing apparatus.

The IAFF has been deeply involved with fire fighters occupational safety and health problems for the past 25 years. We have worked with a number of government agencies on research and development projects designed to improve fire fighters' personal protective equipment. For example we have worked with the National Aeronautics and Space Administration on a project designed to incorporate advancing "space age" technology into the development of a new generation of self-contained breathing apparatus. In another project with NASA and the United States Fire Administration we are continuing work on a complete integrated fire fighters protective ensemble. Our organization developed specific standards under a National Bureau of Standards grant for fire fighters personal protective equipment and we have worked and will continue to work with various government agencies, such as the Occupational Safety and Health Administration and NIOSH, and consensus standard organizations, such as the National Fire Protection Association, on developing better standards for the protection of fire fighters' safety and health.

Another area which I would like to discuss briefly is the incidence of IAFF members' deaths, injuries, and illnesses. Each year we conduct an annual Death and Injury survey with the cooperation of our affiliates and the various fire department administrators. Over the past several years this survey has indicated that fire fighting is the most hazardous occupation in the United States. Our latest report indicates that a total of 135 IAFF fire fighters lost their lives in on-the-job accidents or from occupational diseases. There were 74 deaths of professional fire fighters in the line of duty during that year and 61 deaths attributed to occupationally induced diseases. Of those fire fighter deaths attributed to occupational diseases, heart disease is single greatest contributor to death at 77 percent and lung disease is second at 21 percent. These figures reflect recognition as an occupational related disease required by the applicable heart and lung statutes. An uncounted factor is the number of fire fighter deaths each year that occur due to occupationally induced diseases that are not recognized by statute and not included in the total.

The latest survey also indicates that 391 fire fighters were forced to retire or change occupations because of occupational diseases. Of this number, 260 had heart disease, 53 respiratory disease, and the remainder suffered from other ailments.

During the same year, 46,668 injuries were sustained by fire fighters, of which 33,353 injuries were sustained

while at the scene of a fire. Injuries sustained on the job forced 587 fire fighters to leave their departments or retire.

Our statistics also reflect that 10 percent of the total injuries were caused by inhalation of toxic gases. While our survey does not identify the causal factors involved in fire fighter fatalities, a review of our files indicate that a large percentage of IAFF membership deaths can be contributed to the inhalation of toxic gases. Most in attendance here today have heard of the fire fighter deaths in Syracuse, New York, Lubbock, Texas, Los Angeles, California and most recently Dade County, Florida and Saskatoon, Saskatchewan, where the use of self-contained breathing apparatus played a role. These fire fighter deaths and many others that have occurred while utilizing SCBA can be attributed to breathing apparatus performance (demand versus positive pressure), deficiencies in fire department procedures governing SCBA use (testing, maintenance and repair), breathing apparatus malfunction (poor engineering design or lack of maintenance and/or repair), or entrapment and/or disorientation with subsequent depletion of air supply.

While all fire fighters recognize the danger of a collapsing wall, explosion, backdraft, or other unanticipated events on a daily basis, they must also contend with fire, smoke, heat, and toxic gases as a regular condition of their employment. It is therefore, essential that there be sufficient and adequate personal protective equipment for the fire

fighter to execute each and every hazardous assignment. In addition, the fire fighters' SCBA is his life line during a fire emergency and each time he enters a burning structure he places his life on its integrity.

Because of the importance of the SCBA's and the IAFF-SCBA's, the IAFF has, in the past, alerted NIOSH of the various problems we have uncovered in the field.

Our efforts, as well as those of NIOSH, I'm pleased to say, have especially intensified after the Lubbock, Texas, incident. We are hopeful that this public hearing results in a program that will benefit the users of respiratory equipment.

To begin our testimony today, I would like to say that the IAFF fully concurs with the NIOSH position where, under the Department of Health and Human Services, NIOSH would alone develop a new testing and certification program, and become the sole agency to test and certify respiratory protective equipment.

To illustrate the strong feeling of the IAFF on this position, the following resolution will be submitted for membership vote at our 35th convention this August which was sponsored by the IAFF executive board, our international standing committee on occupational safety and health and a number of our affiliates.

It reads, "Whereas the National Institute for Occupational Safety and Health is currently revamping its testing and certification branch, which tests self-contained breathing apparatus and other personal protective equipment to assure that it conforms to government regulations, and whereas some manufactures of personal protective equipment would like to see NIOSH get out of the certification and testing business so as to allow for certification by independent labs or self-certification by the manufacturers and whereas other government agencies such as the U.S. Fire Administration have expressed an interest in doing such certification and testing for which they are not qualified to perform, do not have the funding to perform or have the credibility to perform, therefore, be it resolved that the IAFF support the concept that the National Institute for Occupational Safety and Health be the sole government agency for the certification of personal protective equipment, including self-contained breathing apparatus."

Our rationale for this position includes the following: number one, while MSHA has played a relatively passive role in the NIOSH MSHA certification and testing program of respirators in the past, the potential jurisdictional disputes, bureaucratic entanglement and duplication of efforts would not benefit the users

if this agency decided to play an active role.

In addition, the limited government resources and personnel should be utilized where they would be most beneficial, and that, we strongly believe, would be under a single agency jurisdiction.

We are well aware that during the course of these hearings, those in attendance will hear a number of views on the advantages and disadvantages of NIOSH certifying private laboratories for the actual testing and certification of respirators using NIOSH specified performance standards.

We do not believe that this would be a viable alternative. First, our members would have less trust in the integrity of the product, which would certainly hamper this international union's efforts in educating our work forces -- our work force's need to don SCBA's at all fire emergencies.

Second, NIOSH expertise and general understanding of a specific respiratory protective device gained during a certification and testing exercise will be lost. This loss would hamper the proposed field auditing program and would inhibit and delay any stop-sales recall procedure if engineering defects or unapproved changes were uncovered in the field.

Third, the consistency of actual testing between

various certified laboratories would, at best, be marginal.

Recent experience with NIOSH and different manufacturers have proven that testing performed at different locations while following specific criteria have differed.

The use of different types of equipment, geographic location, altitude, test protocol and a number of other variables may play an important part in the actual testing.

Thus, to remain consistent, one location should be utilized for the certification and testing of all manufacturers' products. We also believe that the policing of the independent laboratories and/or the manufacturers would use up as much resources as in-house testing by NIOSH.

The following comments formulate the IFS position on the specific issues outlined in the June 18, 1980, Federal Register, performance standards.

Most in attendance here are well aware that the 30 CFR part 11 regulations which specify the required tests we perform in certifying respiratory protection devices were developed by the Bureau of Mines, a government agency whose principal concern was for miners.

Unfortunately, while NIOSH whose statutory concern is for all workers now certifies and tests respirators -- only very limited changes have been made to the original BOM testing requirements.

In essence, the testing and certification procedures do not take into account the hostile environment faced by today's fire fighters.

I would like to give some specific examples of the shortcomings of the present schedule which adversely affects the performance of the SCBA's used by firefighters.

First, though, I would like to point out that the equipment manufactured today is built to satisfy the NIOSH MSHA requirements. The requirements are essentially the recipe that each manufacture follows for each piece of equipment. Because of the present expense and the procurement practices of federal, state and local governments, i.e., competitive bidding for products and services, manufacturers rarely diverge from the 30 CFR part 11 requirements.

Thus, any innovations or changes on present equipment that would enhance the protection of users are not incorporated because the expense would place the product out of the competitive bidding market.

Some examples of the short-comings of the present SCBA requirements in relation to fire fighters' needs are as follows: one, in the present requirements, SCBA's are not required to pass either heat or flame resistant performance tests. A minimum specification for

the high -- for the extreme high air temperatures and radiant heat loads experienced by fire fighters on a daily basis in some areas must be set.

Testing by Lawrence Livermore Labs have shown that present SCBA components will not withstand many of these extremes. They have recommended -- and the IFFA concurs -- that minimum specifications should be set at or slightly above those temperatures at which man can survive. 2) Corrosion and moisture resistance should be addressed in NIOSH criteria.

The effect of corrosion is apparent: Failure of breathing apparatus or increased breathing resistance to the user which can cause hyperventilation and injury.

The causes of corrosion in fire fighter SCBA components is due to the exposure of moisture or water, high expansion foams used in certain fire fighting instances and exposure to certain toxic chemicals.

Corrosion is also accelerated by the use of electrochemically dissimilar metals such as copper alloys and aluminum which are used in some manufacturers regulators.

High relative humidity or direct water contact may also cause regulator malfunction and must also be addressed.

3) Cold temperatures are also a problem for fire

fighters. As specified by most manufacturers today, SCBA's are tested and certified at minus 25 degrees Farhenheit.

Since the passage or the failure of the tests is determined during man testing, i.e. a highly subjective test, and equipment would fail if the test subject experienced undue comfort or breathing resistance.

Questions regarding this test include whether it is adequate to ensure proper performance of the SCBA is northern locations during the winter months and whether there is a need for cold soaking of the device prior to any tests.

4) Thermal shock is also a problem experienced by fire fighters and may be a cause for equipment malfunction. Therefore, it should also be addressed. 5) There should be performance standards for durability and dependability of the SCBA which reflects the fire fighters' needs.

6) Face piece size must also be addressed. Manufacturers presently have only one size face piece which do not allow proper fit for those who have smaller and slimmer facial features such as women.

7) More audible and more effective low pressure warning devices are needed to be specified in the testing criteria. While present alarms are clearly audible in the station house, they can barefly be heard or differentiated

from others while in a hostile fire environment.

8) Aside from these specific criteria, the fire figher also needs communication capabilities built into the SCBA, a buddy-breathing capability that will not affect the performance of the device, and the need to allow interchangeability of air bottles during mutual aid responses if, and only if, they are identical, standardized bottles.

The AIFF realizes that the first priority of NIOSH is the development of new testing and certification program. However, considerable research has already been conducted in many of these areas which NIOSH should utilize so as not to cause any considerable delay in the upgrading of the approval criteria.

Quality control: The AIFF is in agreement that NIOSH -- with the NIOSH position that the applicant's quality control program should be the applicant's responsibility. The onus and liability of such a program must rest with the manufacturer. We also agree with the need for field auditing of both used and unused equipment.

The field audit of used equipment could be used by NIOSH in upgrading the approval criteria and to point out areas that need careful examination during approval exercises.

Engineering drawings with dimensional tolerances:

While there might not be a need for careful NIOSH review and approval of engineering drawings, they should remain part of the approval package so that they remain onhand of a design problem does arise that needs immediate attention.

This would avoid the delay in procuring the information from the manufacturer, and thus afford the user better protection.

Changes to approved devices: While we agree with the NIOSH position in regards to handling changes to approved devices because of their present tax on TCB program resources, there is a need for better and specific definitions for form, fit and function.

Also, one question that must be addressed is would approval be voided if components from previously approved devices such as the face mask or the air bottles are used on the newer models which may be essentially similar but, for example, had engineering changes within the devices regulators.

Witnessing of approval tests: From our own experience in seeing firsthand the bickering that has accompanied the testing in Morgantown, we certainly concur with NIOSH's position.

Duration of approval: The IFF agrees that respiratory devices be submitted for reapproval every five

years. We feel that this procedure would give the user greater confidence in the utilization of the device, knowing full well that the device has recently passed approval requirements.

Unpublished test requirements: We agree with the need for the publishing of test requirements -- we agree with the need for the publishing of test requirements. We also believe that the test requirements be very specific and clear. This should include the type of equipment used, the manufacturer or manufacturers of test equipment components, the protocol of the tests, including how equipment was calibrated, and the conditions in which the tests will be performed -- temperature, humidity, et cetera.

This would allow the manfacturers, if they wished, to procure and utilize identical equipment and procedures as those that NIOSH will use during the certification of their products.

Approval tests: We agree that only production models of respirators, identical to those sold to the user, be tested. The reasons are quite obvious. We believe that present devices that are submitted for approval are carefully examined and tested by the applicant's engineering staff prior to the submission to NIOSH. This equipment may, therefore, be different, for example, in

quality to those that are sold in the open market. The field auditing would also verify that those devices submitted for approval are identical to those sold to the user.

Group testing of respirators: The IFF reserves comment on the group testing of respirators until such time that the designated acceptance periods are defined. If these accemptance periods are spaced so far apart in time so as to preclude or delay new and advanced equipment from reaching the user, we would have to take exception to this procedure.

User and maintenance manuals: Again, the need for specific user and maintenance manuals are obvious. We would hope that there would be two separate and distinct manuals so that the users do not perform maintenance and repair on his own equipment.

The IFF position is that only personnel that have been certified by the manfacturer or government agency be allowed to perform these tasks. We would also hope that there would be uniformity of the various manufacturers' manuals to avoid any confusion in the field.

NIOSH systems manual: We would agree with the need for specific manual that defines the entire operating procedures of the testing and certification program. We would hope that each part of this manual be worded or, in the

case of highly technical areas, summarized so that the user can clearly understand the proceedings.

Publishment of test data: The IFF strongly agrees with the publishing of test data. This information can -- could also be summarized so that the user would understand the results. We would certainly agree that this would make the manufacturers much more responsible while preparing the approval package, and it would also give the user a specific data base to use in deciding which manufacturer's equipment would suit their needs.

While we're sure that there would be a disagreement by the manufacturers on this issue, it should be stated that much of this information is presently available under the Freedom of Information Act.

In summary, the IFF supports the program that NIOSH is planning to develop, and we certainly hope there is a limited delay. We will be available for any assistance that NIOSH may need during the development and implementation of this program.

We certainly hope this program will eventually allow the user to have confidence in the NIOSH approval label. Their life depends on it. Thank you.

DR. MAY: Thank you, Rich. Does anyone have any questions of Mr. Duffy or comments or -- Bill, from the D.C. Fire Department? You're not going to let him get

off that easy?

Okay. Thank you very much, Rich. The next speaker on the program is Roger J. Amorosi, president-elect of the American Council of Independent Laboratories, Incorporated. Roger?

MR. AMOROSI: Good morning. I appreciate this pleasure in making this presentation. My name is Roger J. Amorosi, president of Amorosi Associates of Alexandria, Virginia. I am testifying today in my capacity as president-elect of the American Council of Independent Laboratories, better known as ACIL.

ACIL established in 1937. It is a professional association.of independent engineering and scientific laboratories. Its membership includes leading testing, materials engineering, research, development and inspection firms in the United States.

An independent laboratory, as defined by ACIL, is a tax-paying corporation or proprietership unaffiliated with any private manufacturing or other company, government institution or academic institution in any manner which might affect its ability, capability to conduct investigations, reports, or give professional counsel objectively and without bias.

EAch laboratory has special fields of experience and expertise. These include sampling, inspection,

physical or nondestructive testing and chemical analysis or microbiological testing of raw, intermediate and finished materials and products.

The quality control of materials composition and product performance, the professional consultation in various fields of scientifiec technology -- I will, at the end, provide this directory as evidence of our presentation.

On the matter of issue, the restructuring of the NIOSH testing and certification program, ACIL strongly recommends that alternative three in the June 13, 1980, notice be adopted and private sector resources be used to the maximum feasible extent in the future operation of the NIOSH program.

This approach is mandated by the requirements of the Office of Management and Budget -- OMB circular A-76 entitled, "Policies for Acquiring Commercial or Industrial Products and Services for Government Use," Published in the Federal Register on April 5, 1979, pages 205, 5, 6, 7.

The policy circular, "Reaffirms the government's general policy on reliance on the private sector for goods and services while recognizing that governmental functions must be performed by government personnel, and that proper attention must be given to relative cost."

Testing and certification are not inherently governmental functions. And the number of federal agencies such as HUD and the Coast Guard presently rely on the private sector to implement certain of their testing and certification programs.

Additionally, under the new A-76 cost comparison procedures, we believe that it is demonstrable that it could be more economical for NIOSH to purchase these services from the private sector. General analytical data in support of this conclusion has recently been compiled in a special study prepared for the National Federation of Independent Business.

This report entitled "Tax Reduction without Sacrifice, Private Sector Production of Public Sector Services" demonstrates the efficiency and cost effectiveness of governmental purchase of services from the private sector.

I will also put as evidence the circular A-76 and also the paper I just referred to, "Tax Reduction without Sacrifice, Private Sector Production of Public Services."

In the time that remains, I want to discuss in summary fashion how and where NIOSH might locate within the private sector the full range of services needed for an effective testing and certification program.

First, a significant capacity exists in the private independent laboratory community to provide needed testing and certification services for personnel protective devices including respirators.

As an example of the private sector's capabilities, I would like to submit for the record a copy of ACIL's 1980 directory of member firms, and the scope of their activities. This listing represents, of course, only part of the total number of private independent firms qualified to serve the needs NIOSH has identified.

Despite the reference on page 26 of the consultant's report to liability considerations as deterring private laboratories from assisting NIOSH, ACIL is satisfied that qualified laboratories are available for this purpose.

Further, once NIOSH determines that it is appropriate and advisable to rely on qualified private laboratories to undertake needed testing and certification services, the OSHA part 1907 procedure, which was referred to a number of times yesterday, to accredit laboratories for this purpose, should be utilized.

We understand that OSHA is in a position to implement its accreditation procedure in the near future.

In this connection, we urge that the language

used by NIOSH and its consultants be clarified. ACIL suggests laboratories be accredited, not certified, and products be certified.

The general terminology, at least private sector, refer to laboratory accreditation and product certification.

Proper standards are also an important element in a testing and certification program. ACIL members through years of direct involvement on technical committees of private sector standards organizations have developed an understanding of the important role performed by organizations such as American Society for Testing and Materials, ASTM, and the American National Standards Institute, ANSI.

We suggest that organizations such as ASTM and ANSI be effectively utilized in the standards development part of this NIOSH program. The safety equipment industry might also contribute to a successful program for testing and certification of respirators and other personal protective equipment.

The Industrial Safety Equipment Association -- ISEA -- made the presentation yesterday as a primary spokesman for that industry. We recommend that NIOSH explore the possibility of a certification program sponsored by ISEA which relies on qualified third-party

laboratories.

I thank you for the opportunity to present these brief remarks on behalf of ACIL today. Once we have had the opportunity to review the full record of these hearings, ACIL expects to submit on or before your indicated deadline date of August 29 more detailed and comprehensive written comments on the issues raised by NIOSH.

DR. MAY: Thank you, Roger. Are there any questions? Rich?

PARTICIPANTS: Do you know how many independent labs today have the capability, including equipment, resources, et cetera, to conduct testing and certification of respirators?

MR. AMOROSI: ACIL initiated a review and we do not have complete numbers. All I can say at this time, that there are a few. We will submit this giving names, addresses, and other pertinent information with our final presentation.

I can name a couple of them, but I'd rather not indicate any until we have the complete list, but we will supply that.

PARTICIPANT: Okay, and do you know or could you supply the record the approximate or estimated costs of approving and certifying a particular respiratory

protective device such as an SCBA and its approval package?

MR. AMOROSI: I don't -- you're saying what are the testing costs? I don't have these figures, but if this would be helpful, I could obtain this from some of the labs and submit it -- at least as an average figure.

PARTICIPANT: Thank you.

MR. SHUTES: I'm Bob Shutes from NIOSH. I believe you indicated that there is expertise in private laboratories which would be of help to NIOSH in developments of performance criteria for respirators. Is there some way this expertise could be identified?

MR. AMOROSI: Well, as I understand, this is essentially the same question that was just asked. We have here the ACIL directory, which includes 240 laboratories.

However, this does not -- as I indicated in my presentation -- this does not include all independent laboratories. ACIL has offered to review its own laboratories and to solicit information from non-ACIL laboratories to determine how many and specifically to provide this information to have the capability on respirators, and we would also do it if it's appropriate on other personal protective devices.

But I cannot provide -- I can give some names,

but I'd prefer not to at this point because I don't have the full list.

MR. SHUTES: Would you look for both testing and criteria development capability? Thank you.

MR. AMOROSI: I know that there are a number of laboratories that have also been involved in research work similar to that required for these particular devices, sowe will also indicate that information.

MR. POWERS: Jim Powers, Portable Air Supply. I notice that IFCA and yourself both recommended using the OSHA accreditation program. I'm a little curious why the people from NIOSH haven't given some talk on the subject of the fact that they spent 2-1/2 years headed up by Jim Cavender on a laboratory accreditation program of their own, which was bound to have had some results, and I believe that there is a criteria document available on the subject.

So I wonder if we could get some comment on what NIOSH has found in their own program.

DR. MAY: I'll refer that one to Dr. Ruckles.

DR. RUCKLES: Well, we've obviously had a number of discussions with the OSHA staff, particularly in the directorate of safety standards. And it is our -- it was our belief -- this was about a year ago -- that we should pursue the testing and certification program

within NIOSH. Number one, it was established. Number two, OSHA was in no position at that time to initiate their creditation program. And even though three -- even though OSHA at that time was talking about personal protective devices such as safety nets, lifelines, even head protection devices, this type, they had shown or indicated to me that they had no reason to initiate a new program in particularly the respirator protective area.

So with that background, NIOSH proceeded and continued to carry out the program which was underway at that time.

I don't know if you have another -- a further question on that or if that's --

DR. MAY: Go ahead, Jim, do you have a question?

Okay, I've asked Roger if he would very briefly explain to the group and put on the record any changes that OSHA is making in their laboratory accreditation regulation and briefly comment on how a program would work under OSHA system.

MR. AMOROSI: I think perhaps now I put on a hat where I'm deeply involved in AALA -- The American Association for Laboratory Accreditation.

AALA had completed a contract with OSHA to extend to elaborate upon the part 1907, laboratory

accreditation procedures. This contract worked, which included the preparation of laboratory application and inspector's check list was completed last November. These documents are being reviewed, and I understand that OSHA is considering just how they would implement 1907.

There are a few areas that, because of comments they received from some trade associations that they are contemplating some changes.

These involve personnel requirements and the definition of independence. I believe Mr. Wilshire yesterday reported that OSHA expects to take some action on this in September of this year.

How the program operates is the other part of the question. The AALA program was in two parts. The first part involved the accreditation of the laboratories that would apply in the normal -- for normal AALA accreditation by discipline. If the products were electrical in nature, it would be under the electrical discipline with details regarding the particular products.

Now, some of you may be aware, the requirement for certification of products by OSHA is covered in their parts 1910 and 1926, which refer to products and installations. And where their standards require that the product be approved, the interpretation of this is that the products are to be certified.

Back on the AALA-OSHA program, it would be in two parts. One part is the accreditation of the laboratories in the particular applicable discipline, be it electrical or mechanical, and AALA would accredit the laboratories for their technical expertise in performing the required tests of the products to be certified.

Part II, AALA would obtain information from the manufacturers, probably at the same time that they are inspecting the laboratories for the laboratory accreditation portion. They would obtain information from the laboratories relating to their certification program.

This would involve thier follow-up procedures, et cetera. This information would be accumulated by AALA and turned over to OSHA for their determination as to whether the laboratories' product certification were adequate. The determination of the adequacy of that product certification program by the laboratory would be done by OSHA.

In other words, in recap -- the two parts, one is the accreditation of the testing function of the laboratory by AALA; and part II is the accreditation of the laboratory for its product certification program based upon information obtained by AALA in its inspections and so forth.

DR. MAY: Thank you, Roger. Did you have a question, Jim?

MR. OPHOLD: Jim Ophold. I'd like to pursue, Roger, just a little bit further some of the details of your, I guess, proposal with AALA. One of the, I think used to be a $64 question. I think escalation has got it up to at least $100 question now, but it seems that the problem with the outside laboratory accreditation is who is going to do the research to come up with the performance criteria?

Did I understand you correctly to say that you would get this information from the laboratories in your system or in a system, and then use the concensus type of approach that ANSI and ASTM have or are using?

MR. AMOROSI: Are you referring to the performance requirements for the products that are being certified?

MR. OPHOLD: Yes, in other words, the test that would have to be carried on, have to follow some type of performance criteria, and that's exactly what I'm asking.

MR. AMOROSI: Okay. AALA will not be -- and likewise, the NAVLAB program themselves are not involved in the development of the test requirements, the test protocol or the requirements for the products themselves.

These are developed by the organization such as OSHA or NIOSH. In other words, your requirements could be applied to the program. This is requirements on the performance of the product. AALA and NAVLAB developed, based on other standards, the criteria for the accreditation of the laboratory, how it performs -- its organization, you know, the level of education and background of the personnel, the equipment, the calibration, the laboratory's quality control, et cetera.

But the actual requirements for theproducts that are being tested, those are established in the case of the OSHA program by OSHA's referenced documents, and in your case, it would be your own NIOSH documents.

Now, if you refer to ANSI or ASTM standards, those could be applied.

MR. OPHOLD: I just have one question. Not being real familiar with the American Council of Independent Laboratories, I would like to ask a question. Of all the -- I don't know how many members you have -- how many of those would you estimate are independent state laboratories, private laboratories, university laboratories, in that nature?

MR. AMOROSI: There are 240 laboratories in ACIL. And in my original presentation, I indicated that the ACIL definition of independent laboratory -- and if I

may, I'll just repeat it -- is a tax-paying -- an independent laboratory is a tax-paying corporation or proprietership unaffiliated with any private manufacturing or other company, government institution or academic organization in any manner that would affect its capability to conduct investigations, reports or give professional council objectively and without bias.

In other words, it is a tax-paying -- all these are tax-paying corporations or proprieterships which means that none of the university laboratories are covered in the ACIL.

Likewise, no government laboratories are included, and no nonprofit. Only tax-paying corporations. That is the way that ACIL was structured.

MR. OPHOLD: This is Jim Ophold again. I'd like to go back to the mechanism or the function of the independent laboratories. Would you see NIOSH being the evaluator or the auditor of these independent laboratories?

I guess my basic question is, and would have with any kind of a system, is who evaluates the laboratories -- whether they're doing a good job, a mediocre job or a poor job?

MR. AMOROSI: I believe your proposal -- let me just pull it out -- is that your proposal III, which

calls for the utilization of -- now, there the term was used "private laboratories," and I was tempted yesterday to ask the question of some of the speakers just what their definition of private was.

Generally, I believe it is referred to as nongovernment laboratories. However, some of the speakers, I think, were talking of strictly independent laboratories. They could be for profit or nonprofit, and I think they were referring to nongovernment, but independent with no affiliation with manufacturers.

Now, private in the true sense could include manufacturers' laboratories, but that, I don't think -- I don't think that was the intent of the Federal Register notice or the consultant's report.

Now, the second part of your question, who would approve -- I'd like to use the word, if I may, accredit the laboratories that would do the testing. Now, this could be done -- this could be done by NIOSH or NIOSH could hire another organization to do the accrediting of the laboratories, and there are two national organizations now.

One is AALA -- The American Association for for Laboratory Accreditation; and the other is NAVLAB -- National Voluntary Laboratory Accreditation Program. Some of their principal people are here in the audience, so I

couldn't possibly just talk about AALA. I had to bring NAVLAB into the picture. Your last speaker is John Locke, who I'm sure is going to go into more details on the NAVLAB Program.

MR. OPHOLD: Just one sort of final comment. It seems to me that if NIOSH is expected -- and I think there is some agreement to the idea that NIOSH would be the research laboratory to come up with the performance criteria -- if we have that brain power or think-tank type of scientist in our organization, would it not be just one step further to have that knowledge extended for evaluation of outside laboratories?

MR. AMOROSI: You could. Frankly, I believe that this is a routine function that it's questioned whether the government should be in the picture or not.

We've had some discussions -- NAVLAB and AALA. You could do it. You'd have to develop your own criteria or use some. There are standards that give the rudiments of how to operate a laboratory accreditation program. These are ASTMA standards developed by the E-36 committee -- standard E-54D8. So you do have that criteria.

And then other criteria that go into the various disciplines and subdisciplines are also being developed by ASTM and by a few other organizations.

I might just add one more thing, if I may.

You indicated who, beside NIOSH, could do the accreditation, and I mentioned AALA and NAVLAB. And, of course, this falls back onto the program that was developed by OSHA, their 1907. So you might -- that's one of the proposed -- that's part of our proposal here is that if you are going to credit laboratories, since OSHA has gone through this and, of course, they have had 1907 sitting on the books ready to be implemented for about five or six years. They know what all the comments are, and I think that if you were to start your program, you are going to get the same kinds of comments from other organizations so I would strongly recommend you consider using the OSHA 1907 for your laboratory accreditation program.

MR. WALTERS: Woody Walters, Minnesota Firefighters, or shall we say the users, part of the users. I'm getting so confused. I hope there are more people in the room understanding what's going on, because I don't.

And it's a lot of the politics or whatever you want to call of what's going on here. But here awhile back, another product, lifesaving product came on the market called smoke detectors. And they've saved a lot of lives, and when a salesman gets up to give their pitch about their smoke detectors, on the back

page it has all the accreditations, X, Y, X and A, B, C, all the way through down the line.

One salesman says, "This unit is approved by ABC, and it's the only unit on the market that's approved by ABC." And the next salesman comes along and says, "Well, that may be so, but ours is approved by some other company, and it's the only one on the market approved by them."

It's so confusing by the consumer, by the person using the product, he don't know what to buy. If we have an agency that says, "This self-contained breathing apparatus is usable, is safe," that's understandable.

But when you get a whole list of accreditations that one company does not comply with what the other company is in their sales pitch, we don't understand all that.

And I think I definitely would like to go on the record as saying we would like an approval agency that can approve it for us, and only one.

MR. AMOROSI: As far as the government is concerned, there is no central agency that is handling -- and I gather you're referring to safety labeling of products rather than performance labeling. And I should mention that there are a lot of trade association programs.

There are some government sponsored programs where they involve the requirements for the performance of products, and there are others relating to the safety labeling of products.

As I say, there is no one government agency that is handling all of this. In the private sector, I'm sure that you're aware of Underwriters' Laboratories, and two of their representatives are in the second row from the rear.

You'll see on practically all of your electrical, fire and many other -- including your smoke detectors, you will find the UL label. Now, UL is a private organization. It is not a government organization, as many have misunderstood.

UL is a truly independent laboratory. It is a nonproduct and that is, I'd say, probably the only reason why they are not in ACIL.

They are a nonprofit, independent laboratory. UL also writes its own standards, but puts them through various types of concensus system, including passing most of their standards through ANSI.

I think you can rely -- I think an awful lot of people rely on the UL label. If you see other labels, I would certainly suggest that you determine who that organization is, where they come from, et cetera. I think

that's about all I can say on -- we're getting into an awful lot of deep topics.

MR. TERRY: Sam Terry, NIOSH. Mr. Amorosi, I think it's quite important that when you do reply back to the record that you differentiate quite clearly between material and equipment capabilities and personnel with experienced capabilities. Certainly, resumes would help; experience in personnel in terms of R&D that's been done, respirator programs, critiques, standard developments, whatever materials you have available that we could look at.

And it seems to me that certainly today, we have a gathering of a large majority of the experts in the field right here in the auditorium.

MR. AMOROSI: I will be sure and include this in our package, and I might state that these qualifications for each laboratory, where available -- and I expect that in 75 percent, this information will be in the form of a qualification manual. ACIL has been pushing very hard on its laboratories to write their qualification manual which includes in it practically all the information that is needed in any of the laboratory accreditation programs.

It gives the history of the laboratory, its key personnel, who owns it, the background, their organization chart, their internal procedures, how they process

the product. It lists their major pieces of equipment, and how they keep it in calibration, how they write reports, et cetera.

It is a complete document on the laboratory, and any laboratories that are looking to be accredited which is the coming thing now. Better have a qualification manual, and we will be sure, where available, to include these in our submittal to you.

DR. MAY: We have time for two more questions or comments.

MR. BOLTON: Paul Bolton, Reynold's Electrical and Engineering Company. Going back to the previous topic that was being discussed regarding the approval and testing.

It appears to me that maybe there is some confusion where maybe people are viewing approval and testing as being synonomous. I don't -- didn't understand your recommendation that way.

I gathered that you meant that the private or independent laboratories would do the testing by giving performance or test procedures, but approval then could be granted by some other agency. Am I correct in that understanding?

MR. AMOROSI: You're referring to approval of the laboratory?

MR. BOLTON: No, I'm referring to approval of the device.

MR. AMOROSI: Of the device, okay. We refer to that as product certification, if I may. In the case of safety, it's often referred to as safety labeling, but really, safety labeling is product certification.

The independent testing laboratories can perform two functions. Some perform only the testing of the product, issue their report giving details of what the source of the product was, what standard was used, the test results, and sometimes they indicate the accuracy and repeatability of the test data.

Then the second function that may be performed by a testing laboratory is that of product certification but this must be or should be an industry-wide program where there is clearly defined what is involved in that product certification program -- how it is sampled, how it is tested, its initial qualification and so forth.

Now, there are trade association product certification programs that have operational manuals that tell you all the details of how that product certification program is operated. UL has its own procedures, and they are clearly defined.

They, of course, have the license agreement with the individual manufacturers. Likewise, in an industry

certification program, there is a license agreement with each of the manfacturers, and those license agreements, of course, are identical.

So, yes, we have two -- we have testing and product approval, if you like, and we call the process of approving these, the laboratories that are doing that, we call it laboratory accreditation for the testing, and we call it product certification and you have a product certification program. You have to approve the laboratories that are doing that part of the process.

MR. BOLTON: Is it true that if the private or independent laboratory did do the product certification, that that certification would be a single, identifiable certification under one label, readily identifiable in the market place then? It would not be the same product coming out with like an ABC product certification or an XYZ certification, but a single identifiable certification?

MR. AMOROSI: Well, this would depend upon who structures that program and how they call it out. If NIOSH were to call it out, they would have to indicate the manner in which the product is identified. You could put NIOSH on or something else. UL puts the UL mark on the product.

There is a program on air conditioners -- AHAM, Association of Home Appliance Manufacturers -- and AHAM puts

its mark and identifies the standard to which the product is being certified, and it also differentiates if they are only using part of the standard, which portions are applicable in this certification process.

MR. JACOBSON: Murray Jacobson, MSHA. It seems I'm a little confused as to the authorities for issuing approvals of certifications. Both OSHA, MSHA and NIOSH have certain authorities which come down through their secretaries that says they shall certify or certify that certain things are approved.

I haven't seen where you could delegate the statutory requirements that Congress passes down to private concerns. They can do the testing. They can write the standards for concurrence by the agency or agencies. They can review the reports, but the question of whether the authority to delegate from the government sector to the private sector, the authority for certification, that it meets certain standards would have to be a question that would have to be answered by the lawyers, I'm sure.

But that would be like us going out and hiring inspectors such as you hire guards -- so-called police guards. By law, we can't do it. There are certain responsibilities that must be retained by the government, and I firmly feel -- and as I said yesterday that NIOSH must retain their right to issue approval of certification

regardless of who does the testing and what the standards are.

MR. AMOROSI: If I may comment on that. I will not attempt, in the case of NIOSH, as I think there are some questions as to what all you're doing now, if it's proper..

But on OSHA, I can state that it is quite clear -- and there's not really been a challenge of OSHA's right to designate that approval of a product means that it shall be certified. It shall be safety labeled, and that is written up.

Originally, that was written to cover merely UL factory mutual and however, since is now interpreted as being organizations that are equivalent to UL and factory mutual, et cetera.

And I don't believe that there has been any challenge as to the right of OSHA to delegate that responsibility to UL and any other laboratories that they accredit under pat 1907. And that's the whole crux of 1907.

MR. JACOBSON: Mr. Amorosi, what it amounts to -- I agree with you for other things, but when you get to respiratory protective equipment, this has been covered since about the mid-1910, 1915 under existing regulations and the existing standards which come down as a matter of

law, and I'm not a lawyer but I've worked for the government for a good while. And I'm saying, these particular things have been covered. I'm not talking about any other areas or any other types of equipment, just respiratory protective equipment.

DR. MAY: I'm going to interject at this point as chairman and say that the legal ramifications of what we're discussing are humongous -- for a good Pennsylvania term.

Obviously we'll have to consider them, and I'm going to end the discussion at this point and go on with the next presentation. If there are any other questions that arise later in the program or we have more time, questions directed toward the independent laboratory program, we will raise them at that point.

Thank you very much, Roger.

MR. AMOROSI: Okay.

DR. MAY: The next presentation will be by Earle P. Shoub, consultant, Safety Products Division, American Optical Corporation. Earle?

MR. SHOUB: Thank you, John. I am Earle P. Shoub, consultant to the American Optical Corporation. Accompanying me here today are Mr. William A. Carruth, quality assurance manager, and Dr. David Dreyfus, 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 timeof 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 basis 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 affect improvements in the procedures and program for the certification of respirators.

In many instances, however, the discussions and conclusions require temperingin 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 --

(END TAPE IA/BEGIN TAPE IB.)

-- 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 representative 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 reigster of June 18, 1980, the American Optical Corporation would like to offer the following comments.

One, 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 in this topic which require consideration.

Among these features are: 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 predetermined 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.

Determination of compliance with the 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 it 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 quantative measurements indicating the level of quality. It would become almost inescapable if there should be more than one source of certification or field audit.

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.

Quality control: The thrust of this topic appears to be an assertion that the manufacturers shall be responsible for the quality of its product at the time of sale, while in the distributors and purchasers' stocks, and during and after use including extender use.

At the same time, NIOSH proposes to eliminate or reduce considerably the information concerning the manufacturers' quality control plan presently required as part of each application.

Some comments immediately come to mind. 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 regulation and be the same for all manufacturers.

Sampling by NIOSH from manufacturers, distributors and purchaser 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.

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 deviations from any of the requirements from respirator design based on sound engineering and scientific principles and evidence of good workmanship subject to and approved by NIOSH.

Accepted instances of immediate urgency and severity and adequate opportunity for administrative and other appeals should be available before action is required or adverse information published.

The proposal to publish the results of market and work place surveys is of doubtful value. It 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.

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 who NIOSH would exercise its responsibility 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.

Changes to approved designs: 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.

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 a 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 this should only be conducted in secrecy without professional scrutiny by those affected.

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 should 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. 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.

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 in the tension with other testing.

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 were dependent on respiratory protection to help preserve their health.

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.

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.

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.

Mr. Chairman, that concludes my prepared remarks. I'd be delighted to attempt to answer any questions.

DR. MAY: Thank you, Earle. Are there any questions for Mr. Shoub?

MR. BRENNAN: Bob Brennan, Scott Aviation. Several times during the course of the day yesterday and again today in your presentation this morning, the witnessing of the testing has come up. If I remember, I believe during the discussion yesterday, a possible alternative of witnessing a demonstration and letting the testing go ahead unwitnessed was brought up.

Do you have a comment on that approach? Is that satisfactory with you, sir?

MR. SHOUB: Yes, Mr. Brennan. Under the topic of witnessing of tests, we really, I think, have been talking of two separate operations.

One would be demonstrations by presumably the

senior personnel, the most skilled personnel in NIOSH for the benefit of private laboratories, public laboratories, manufacturers and others who would like to witness how NIOSH performs the tests so as to learn how to perform them.

The other would be the issue of an applicant wishing to be present to feel secure that the testing, which might not be performed by the same people who would give the demonstrations, would be -- is performed correctly, the data recorded without error, and that the product is not either over-rated or under-rated.

I think this difference came out very clearly last night or yesterday afternoon when Dr. Ophold explained to Mr. Moran that NIOSH was proposing the former -- that is, the demonstration type of lectures and presentations and not the latter.

My comment is that I'm in favor of both. I think it is a very desirable thing to have an opportunity to learn from the people who are the reference laboratory and the ones upon whom we rely upon or rely for primary certification.

I think it is also only right that anyone who wishes to submit a product for certification should have an opportunity to observe but not interfere in the testing procedure so that that person can go away assured that a

fair deal has been given.

MR. SHUTES: Bob Shutes of NIOSH. Mr. Shoub, are you aware in other certification or approval programs whether or not witnessing of tests is permitted?

MR. SHOUB: I must admit, Mr. Shutes, that at this -- I'd better use the microphone. Sorry, I forgot we had a microphone.

I started to say, I must admit, Mr. Shutes, that at this moment, I can't think of any details of any testing program which either permit or do not permit participation of this type. And I'd be delighted to be enlightened if you had any in mind.

MR. SHUTES: I do not. I think we should look into it.

MR. JACOBSON: Murray Jacobson, MSHA. In the approval program that MSHA conducts, which we do over 6000 approvals a year, the applicant for the approval has the right to witness every single test that's run. In fact, we welcome them in some instances.

However, they cannot and do not impact upon a test. They have to stand back, and they cannot influence the test in any manner. In fact, we've heard that some people have misinterpreted one of our newer regulations on intrinsic safety in which it was thought that people would not be permitted to witness the test.

They will, but they will have to stand back from the area, from the test area, and cannot influence or be involved with the people who are conducting the test. But that's written in the regulations under 30 CFR -- each of the appropriate parts.

MR. SERE: I'm Rob Sere of Scott Aviation. In the military field, we've found that the manual that they use requires, in most cases, that the manufacturer--developer of the device which is undergoing field trials and evaluation must have a representative on hand in order to review the results and to provide, perhaps, advice to the military people on how the article is being tested, and also to give feedback to the manufacturer or developer in his development process so that there are situations where the manufacturer and developer is involved in the evaluation program.

MR. SHOUB: May I interpolate a comment, please? Before there are too many remarks from the audience, and I won't be able to reply in the right order.

To Mr. Jacobson, I'd add that in my thinking, first, the program which is operated by MSHA for permissible certification and the certification of respiratory protective devices operated jointly by MSHA with NIOSH are synonomous programs so that I didn't feel I should -- there's any differentiation with what Mr. Shutes requested.

And I would add, second to what you've said, there is a special provision in the portion of the regulations, the old schedule 2G, that deals with electrical testing under which it can be required that the manufacturer not only provide witnesses, but provide physical help in the dismantling and assembly and reassembly and so forth of equipment.

With regard to the second comment, I didn't -- I wouldn't look upon that as a certification program, but as a proof of meeting specifications. I'm still left, personally, with the feeling that I don't have a good example to point to that goes either way.

MR. PARKER: Fred Parker, Biomarine Industries. Our company is presently a primary supplier to the Navy and other government agencies of sophisticated life support equipment. And these government agencies do have very highly organized acceptance programs, qualification programs for the equipment which they purchased. And during this qualification program, they not only permit us to be there, but welcome us to be there. And in fact, in some cases, insist that we be there.

DR. MAY: One comment from the chair, and then one last question from Captain Shirts.

As Mr. Wilshire said yesterday in his presentation, and in fact, gave us a document, their position is that --

and has been for quite some time -- that NIOSH implement a functional witness program. In the June 18 Federal Register announcing this meeting, there are the positions listed regarding the program, and of course, we took the position in that that we would not allow -- did not see that the witnessing of our tests was a necessary and beneficial thing for either party.

We have, however, effective July 1, implemented, in fact, a program whereby the applicant can witness the testing of his equipment. This is a result, quite frankly, of some feeling within the program that that is a necessary and justifiable event and also some -- I'll be honest and use the word "pressure" from the IFCA and from several other companies that we implement such a program.

So there is some controversy within our own organization on that subject, and I'm raising -- I'm stating this simply to say that today, there is, in effect, where by the applicant can witness the testing of his equipment. Captain Shirts?

CAPTAIN SHIRTS: I'd like to -- this is Captain Shirts from the Space Division. I'd like to clarify the use of contractors to develop protective equipment, as far as I can speak, and I can only speak for the space division.

When we ask a contractor to witness or assist

us, basically what we do is develop a technical need. Then a contractor -- and it could be MSA, Scott, Arrowhead, Mart-Marietta, whatever, will develop a military specification for a piece of protective equipment that is highly specialized to do one specific task.

Then, depending on a sole source purchase or a general buy or a general competitive buy, a second contractor will take that specification and he will develop that piece of equipment.

And that piece of equipment is built and tested by him to the specifications of the environment within which that equipment will perform.

So I'd like to clear that up. It is not -- we do not really certify equipment as in the sense of NIOSH, and therefore, we do not have our contractors witnessing the Air Force testing the equipment that they have developed for us.

We basically tell them what we need that equipment to do, and they will build that equipment. They will test that equipment to make sure that it satisfies our specifications.

So I just needed to clarify that for the record.

DR. MAY: Thank you, Captain Shirts. Okay, I'm going to end the discussion on the subject at this

time. Mr. Walters is scheduled to presently present his talk starting at 10:45. If he has no objections, I'm going to give a 20 minute coffee break and move it up to 10:55 because we will undoubtedly have sufficient time for the rest of the speakers, based on what has happened so far. No problem there.

So please be back here at about 10:55, close to 11:00.

(Whereupon, a short recess was taken.)

DR. MAY: Here is Woody Walters, field instructor, fire fighter training, Minnesota State Department of Education. Woody?

MR. WALTERS: Thank you, John. It's a privilege to be here and to speak to you, knowing many people representing the self-contained breathing apparatus companies. I don't see a familiar face in the crowd so evidently, the fire fighting segment of self-contained breathing apparatus is different from what comes to meetings like this.

The State Department of Education has a word processing center of some 500 words a minute that I would like to offer -- go on the record of offering that if you would furnish me with the cassettes of this, I would be glad to reprocess that for you and not -- I feel that the reprocessing of what is said here would include the

answers and questions rather than the reprocessing of what is handed in. And then it would be up to you to recopy it and mass mail it. If you'd like to do that. But we can do this very quickly from any size cassette tape.

A field instructor or a state fire instructor for you that don't know what they do is to travel from town to town, working with individual fire departments training in the occupation of fire fighting.

Through these responsibilities, we come up with probably more problems than any other person involved in fire fighting because we're dealing with so many different aspects, so many different departments and so many different fire fighters.

As of lately, we are a lot more concerned about this self-protection or the personal protection of the fire fighter than we have been in the last 50 years, and I think during the next two to five years, you're going to see more money spent and more time spent on training in this area than you've ever seen before.

In the state of Minnesota, we are very proud to -- what we consider be a leader in this, and I'm going to familiarize you with some of the total concepts that what we are having and then in the end, for you to place where you feel the self-contained breathing apparatus was,

is, and you know more than I, where it will be.

The fire fighter, to start with, needs protection on his hands, and the state-of-the-art right now, there's a pair of gloves referred to as what we call the California OSHA glove.

Now, California OSHA is ahead of us in having a mandatory requirement for the minimum standards for protective gear for fire fighters, and a particular version of that California glove, we've been wearing for about a year and a half, and the hands are protected up to about 900 degrees. It's made out of a Kevalar material which is also used for bullet-resistant vests for law enforcement people, and it's a fantastic glove. Now, that's the state-of-the-art for gloves to date.

A prototype of gloves is a very similar glove, except it has more water -- does not absorb water as much as the state-of-the-art does. The finger protection has been changed somewhat. This glove is not on the market yet. It is just a prototype that we are experimenting with that, and that's basically where we are on gloves.

One of the leading glove manufacturers has been wholeheartedly working with us on coming up with prototypes, letting us experiment, field-test with them and is a great asset to us.

Of course, the cost of experimenting with a pair

of gloves is considerably different than experimenting with breathing apparatus.

I did not bring the state-of-the-art as far as fire fighting helmets is concerned because, as far as I'm concerned, there is none. There is no helmet on the market today that is designed for fire fighting. Most of them are extremely adequate as long as you do not wear them around heat.

I do have a letter from one of the leading manufacturers who has been working with us, and in September, we hope that we will have our prototypes that we will start to field test, and maybe within a year and a half, two years, there will be a marketable helmet that is designed for fire fighting, and we are very excited about that.

The total body of the fire fighter also must be protected, and I brought one of the prototypes that we have developed in Minnesota. This is called the Arctic-ray structure fire fighting suit. It is very similar to that of Project Fires' structure fire fighting suit that they are in the process of arranging for field testing. We're approximately a year ahead of Project Fires, but working as closely as we possibly can with them. And other than the vested top instead of the bib top, the design is very similar.

our gloves out of the pockets, and there's a lot of things constructed into this new fire fighting suit that's for less stress, more protection for the fire fighter, and I do have a few copies of some specifications of how the suit is designed. If any of you are interested in them, I have laid some up on the table.

And during lunchtime, if any of you would like to discuss it further, I would be glad to do that.

You can see that we are concerned about the total package of the fire fighter, and the old story about the weak link and the chain is definitely an existing factor here.

No matter how much head protection we have, hand protection and body protection and foot protection, we cannot enter that structure safely and save your children and save your relatives without our lungs protected also.

I was quite shocked when other people got up from the fire service, and started discussing the inefficiencies of the breathing apparatus that's on the market for fire fighters today, going through detail by detail as to what some of the problems are.

And during the question time, I didn't hear one manufacturer stand up and defend his product.

We are quite concerned with visibility, and when you put breathing apparatus on, especially in cold

weather, a fogging situation takes place and you can't see what you're doing.

In Minnesota, we are very high on snowmobiling. In the art of snowmobiling, for $25, you can buy a face shield that is a two-ply air space in the middle, insultated some way or another -- I don't know anything about the engineering of it. But it's sold as an anti-fog face shield for riding snowmobiles, and this is a cost of $25.

It's unbelievable to me that when a tool costs $800, that even with a little more money, we can't devise some way of fixing it so that the fogging is, at least, less than it is now.

We have experimented with solutions to slap on and wipe off of your lenses to make it more usable. And we are quite concerned, then, after we put our solution on, which helps prevent fogging, maybe we're doing something to this mask that, when we expose it to heat, give off a toxic fume for the fire fighters so we have sent a mask with our solution in to have it tested because we feel this is very important.

The tests were run, and this is a solution of a detergent and a silicon of some sort. And in the tests they ran, they ran the heat ranges quite high at 400-500 degrees. The detergent -- but, of course, the

detergent has already done it's thing. That's just to clean the lens -- did disappear. Did destroy at 400-500 degrees.

At 800-1000 degrees, the silicon broke down and was not doing its proper -- keeping the fog off. They did not have any toxic vapors coming off of the solution at any time. But in the last paragraph, we got a paragraph that we did not expect. They did state that the solution was harmless. It did not hurt us in the heat range they are talking about.

We are much more concerned about the gases from the plastic and the rubber in your face piece. Now, this is an independent testing agency. Of course, they ran the heat range up to a lot higher than what you are recommending that they be wore at.

But in the prototypes of what we are doing for the rest of the protection of the fire fighter, we are talking in the range of 5-6-7-8-900 degrees. Not for long durations -- the human body can't stand it.

But when we are in lesser temperatures, unforeseen things happens and for a few seconds, we are exposed to extremely hot temperatures.

We are kind of wondering where the weak link in the chain was yesterday, where it is today and where it's going to be tomorrow. We are not at all concerned if

NIOSH lets us know that there is a problem. As a matter of fact, we welcome this. Sometimes, even a little bit heavy, some people might feel.

But as we go over the years of the end results -- now, a lot of people are complaining about trying to save my job and let's test it so that my job is secure, and let's do this and let's do that.

But all the fire fighter is asking is that no matter who does the job, let's do it so the fire fighter can live. And so the end result is the life of the fire fighter that this whole thing is about.

Now, one agency testing or 25 agency testings -- we're not as concerned about that as some of you are. But we are very concerned that when you do run a test, you are testing it in an atmosphere in which we wear it. We've been saying this for years. People have not listened to what we've said because we still do not see the unit tested.

So basically the first time your unit is tested in our atmosphere is when we put it on our back and enter the burning structure.

As I travel around the state of Minnesota working with fire departments, I am the goat that they unload on. You know, the state fire instructor is going to solve all problems. We are the -- you tell us and we'll

fix it for you type of things.

Well, you enter a fire department who has purchased a particular breathing apparatus and they've heard something about a stop-sales recall order on a unit because of a spring or something in there. And the fire chief asks me, "Should I let the men wear the equipment? The manufacturer has not contacted me. And also a few months ago, there was something about the hood. We haven't got the hood yet either. Should we wear it?"

"I don't know whether you should or shouldn't wear it. That's your decision."

You go onto the next fire department, and they have a different type of mask. And they say, "Hey, I heard something about some kind of stop order, a recall order, and we're supposed to get some kind of a kit and add to our unit. And this was a year ago, and we haven't seen any kits yet. Should we stop wearing them?"

"Golly, I really don't know whether you should stop waering them or not. I wonder why you haven't got the kit yet."

Well, of course, there's an awful lot of units in the field, and it takes awhile to get around, but we're talking a year ago.

Go into the next fire department, and they sent

their high pressure system in because it was recalled, and today, they have not received it back yet. They bought the unit. They sent it back. No money exchanged back and forth after they sent it back, and they are still waiting for this unit to be sent back to them, to get back in service.

They have questions. And the other unit in the market that, right now, is not recalled, as we go in there and teach that fire department to unscrew the cover and dump the water out that practically after every use is in there, take a little clean rag with maybe a cleaning solution, clean it out good. Now the diaphragms are falling apart. The little scotch tape that's around the outside of the diaphragm that holds the two pieces together cannot stand much -- if you leave it alone and never maintain it, that diaphragm lasts quite a little while.

But, of course, we cdan't do that. We have to maintain it. And then you go to the representatives and say, "Hey, I just want a roll of that scotch tape because as I go into all these fire stations, all the units -- it's either coming off of or it's loose inside the regulator."

And they say, "No, we don't have the tape. You have to buy the whole diaphragm."

Well, I don't have any -- I can't carry those.

They are too expensive for me to buy and pass on. And you say, "Well, why don't they contact the person that they bought it from?" Well, that was maybe a few years ago. They forgot who that was, and Duluth is 200 miles away. St. Paul is 300 miles away. And Podunk Junction Volunteer Fire Department is kind of lost as to what to do.

So you see why we are the goat, and I still don't have a roll of scotch tape to fix it with.

But we are very concerned about what happened and what is happening and what's going to happen. And I tried to put it right on the line to you, and I'd appreciate the same back. Thank you very much.

DR. MAY: Thank you, Woody. Questions? Comments?

MR. GATOL: My name is Bill Gatol, and I work for Robertshaw Controls.

In 1960 I entered the fire service as a volunteer, in Long Island. Served 10 years in Engine Company, five more years in the rescue squad and the last five years as a paramedic instructor. What temperatures are you referring to? How hot do you want that helmet to go?

MR. WALTERS: Well, the prototype that's -- that we've been promised for September is between 900 and

1000 degrees for short durations.

MR. GADOL: Is this so when you drop it through a hole, it doesn't melt? Because you sure can't wear it on your head at that temperature.

MR. WALTERS: Absolutely. When we are caught in flashback, you will be exposed to 1000 degrees, not just for a few seconds. Hopefully you have a backup crew that has a hose line that will instantly push this heat off of you.

I have slides -- I have slides because a photographer happened to be at the right place at the right time of a fire fighter in good protective gear who was completely submerged in a ball of flame for a few seconds, but the hose line immediately pushed it off of him. This happened in Phoenix, Arizona. Call him up and talk to him about it. And the fifth slide is showing this fire fighter splashing water on his face, and doesn't even go to the hospital because it was a very short duration.

Okay, what we want now is a little more time in case we are in there -- you know, if it's 1000 degrees -- not misunderstand me. If we know it's 1000 degrees in there, we're not going to send anybody in.

MR. GADOL: I can do a roast beef pretty quick in that kind of temperature.

MR. WALTERS: And you can a fire fighter also.

MR. GADOL: Yeah, have you talked to Louie DeChime in Miami about any of this?

MR. WALTERS: Beg your pardon?

MR. GADOL: Have you talked to Chief Louis DeChime in Miami about any of this?

MR. WALTERS: No, I don't know --

MR. GADOL: That might be a good idea. From Robertshaw as a manufacturer, you commented that none of us stood up to protect us or to defend our position on equipment.

I think the reason for this hearing is to attempt as a manufacturer to redirect the certification process of NIOSH and not to defend our equipment. We all know that there are problems but to -- for each of us, Scott, -- Survive Air, who's not here, I don't believe, Biomarine and Robertshaw to get up and comment on all that would be terribly time consuming, I think, and wouldn't really resolve too many problems.

MR. WALTERS: Well, the comments have been going back and forth on everything else except the problem the fire fighter is having.

MR. GADOL: Uh-huh. On the nose cup -- are you familiar with the nose cup insert on masks?

MR. WALTERS: On whose units?

MR. GADOL: Robertshaw has got it. Survive Air

has got it. I think Scott has got it.

MR. WALTERS: Not on the Robertshaw, but I'm familiar with the nose cups.

MR. GADOL: All right, that will reduce your fogging.

MR. WALTERS: We realize that.

MR. GADOL: Okay. Have you been able to recreate a hypothetical fire in your training academy?

MR. WALTERS: We don't have a training academy. Our training program, "Learning by Burning," is in actual houses thatare destroyed or buildings that are destroyed. And we are -- I don't know whether it's fortunate or unfortunate. At least, when we burn a house, we are burning a house, and not recreating the fire.

We also would like to have a training academy where it's concrete where we can keep redoing it and redoing it because houses are getting difficult to find.

MR. GADOL: Yeah, they're getting difficult to buy, too. We've found in my experience that you can't recreate a fire very well unless you have a training center like that. There is one in Long Island that's really quite good.

From a manufacturer's standpoint, it is difficult, I'm sure, for Scott or any of the rest of us to go out and buy a couple of old houses and burn them up to make sure our

masks work well so we have resorted to using the Los Angeles Fire Department, the New York City Fire Department, the Boston Fire Department to do this testing. And based on their feedback, we have attempted to create the optimum breathing apparatus.

I'm the first to admit that that hasn't been done yet, but we are working on that and I would welcome any input that you might have on design and things like that to perhaps help us along.

MR. WALTERS: I'm glad you do. But, you see, for some reason -- I don't know what -- you are not the person that I talked to -- I don't know that much about Robertshaw.

But when I talked to MSA, Survive Air, Biomarine, it's a different individual than you people. And we are talking to those people very heavily. Now, I don't know what they're telling -- talking to you about, but believe me, they hear our story.

MR. GADOL: All right, thank you.

DR. MAY: Other questions or comments?

MR. SULLIVAN: John Sullivan, Scott Aviation. There are two points that I want to make in regard to the heat load. This is a fairly complicated problem, and a lot of people are looking at it. The basic fact is, there are not a lot of examples of people who are surviving

fires, using breathing apparatus that where you have melting and failure of parts that you would have at 500 degrees.

There are some examples. When a person is trapped and the building comes down on them, where there is quite a bit of damage. But there is a real problem with the air tank and the cylinder in typical self-contained units.

And as we dry temperatures up, you have to start concerning yourself about the safety of that device. And when you start getting over 300 degrees on that, get the bottle temperature above 300 degrees, you're going to blow the relief device as it is designed and lose the air supply.

So in looking at the garments that have been proposed, it seems to me that we are still missing the boat because, in addition to protecting the man, we'd better start protecting that cylinder.

In regard to the visor, during the program that was run by NASA, this was a subject of discussion and it was realized that the air coming into the visor is cooled because it is coming from the tank, typically cool. So it tends to keep that visor intact, whereas the visor on the helmet quite often would melt.

MR. WALTERS: We've had definitely considerably more problems with the visor on the helmet, and less on

the mask. We do have a mask in our department right now that -- anyway, a couple of days ago, they replaced because of a heat situation of warping and the seal had broken.

Definitely -- practically every night when we learn by burning -- when we burn a house -- a couple of fact shields that are permanently attached to a helmet that are flipped up -- because you have them up when you have your mask up -- are thrown away because they have warped.

When you talk about polycarbonate and dealing wiht the engineers that make polycarbonate -- not helmets but polycarbone from Mobi-industry and G.E., they don't understand why we're using their product.

MR. DUFFY: Rich Duffy, Fire Fighters. Just to clarify some of the statements made by you and Robertshaw-- the gentleman from Robertshaw -- the Project Fires' helmet that's been developed and tested has withstood a 1500 temperature -- Farhenheit temperature at I believe 1.5 calories per cubic centimeter for 10 seconds without allowing the thermal couple inside the helmet of the mannequin to go over 113 degrees. It's preliminary data hasn't all been put together yet, but that's the rate of -- I believe the irreversible skin damage to a human being is 141 degrees and it stayed within that 113 degree temperature requirement.

Speaking to where you talked about your face piece

and the detergent, the additive that you used on it, I can't see how it could stand polycarbonate face shield to withstand temperatures of 1000 degrees Farhenheit. Did it work?

MR. WALTERS: Well, I think you misunderstood what I said then. Ask me the question again?

MR. DUFFY: The face shield, when you were discussing the chemical and the detergent that you were applying to your face shield, and you said that you tested it at --

MR. WALTERS: No, I didn't. We sent it -- I don't know anything about testing. Believe me, I don't. So we sent it to this company here. I don't know what they did, but we told them that we were designing equipment to go up to 1000 degrees. And you're right, that's probably why the toxic fumes was coming off the face piece because the face piece could not exist. And it did, by the way, destroy the face piece.

But they said that when they ran the product that we gave them up to this -- these temperatures that we asked them, because maybe someday we'll have a face piece that will go to 1000 degrees -- and we still want to use this anti-fog device or solution, they did test this solution to --

Okay, the detergent was of no value from 4-500

degrees. The silicon was of no value for anti-fogging at 800-1000 degrees. Long before that temperature, the face piece itself was destructed from heat.

Now, they did say there was considerable -- they had a considerable concern about the toxic fumes coming off of the face piece as it was destroying itself from heat.

MR. DUFFY: The only thing we found to withstand a temperature in Project Fires was Ken-Tempered glass that withstood that heat so there is a possibility, but you have to pay the expense.

And also the helmet was not made of polycarbonate. It was high temperature, epoxy-wrapped fiberglass, and it did withstand the heat load.

MR. WALTERS: Yeah, we're real excited about this helmet. We were promised this same helmet --

MR. DUFFY: Is this from Karns?

MR. WALTERS: We are getting six of them in September that will go with these suits, and right now, we have definitely more protection on the body than we have on the head, but we wear what we have.

MR. DUFFY: And he's using a polycarbonate face shield, just to make you aware of that.

MR. WALTERS: But it is going up inside rather than on top which, to me, is an improvement.

MR. DUFFY: That's the Project Fires' ensemble.

MR. WALTERS: Yeah, right.

MR. DUFFY: And secondly, when you talk about test rooms, also Cris Kooms from Karns in New Jersey has done heat measurements at Fairfax County Fire Department training where they found temperatures at actual simulated fire exercises up to 400-500 degrees. And he has full results of that, and people can write directly and he'll certainly supply them.

MR. WALTERS: Yeah. I have a hard time wondering why that we, in the fire service, have a hard time convincing those that are not in the fire fighting service as fire fighters, that it's hot in there. We do have documented tests that have been run during a typical structure fire which only tell us how hot it was on that fire. It doesn't mean that another one isn't even hotter, but we know it's at least that hot.

And it is printed in International Fire Chiefs, International -- or Fire Engineering, all these fire magazines which I'm sure you read -- I don't know if you don't believe what you read or whatever. When we start talking about 5-600 degrees, gentlemen, it's there, and so are we.

DR. MAY: Okay, thank you very much, Woody.

MR. OPHOLD: Woody, this is Jim Ophold. I

have one quick question, and you probably have a yes or no. Would it be possible for you to supply for the record the number of self-contained breathing apparatus used in the state of Minnesota?

MR. WALTERS: Oh, yeah, I would be glad to submit it later. I don't think I could ever really get -- we have 800 fire departments. Some fire departments have 60 units. Some fire departments have two or three. And I don't think I could make contact with 800 fire departments and get an exact count. If you'd let me, say, take five times 800 or a round-off figure, we could come up with an estimate.

But it takes five years to teach a class in these 800 fire departments.

MR. OPHOLD: The best approximation you could provide would be of help to us.

DR. MAY: The next presentor this morning is William Gadol representing the Industrial Instrumentation Division of the Robertshaw Controls Company. Bill?

MR. GADOL: My name is Bill Gadol, from the Industrial Instrumentation Division, Robertshaw's Controls.

My company offers the following comments on NIOSH's role in testing as outlined in the Federal Register of Wednesday, June 18, 1980.

Item one: The quality control section states

that used units would be obtained from the field, tested for performance for Title 30, and the results published. There is no control over the condition of the units once they are in the field.

Unless the units are properly maintained by the user, the units could fail due to improper handling, storage, maintenance or repair.

Therefore, proper evaluation of used units can only be accomplished by the manufacturer. Regarding the publishing of results, this should be limited to a pass-fail notation, and not include data that could be used by competition.

Further, the procedure does not include a method of appeal from NIOSH findings. Some method of appealing test results should be included.

Item two: witnessing of approval tests. This entire paragraph is now useless as per your change of July 1. We certainly disagreed with the proposed change in the June 18, and wanted to stick to the June 20, 1980, document issued by Dr. Ophold.

Item three: duration of approval. It is felt that a five year reapproval requirement is not needed. Since Robertshaw favors the ISCA position as outlined by Frank Wilshire yesterday, and I would call you to look at that to see exactly where we stand on that.

If every approved device requires recertification by NIOSH, our question is what percentage of NIOSH's time would this consume.

It is conceivable that in time NIOSH would be spending full-time merely recertifying. It is slow and cumbersome enough under the current program to get initial certification of a new or modified product.

Item four: testing of prototype respirators. It is felt that this clause should be entitled, "Testing of Development Respirators." This assistance could be requested by a small company which does not have the financial capability of buying exotic engineering test equipment involved in programs.

This paragraph should not be confused with preproduction of prototypes being submitted for certification of tests.

Item five: approval tests. It is felt that this clause should be deleted completely or rewritten to permit samples of respirators to be supplied with machined parts in lieu of parts which would be made an expensive production tooling such as production molds, mass molds, die, casting, et cetera.

Equipment of that type can cost $25,000 to $100,000.

Group testing of respirators. This paragraph

restricts marketing of new products to the industry. It is not acceptable because of this restriction and could involve considerable losses to the manufacturer. The manufacturer could have equipment ready to submit. It be required to wait for NIOSH to schedule that type of device for submittal.

Item seven: publication of test data. Publication of data should not be allowed because it permits competitive companies to use comparison literature which is detrimental to good business, particularly if the company is unethical in its marketing practices. Test data should be published only as to whether it failed or passed.

That concludes the comments from Robertshaw.

DR. MAY: Thank you, Bill. Are there any questions of Mr. Gadol, any comments?

MR. DUFFY: Rich Duffy, Fire Fighters. I have one question -- it's either you, John, or Robertshaw can answer. What material is now available from NIOSH regarding certification and testing and specific apparatus under Freedom of Information Act?

DR. MAY: Repeat the question. I'm not sure --

MR. DUFFY: What test data -- test results from your certification and testing at Morgantown are now available to the public under the Freedom of Information Act?

Are there any specific exclusions? Or have there been such requests?

DR. MAY: Okay, I'll try to answer the question. I'm not sure. Under the present system of witnessing, the applicant will receive a copy of the test results, and based thereon, he can file an appeal that something was not right or he accepts the test results as presented.

MR. DUFFY: Now, is that file available to the public under Freedom of Information Act or were there exclusions placed on it?

DR. MAY: I'll be honest. I would have to defer that to legal counsel because at that stage, when we're talking about either granting or denying a certification --

MR. DUFFY: No, not during that stage. The file is -- once it's approved and the company file is placed wherever it may be placed, is that information available to the public? If you don't know, you can have -- I'd like that a part of the record.

DR. MAY: I'm not even going to take a stab at it. Mr. Drew, legal counsel from HEW or HSS is in the audience. If he has an opinion he'd care to provide or if the program does. There is very little these days that's not available through FOIA, if you're not an enforcement agency. Glen?

MR. DREW: Glen Drew, HHS, Office of General Counsel. The information that would be released is a departmental rather than NIOSH decision to make, and I suspect most of it which is not -- any that's not trade secret would be available.

MR. BRENNAN: Bob Brennan, Scott Aviation. I believe this one will probably be answered by Dr. May, but it was occasioned by your remark during your presentation that due to the present change, the question of witnessing is no longer a discussable point.

And basically, I think I have to ask for clarification. As I understood it, part 11, since its last revision, has certainly allowed a manufacturer to request to be present a witness in approval test.

I guess I do not understand the change that you're referring to in your presentation.

MR. GADOL: You're talking about -- when you say my comment?

MR. BRENNAN: Yes, sir. The presentation said thatdue to the NIOSH recent change, the question of witnessing during the test wouldn't be addressed during the presentation.

MR. GADOL: Right.

MR. BRENNAN: And that occasioned my question of the extent of the change, which I don't understand.

MR. GADOL: Okay, my comment referred to the fact that we now have written procedures for the witnessing that have been made available to the manufacturers. In the past, it is my understanding that there was never any formal, commited to writing scheme for the witnessing and you are correct that 30 CFR talks about the manufacturer or his agent witnessing tests.

And what we have, in fact done, is really not something different from 30 CFR 11. But in fact, that we have now committed it in writing, made it available, outlined the whole procedure. That is, in fact, to me a change -- not a change in the legislation, but in the way we recognize it and the way we operate the program.

MR. BRENNAN: Just to be certain, this document you're referring to outlines three suggested reasons under which a possible witness test could be challenged. That is the document we're referring to?

MR. GADOL: That is correct.

MR. BRENNAN: Thank you, sir.

DR. MAY: I guess I should make on e comment in light of the remark you made to Bill Gadol, and that is that although we now have that program in effect, and it is committed to writing, and the June 16th Register says that the institute is opposed to the witnessing, that is a position that we are adhering to today.

In other words, we are saying that in any new legislation that we may adopt, we are at least contemplating changing the regulations to exclude the witnessing, and so thus, we are asking for comments on that specific issue.

MR. GADOL: In that case, I want to read that into the record. I'm going to go back to paragraph 2 and read it into the record.

Item 2, witnessing of approval tests. This particular specification conflicts with the June 20, 1980, document issued by NIOSH entitled, "To all manufacturers of NIOSH and MSHA certified products," and signed by Dr. Ophold.

In this document, manufacturers are allowed to prearrange their appearance and witnessing of their products being tested. Further, it is possible that the manufacturer, because of his complete knowledge of his own product could see what, to him, is an obvious error in the test procedure that would falsely fail the unit.

This could and probably would result in considerable and unnecessary delay in approval and would require additional, unnecessary time by NIOSH personnel to retest.

DR. MAY: Thank you, sir. Thank you, Bill.

Are there any other comments or questions for Bill?

If not, we will go onto the next presentor who is Carol A. Dupraz, a consultant from White Plains, New York. During this part of the presentation, Ms. Dupraz is representing her own philosophy, concepts and ideas. You will notice that later she is also listed on the program on Wednesday as representing Racol Air Stream from Rockville.

MS. DUPRAZ: Thank you very much, John. I think I might appear somewhat as a mystery guest on the agenda, but I have been involved in a lot of the various testing and certification procedures, and how they operate, not just respect to occupational health and safety products, but a fair amount with the consumer product safety commission and a lot of the problems that those folks got into need to be looked at and I'll try and point some of the ways I think might help here.

I appreciate this opportunity to share my views today on some of the items that were put forth by NIOSH on the subject of testing and certification.

The June 18th notice of this public hearing outlined four possible roles for NIOSH in testing and certification of personal protective equipment and hazard monitoring instrumentation.

Selection of either a single option or even

a combination of alternative approaches requires consideration of a number of factors, however.

What is the size and type of effort needed to provide equipment users with a high level of confidence in the performance of their products? What personnel and facilities are needed to accomplish this objective within a reasonable or acceptable time frame? And what type of structure would best utilize all available resources.

Although the issues and topics on which this hearing is focusing specifically relate to respirator approval system, that consultant's report recommended the testing and certification activities be restructured to include all personal protective equipment and hazard monitoring instrumentation. As devices of integrated design emerge, this broader scope is increasingly desirable. Most of the elements of a restructured respirator testing and certification program should therefore be broadly applicable to all PPE and HMI.

Three major components of the proposed testing and certification program - performance specification revision, new product testing and approval and field audit assessment of in-service product performance - can be examined with this broader program scope in mind:

Performance Specification Revision and Development

Because parts of 30 CFR 11 have long been recognized as technological anachronisms there have been repeated attempts to upgrade existing procedures or develop new ones by NIOSH itself, through contract work at LASL, by concensus standards organizations and other technical groups. These

activities have entailed extensive laboratory testing and data analysis. The situation has been much the same in developing performance test methodology in other product areas, i.e., flammable fabrics. There is no reason to believe that this will not be the case with respect to occupational health and safety products. Indeed, one of the most wanting characteristics in current performance test methods is demonstrated interlaboratory reproducibility of data.

Consequently an increase in the number of testing facilities available for participation - in at least the final stages of test method development - should be encouraged. Effective management of in-house, purchased and contributed technical effort will also be necessary to assure that revisions and new procedures are technically sound, up-to-date and become available in a timely fashion. Use of qualified independent testing laboratories as well as NIOSH and manufacturers' in-house facilities may be essential to handling this key program element.

The proposal by NIOSH to establish new or revised performance specifications by the rulemaking process should be examined closely in view of the agency's history of previously unsuccessful attempts to change even uncontroversial material in 30 CFR 11. Alternative approaches for establishing updated performance specifications appear to be needed.

New Product Approvals

NIOSH proposes discontinuing certain review procedures which are now part of the testing/certification system but would continue certifying new products and publish results of approval testing conducted by NIOSH. The Consultants' Report emphasized the need to assure users of product reliability in service. New product approvals would better meet this goal if certification were based, at least in part, on the results of field audits of product performance after an initial or trial use period. This could be achieved if manufacturers' were to stipulate that products met minimum standard performance specifications and provided the initial product performance test data on which this claim was based. Some mechanism for verifying manufacturers' claims might be needed so that users could confirm that new products can be expected to perform adequately during the trial period between product introduction and successful completion of an in-service field audit.

This approach would utilize NIOSH and manufacturer in-house testing facilities and personnel somewhat more efficiently than the present system by eliminating duplication of initial performance testing of new products. If necessary these resources could be augmented by the services of qualified independent testing facilities.

Field Audit Assessment of In-Service Product Performance

An effective field audit program would go a long way towards providing a higher level of confidence to users of occupational health and safety equipment. Performance

data would be particularly meaningful is the audit program involved testing multiple units of a specific product, both as purchased and after the product was placed in service, against standard performance specifications and perhaps against proposed new performance requirements. Analysis of the type and frequency of functional product deficiencies found in field audits would assist in setting priorities for tightening and/or redirecting manufacturer in-house quality control, developing new product designs or performance criteria.

A well-organized and completely detailed field audit protocol should be developed, offered for public comment and revised as necessary prior to adoption as an operating plan. This protocol should include product sampling procedures, complete, by type of product description of specification and performance test methods on which the audit will be based, mechanisms for identifying in-service product performance inadequacies due to misuse, abuse or improper maintenance, description of the process for publishing results of field audit, provisions for varifying contested field audit data, options for including proposed or tentative test methods as part of the performance audit, procedures for assuring removal from service of unreliable or technically unsound products.

While the extent to which the services of qualified laboratories other than in-house NIOSH and manufacturers facilities would be needed in conjunction with the field

audit program is uncertain at this point in time, restructuring of testing/certification activities should not preclude either their existence nor ignore their usefulness.

I would like to point out here that the Consultants' Report suggests that the Consumer Product Safety Commission operating system be examined for applicability to testing and certification of occupational health and safety products, as many of its features closely parallel those needed here.

I have only a few additional comments, which relate more directly to specific issues raised by NIOSH in connection with current practices in its operation of the respirator testing and certification program.

Unpublished Test Requirements

NIOSH is proposing to discontinue the current practice of accommodating new equipment designs by basing approvals on special unpublished test requirements, which have not had the benefit of public scrutiny. This recommendation highlights the need for an operating plan which encourages innovation while retaining the safeguarding provisions of uniform performance evaluation. Perhaps this can be achieved by including in the restructured testing and certification program provision for "conditional" or "temporary" approvals. These could be based on the results of both non-standard or tentative test procedures and limited scale field evaluations. Complete details of testing, field trial protocol and data analysis on which any approval is based would be published as a condition of approval. At this point the performance specification development process could be relied upon to

upgrade tentative test procedures and criteria to full acceptance. Successful field audit would remain a requirement for final approval.

Witnessing of Approval Tests

NIOSH has proposed that applicants no longer be allowed to witness approval testing of their products because testing personnel feel pressured by the presence of witnesses. Test methods so subjective in conduct or so highly variable in results that the presence of witnesses can materially influence the outcome should be eliminated in the process of revising performance specifications. In addition testing of multiple units of the same product should dilute possible observer interference to a negligible level. Until the wide latitude in test conditions and high number of unspecified variables which exist in current certification procedures have been eliminated, the provision permitting applicants to witness product approval tests should be retained.

Duration of Approvals

As a practical matter the duration of final approvals, reapprovals and temporary or conditional approvals may have to be governed by the availability of product testing and data publishing resources.

However, all approvals should be limited in duration. Approval duration might be tied to the extent upon which the product is depended for survival, health or safety protection - the greater the reliance, the shorter the approval duration.

Group Testing of Respirators

This has been proposed by NIOSH in an attempt to organize the testing work load and to accelerate product approvals. Testing of the same types of products in a group would offer the additional advantages of off-setting within-lab variations in test conditions and placing product testing on a more comparative basis. However, use of an approval testing application "time window" could result in

(1) inadvertently controlling, in the short term, the type and number of new products available to users;

(2) unintentionally excluding, solely on the basis of timing, competing products from the approval testing schedule for a significant period of time.

(3) unwittingly frustrating occupational health and safety enforcement timetables by delaying approvals of needed or especially desirable products, particularly if only a single facility can provide the needed service.

In Conclusion

One last comment. Since the restructuring of occupational health and safety products testing and certification is so complex I recommend that specific procedural options be developed for each key program element and the transition phase from current to restructured operation and that these be offered for public comment. Each option should be presented with an analysis of its probable effectiveness in meeting the objectives of testing/certification and an estimate of the

personnel and facilities resources required to carry it out. NIOSH might recommend adoption of one of these options, but should also provide an explanation of its reasoning in making the selection.

Thank you.

Some of this procedural suggestion is related to the way the Consumer Product Safety Commission has evolved some of its systems. It has been somewhat cumbersome, but it has worked, I believe, in an equitable fashion for them, and I think that it might serve a good purpose here.

Thank you.

DR. MAY: Thank you, Carol. Are there any questions or comments concerning her statement?

MS. DUPRAZ: Thank you very much.

DR. MAY: Thank you. Okay, the next speaker on the program, your program, is listed as Scott Aviation, Lancaster, New York. A presentation for Scott will be made by Rob Sere, Director of Engineering. Rob?

MR. SERE: Good morning still. Scott Aviation welcomes this opportunity to participate in a public meeting that is convened to receive public comment on the role of NIOSH and testing and certifying personal protective equipment and hazard measuring instruments.

I'm Rob Sere, Director of Engineering for Scott Aviation Division of the ATO incorporation.

Now, Scott's products are presently limited to respiratory protective equipment and hazardous measuring instruments.

We are, of course, interested in all aspects of the regulatory climate as it affects the industrial state equipment -- industrial safety equipment industry.

This is especially true since what is done by NIOSH and OSHA is beginning to affect other markets of prime interest to us, namely the military, aviation, public service communities and some foreign nations, all of which utilize similar apparatus for personal protection and life support, and are not necessarily covered under the OSHA Act.

I'd like to direct some attention to the unfortunate development of what seems to be an adverse relationship between the respirator manufacturing industry and NIOSH in general, and the DSR in Morgantown, in particular.

Speaking from Scott's standpoint, our association with the Bureau of Mines, and NIOSH-DCL personnel had always been one of friendship and cooperation in achieving our mutual coal of improved protection for those needing protective breathing apparatus, and hazard measuring instruments.

That is until about the last 18 months to two years.

We deplore this change, and fervently hope that what goes on here today and tomorrow and yesterday will

the regulatory climate as it affects the industrial state equipment.-- industrial safety equipment industry.

This is is especially true since what is done by NIOSH and OSHA is beginning to affect other markets of prime interest to us, namely the military, aviation, public service communities and some foreign nations, all of which utilize similar apparatus for personal protection and life support, and are not necessarily covered under the OSHA Act.

I'd like to direct some attention to the unfortunate development of what seems to be an adverse relationship between the respirator manufacturing industry and NIOSH in general, and the DSR in Morgantown, in particular.

Speaking from Scott's standpoint, our association with the Bureau of Mines, and NIOSH-DCL personnel had always been one of friendship and cooperation in achieving our mutual coal of improved protection for those needing protective breathing apparatus, and hazard measuring instruments.

That is until about the last 18 months to two years.

We deplore this change, and fervently hope that what goes on here today and tomorrow and yesterday will

lead to a more workable and beneficial relationship.

The June 18, 1980, issue of the Federal Register and the consultant's report of November 21, 1979, provides a fertile field for comments. While our viewpoint may be identical or similar to others presented here, we would like to present our recommendations and comments as follows -- and I'm limiting myself here to respiratory protection and its equipment, which is Scott's main concern at the present time.

As members of the IFCA, we generally concur with and support most of the points made by Mr. Wilshire yesterday, but it seems, from my standpoint, the consideration of many of the pertinent factors, including what we know of the applicable legislation, that NIOSH does not really belong in the regulatory role.

Research on the need for and extent of respiratory protection, plus development for performance criteria for respiratory protective devices should be their main NIOSH role.

OSHA is the basic regulatory agency, and the requirements for the use of protective equipment and the degree of protection to be provided is definitely in their area.

What seems like possibly a viable alternative to present procedure would be for NIOSH, OSHA, whoever --

however it happens to work out, assume a modus operendi on apparatus approvals that is patterned after another regulator agency, the Federal Aviation Administration, who has a new procedure for the issuance of what they call technical standard orders, which is one of the four methods by which materials, parts, processes or appliances may be approved for use on aircraft.

Certainly, the need for safety assurance in aviation is no less than that in respiratory protection equipment.

Following are some exceprts from the revisions to the TSO authorization procedure as reported on the Federal Register on June 9, 1980, and I will also probably make some editorial comments and omit some of the voluminous detail which appears in the Register notice.

One of several methods of obtaining approval is by designing and testing an article, material, part, process or appliance in accordance with the TSO which contains minimum performance and quality control standards for a specific article.

The standards for each TSO are those the administrator finds necessary to ensure that the article concerned will operate satisfactorily. Since compliance with a TSO is only one method of obtaining approval, the

standards contained in the TSO are not mandatory but are only an optional way of obtaining approval for a particular article.

For example, an applicant can obtain approval to deviate from a particular TSO if it shows the design feature provides an equivalent level of safety.

A TSO is not a standard of genre or particular applicability designed to implement or prescribe law or policy. It does not fall within the definition of rule contained in the Administrative Procedure Act, 5 USC 55-51.

There is no requirement that a TSO be published in the notice of proposed rule making in the Federal Register. Future TSO's will, through incorporation by reference, make maximum practical use of voluntary standards as defined by the Office of Management and Budget circular A-119.

By definition of the OMB circular A-119, voluntary standards are established generally by the private sector voluntary standards body and are available by use by any person or organization, private or government.

The term includes what are commonly referred to as industry standards as well as concensus standards. Voluntary standard bodies are nongovernmental bodies

which are broad-based, multi-membered, domestic and multi-national organizations including, for example, nonprofit organizations, industry associations of professional and technical societies which develop, establish or coordinate voluntary standards.

AFAA has determined for the reasons stated in notice 79-15 published in the Federal Register of October of 1979, that in the interest of safety, it is appropriate to adopt new public procedures to facilitate the issuance of TSO's for specific articles used on aircrafts.

I note that it took from October '79 to June '80 in this particular case to get fromproposed rule-making to rule-making.

The safety aspect of this rule-making is particularly important. The fact that TSO's have become part of the complex regulatory structure of the FAA has caused substantial lag time between regulations and the state of technology.

This procedure -- procedural change should advance by months, even years, the implementation of technological improvements in the U.S. Aviation System. This kind of a statement also applies with what has happened with the CFR 30-Part 11, becoming embroiled in the regulatory process.

Interested persons have been afforded an opportunity to participate in the making of these amendments to the limit.-- participate in making amendments and due consideration was given to all concerned presented.

Significant comments received in response to this notice were discussed below. I'm not going to go into all the comments that were listed in that particular notice.

The amendments were consistent with the agency's responsibility to review the continued need for regulation and the need to eliminate unnecessary regulation by eliminating TSO's from the regulations previously published in sub-part B of 14 CFR part 37.

In making them available through multiple procedures below, the FAA has improved the availability of TSO's and make it easier for the public to locate the most up-to-date standards.

In addition, by removing TSO's from the agency's regulatory process, the time available for other matters within the regulatory system will be increased. This will enable the agency to respond in a more timely manner to other issues submitted by the public.

This improvement in the regulatory process to be more responsive to the public is consistent with

executive order 12044 issued by President Carter on March 23, 1978.

Public procedures: The following is a public procedure in detail the FAA will use to develop and issue final TSO's for specific articles used on civil aircraft. The FAA will continue to develop draft TSO's and will continue to use, by reference, in the TSO documents prepared and issued by organizations such as the Radio Technical Commission for Aeronautics and Society of Automotive Engineers and others.

Notices of these meetings -- RTCA and SAE meetings -- and invitations will continue to be published in the Federal Register. This will allow public participation in the early stages of development.

Any interested person may request the administrator to revise or issue a new TSO by submitting a description of the revision sought or description for the new article for which the TSO is requested.

The FAA will use several methods to ensure that the public is afforded early opportunities to take part in the TSO decision-making process.

A draft TSO will be circulated for public comment through the use of mailing lists. Any individual or organization can request to be placed on the mailing list. All those in the list will receive drafts of each TSO. In

addition, in Advisory Circular 20-110, Index of Aviation Technical Standard Orders, will list those TSO's, the FAA anticipates will be issued within the succeeding 12 months.

The advisory circular will also list each current TSO and provide information on how to obtain copies of those desired.

Finally, the FAA will publish periodically a notice in the Federal Register of each proposed TSO and a notice of how to obtain a copy, but will not publish the TSO itself in the Register.

Omitting details on the process to obtain -- get on that mailing list.

When there has been a proposed TSO publicized by the methods described, all comments received are on or before the closing date. Comments will be considered just like in the rule-making process.

All comments will be available both before and after the closing date for comments for examination by interested persons at the FAA location and other places. Copies of the final TSO will be mailed to all persons on themailing list as in the past.

Documents were prepared and issued by the organization that are incorporated by reference, and the TSO will continue to be available to any interested person

only from that organization.

Final TSO's will not be published in the Federal Register.

Copies of all draft and finals are available at FAA headquarters. In summary, the new procedure has numerous opportunities for the public to participate in the development of each TSO.

These are the participation of development of the documents prepared by industry organizations which the FAA may use by reference, mailing lists, circulate draft TSO's to the public for comments, and advisory circulatory lists to the -- for the public each TSO and the FAA anticipates will be issued within the succeeding 12 months, notice in the Federal Register announcing the availability of each draft TSO, and invitation for comment and at least 90 days to submit comment.

NIOSH and OSHA might well consider establishing a similar communications network if they do or do not follow these particular suggestions we're making here.

Some especially pertinent sections are given as follows. On reporting of failures, malfunctions and defects: Except as provided in paragraph D of this section, the holder of a tax certificate including a supplemental-type certificate, a parts manufacturing approval or a TSO authorization where the licensee of a

tax certificate -- these are the four methods by which FAA approval can be obtained on any aircraft device -- shall report any failure, malfunction or defect in any product, part, process or article manufactured by it that it determines has resulted in any of the occurrences listed in paragraph C of this section.

The holder of a tax certificate, including supplemental tax certificate and so forth, shall report any defect in any product, part or article manufactured by it that has left it's quality control system, and that it determines could result in any of the occurrences listed in paragraph C of this section.

Paragraph C lists a whole bunch of typical failures or defects in aircraft which are pertinent to aircraft, and I won't go into detail except to mention one of them, which is the accumulation or circulation of toxic or noxious gases in the crew compartment or passenger cabin of an aircraft as being a typical one that requires reporting by the manufacturer to the FAA.

A failure or a -- wait -- D, yeah. The reporting requirements of this paragraph do not apply to one, failures, malfunctions or defects that the holder of a tax certificate, including a supplemental tax certificate, parts manufacturer, PMA, TSO, authorization or the licensee determines to be caused by improper maintenance

or improper usage, and those that were reported to the FAA by another person under the Federal Aviation Regulations, has already been reported under the Acts and reporting provision in part 430 of the regulations of the National Transportation Safety Board.

There are also a number of references to what you do on reporting defects to -- in foreign supplied equipment.

Each report required by this section shall be made to the FAA regional office in which the holder is located within 24 hours after the holder has determined that the failure, malfunction or defect required to be reported has occurred, except that a report due on a Saturday or Sunday may be delivered the following Monday, and one due on a holiday may be delivered the next workday.

It shall be transmitted in a manner and form acceptable to the administrator by the most expeditious method available, and shall include all kinds of information that are necessary such as the aircraft serial number, the failure, malfunction or defect, and product model, part number, serial number and so forth, the nature of the failure and malfunction or defect.

Whenever the investigation of accident or service difficulty report shows that an article manufactured

under a TSO authorization is unsafe because the manufacturer designed defect, the manufacturer shall, upon request to the administrator, report to the administrator the results of its investigation and any action taken or proposed by the manufacturer to correct that defect.

If action is required to correct a defect in existing articles, the manufacturer shall submit the data necessary for issuance of appropriate air worthiness directive.

I don't know whether you've ever heard of that before -- AD -- air worthiness directive; the chief of the engineering branch or in the case of the western region, the chief of the Aircraft Engineering Division of the FAA in Los Angeles.

These air worthiness directives may call for inspection, repair, correction or replacement of the part with a new design, if necessary, and call for a schedule or whatever is necessary to achieve the desired level of safety.

21-305, approval of materials, parts and so forth, appliances -- under technical standard order issued by the administrator consists a list. Their circular 20-110 contains a list of all the technical standard orders that have been approved so far, and they technical data is there for you to make application

to get approved underneath those particular sets of specifications.

There are a number of references to the procedure required. The technical standard order referred to in this part is issued by the administrator and is a minimum performance standard for specified articles for the purpose of this subpart. The article means materials, parts, processes or appliances used on aircraft.

The TSO authorization is the FAA design and production approval issued to a manufacturer of an article which had been found to meet a specific TSO.

An article manufactured under TSO authorization, FAA letter acceptance or appliance manufacturer under a letter of TSO design approval described in 21-617 is an approved article or appliance for purpose of meeting the regulations of this chapter that require the article to be approved.

An article manufacturer is the person who controls the design and quality of the article produced or to be produced in the case of an application. Including parts within any processes or service related to them that are procured from outside sources.

The administrator does not issue a TSO authorization if the manufacturing facilities are outside of the country, except under certain circumstances.

Except as provided in paragraph B of this section and 21-617C, no person may identify an article with a TSO marking unless that person holds a TSO authorization and the article meets the applicable TSO performance standards.

There is a list here of obsolete TSO's which we can no longer use because the administrator has decided that they are no longer applicable to present-day technology.

Manufacturer and authorized agents shall submit an application for a TSO authorization, together with the following documents to the chief engineering and manfacturing branch, Flight Standards Division, for the region in which the applicant is located or in the case of the western region, to the chief, Aircraft Engineering Division.

A statement of conformance certifying that the applicant has met the requirements of this subpart, and that the article concerned meets the applicable TSO that is effective on the date of the application for that article.

One copy of all the technical data required in the applicable TSO and the actual TSO itself gives a great deal of detail on what must be provided.

A description of its quality control system

in the details specified in the act, in complying with this section, the applicant may refer to current quality control data filed with the FAA as a part of the previous TSO authorization application.

On a series of minor changes in accordance with 21-611 as anticipated, the applicant may set forth in its application the basic model number of the article, and the part number of components with open brackets after it to denote that suffix change letters or numbers or combinations of them will be added from time to time.

After receiving the application, other documents required by paragraph A of the section to substantiate compliance with this part, and after determinations have been made of its ability to produce duplicate articles under this part, the administrator issues a TSO authorization, including all TSO deviations granted to the applicant to identify the article with the applicable TSO marking.

If the application is deficient in any way, the applicant must, when requested by the administrator, submit additional information necessary to show compliance with this part.

If the applicant fails to submit the additional information within 30 days after the administrator's

request, the application is denied, and the application is so notified.

It is interesting that the administrator issues or denies applications within 30 days after receipt or if additional information has been requested within 30 days after receipt of that information, either approves or denies within 30 days. That would be great for a good many of us.

Each manufacturer of an article which has a TSO authorization issued under this part shall manufacture the article in accordance with the part and applicable TSO, conduct all required tests, inspections and establish and maintain a quality control system, adequate to ensure that the article meets the requirements of this paragraph, and is in condition for safe operation. Prepare and maintain for each model of each article for which a TSO authorization has been issued, a current file of complete, technical data, and records in accordance with 21-613, and permanently and legibly mark each article to which this section applies with the following information: name and address, manufacturer, name, type, part number, or model designation of the article, the serial number and/or date of manufacture of the article or both, and the applicable TSO number.

There are some other parts on deviations which

are granted in the case of equivalent safety levels. Then we get into design changes.

Minor changes by the manufacturer holding a TSO authorization -- the manufacturer of an article under an authorization issued under this part may make minor design changes, any change other than a major change without a further approval of the administrator.

In this case, the changed article keeps the original model number. The part numbers may be used to identify minor changes. And the manufacturer shall forward to the appropriate chief engineering and manufacturing branch or, in the case of the western region, the chief aircraft engineering division any revised data that are necessary for compliance with the original TSO.

B - major changes by manfacturer holding a TSO authorization, any design change by the manufacturer that is extensive enough to require a substantially complete investigation to determine compliance with a TSO is a major change.

Before making such a change, the manufacturer shall assign a new type of model designation to the article and apply for a new authorization.

Changes by persons other than a manufacturer -- suprisingly enough, you can do that in the FAA -- no design

changes by any person other than a manufacturer who submitted -- who is eligible for approval unless the person seeking the approval is a manufacturer and applies under 21605 for a separate authorization.

Persons other than the manufacturer who may obtain approval for design changes under part 43 or under applicable air worthiness regulations. They allow people to modify airplanes.

Record-keeping, holder of a TSO authorization shall keep the following records at his factory -- a complete and current technical data file for each type of model, including design drawings and specifications; complete and current inspection records showing that all inspections and tests required to ensure compliance have been properly completed and documented. Shall retain records as long as he makes the article, and if he goes out of business, he will forward those records to the FAA.

FAA inspection - upon request of the administrator, each manufacturer of the article under a TSO authorization shall allow the administrator to inspect any article manufactured under that TSO authorization, inspect the manufacturer's quality control system, witness any tests, inspect the manufacturing facilities and inspect the technical data filed on that -- on those

articles.

The administrator may, upon notice, withdraw the TSO authorization or letter of TSO design approval of any manufacturer who identifies with a TSO marking the article not meeting the performance standards of the applicable TSO, and TSO's are not transferrable.

If NIOSH, OSHA or whoever should adopt a program which parallels this TSO procedure, it would, in effect, be implementing a procedure similar to alternate 4 as described in the Federal Register notice of June 18.

This self-certification program would allow the manufacturer who has sufficient resources to do and certify his own test work in his own laboratory. It would not prevent those who do not have those resources from contracting the work to a third-party laboratory.

Those third-party laboratories could, of course, be subject to NIOSH-OSHA certification if that is deemed necessary. Certainly, NIOSH would have the authority to survey the manufacturers test facilities for adequacy just like the FAA does.

NIOSH, in issuing the approval letter, after the submission of the application by the manufacturer, would review the design, the performance data and quality control information submitted as in the TSO procedure.

NIOSH-OSHA could take any necessary steps to satisfy itself of the adequacy of the product and the ability of the manufacturer to build the device and control its quality and distribution.

The field audits, which have been so thoroughly discussed, could also be conducted as necessary. As a company who has, over the last 40 years or so, been in the life support equipment business, has had to deal with the standards, specifications, certifications, approvals, qualifications, et cetera, of the United States and foreign military agencies, the FAA, the FDA, the Bureau of Mines, NIOSH, Coast Guard, and all the major aircraft OEM's, and some of them are pretty tough, Canadian Standards Association, Department of Transportation's Hazardous Materials Section, Underwriters and factory mutual laboratories and probably a few others that I can't remember. We feel that the FAA's new system probably will produce the best results.

It provides a degree of control which can be made appropriate to the situation, and yet is flexible enough to permit rapid distribution of new technology and approved designs to the using public, something which is certainly not happening very rapidly at the present time in the NIOSH-TCL situation.

Thank you very much.

DR. MAY: Questions? Thank you, Rob. Are there any questions, comments? Dr. Ophold.

DR. OPHOLD: Jim Ophold, NIOSH. I think that we are very interested in your comments about the FAA's new way of doing things.

MR. SERE: It's not necessary new. It's just been revised significantly by this latest issuance of the Federal Register.

DR. OPHOLD: And I think that NIOSH will certainly look into that. I think also it's understood that some of these procedures that FAA has had are being challenged, and I don't know whether these are not, but that is something that we would all want to look at.

I guess not appearing to be defensive in this but you made the comment at the beginning, something about friendship and cooperation, and particularly the last 18 months to two years.

That just so happens to be the time frame that I've been director of the Safety Research, and I'd like to indicate a few things that have happened.

I'm not particularly challenging, perhaps, the friendship part of that as much as the cooperation. And I want to go on record to indicate some of the changes that have been made in the testing and certification branch during this time.

I think that -- to make the analogy somewhat like playing football, and I played that nine years. And we can be friends, Rob, off the field but when you put on the opposing suit and go out to play, I'm going to give it everything I have to block, tackle, and score.

It's not the same. I know analogies are poor. We hope that we can do this in a cooperative manner. And I think we have. And I'm going to cite a few examples of where we've extended ourself to do this.

But the first point I'd like to make is that changes have been -- we are writing protocols. We haven't got them putlished, but protocols are being written. I came in two years ago. I found out that very few things are written down. I initiated this and, of course, we got into a lot of problems with staff and so forth, that we are slow in doing this, but this is being done.

Our records, data and tracking system internally are being computerized so that we don't have the subjective faults or errors that enter in that come with human handling of these types of things.

The second point, our internal review before decisions are being made, is not being done by one person. They are being done by a panel review, and obviously,

that the branch chief has the final say. It now is Mr. Ralph Touch.

But he has his experts give him advice, and then he brings it to me with the full discussion report. And I just want to go on record that this is now -- decisions are based, as we think, on fact and scientific data.

The third point that I'd like to make is that the staff within the testing and certification branch is now nearly entirely devoted to respiratory testing and certification. We have cut back to a bare bone all the other programs -- in fact, nearly eliminated work that was being done in a lot of other areas.

So I think that with our staff devoting nearly full-time to the testing and certification of respiratory equipment, we are able to cut down the turn-around time from application from what used to be, from I understood years ago from nine months to a year to a couple of years, to a few weeks, in some cases to a few months in the maximum case.

We think we've come a long way in that regard.

The other thing that we've done within that branch is to establish a field feedback system. Now, this is a rather meager effort. We have only had I think

three or four people into this at the present time, but we do have a system now in place -- we haven't advertised it very much, but we do have a system in place in which the complaints, users' concerns are brought to us and this is the type of thing that would hopefully help out the people in Minnesota and other places.

And lastly we believe that we're more responsive to OSHA and NRC, MSHA, EPA, any regulatory agency that we have to and should support.

I guess I'll have to turn to you, Rob, and ask when and where specifically my branch, the branch and division of safety research, has been not very cooperative? And I'm kind of surprised to hear that statement, particularly when we had the problems with the Air-Pac, Pressure-Pac II and IIA. I can remember seeing you in my office on Sunday evening working very hard.

And so I'd like to know a few of these specifics.

MR. SERE: I don't want to get into the specifics at the present time, and I don't think it is across the board. There have just been, say, occasions when we have felt that we were not having the same kind of open discussion and exchange of ideas and communication that we had in previous years.

I think it is getting better, but I think that

there has been this feeling by not only our people, but some of the other people in this industry, and I think that some of the comments that have come out in this meeting have indicated that other people have some of the same feelings that I have.

DR. MAY: Okay, another question?

DR. OPHOLD: Okay, the next question I have is, can you supply for the record the number of self-contained breathing apparatus in the field manufactured by Scott? And second part to that question, can you supply for the record the number of self-contained breathing apparatus, respiratory equipment of any nature that the Scott Company manufactures each year?

MR. SERE: I'm not in the marketing department, so I don't have that information available. I could make a guess. I don't think I'd better. I don't know whether Ross would want me to or not.

And, of course, there are very many models and some of them go to -- in America to the Fire Fighters, the industrial-medical laboratories and other places. some of them go overseas so it's a little difficult for me to tell.

And as far as current production, that is sort of a confidential thing with us unless our marketing department wanted to give it to you. I certainly wouldn't

give it to you, even if I knew it, at this stage of the game.

DR. OPHOLD: Well, Rob, then I understand you to say that this information cannot or will not be supplied for the record?

MR. SERE: I didn't say that. I just don't -- I can't do it.

DR. OPHOLD: Will marketing division --

MR. SERE: I doubt it.

DR. OPHOLD: My question is still on the --

MR. SERE: In the case of specific devices which we're involved in, the stop-sale last year, we gave us the best estimate of what we thought was in the field. For that particular device as far as telling the total number that had been out and all models and all modifications I don't think it would be very easy for us to tell.

And as far as our current production, that is kind of a confidential thing with almost anybody in this kind of business.

DR. OPHOLD: Jim Ophold, NIOSH again. I remember last year when we were going through the modification of the Air-Pac, Pressure Pac II and IIA, your company was able to estimate 250,000 of those units in the field.

I would also like to ask for the record, how many of those units have been modified as of this date?

MR. SERE: Again, I can't tell you. It's a number that our marketing department has those numbers, and I believe is in the process of reporting to you, at least on a -- some kind of a repeating basis, the numbers that have been --

Well, let me see. We know how many cards we got back in requesting them. We know how many we've sent out and we know how many cards we've gotten back to tell us that people have made the change. I don't have the change.

DR. OPHOLD: Can you supply those for the record?

MR. SERE: I believe you are being supplied those numbers by our marketing department at the present time so you can get them from other sources.

PARTICIPANT: A comment for the record on that point. A written response as of one month ago was supplied to Mr. Ralph Touch in Morgantown, Virginia, and I assume forwarded to your office, sir.

MR. BRENNAN: This is Bob Brennan, Scott Aviation.

DR. MAY: Are there any other comments for Mr. Sere? Okay, if not -- okay.

MR. DUFFY: Rich Duffy, Fire Fighters. This is not specifically to Rob, but I guess also to John and Jim.

There's a question and a difference of opinion, I guess, from yesterday and today that was talked about in many of the testimony that was given -- is the use of -- is NIOSH looking at used equipment in the field,and the rationale behind it.

And I think that the ISEA and the manufacturers here strongly rejected such a NIOSH program which, of course, we feel is very much needed.

What exactly -- to clarify it for the record, what exactly will NIOSH do with the test results from used equipment? Will it be part of the approval, any part of the approval exercise or will it be specifically to point our or find flaws in the field, whatever?

DR. MAY: I'll let Jim comment on that. I'd like to make a comment on that subject, though. The institute feels that it is very vital that we do field audit equipment, and that we pull used equipment as well as new equipment to try to get a better understanding of how well respiratory protective devices are holding up in the field.

We're also very cognizant of the problems that arise in the mishandling of equipment, in poor maintenance of equipment and in other situations that would, indeed, create bona fide concerns about that particular device.

In other words, our testing something and said it

failed, and that is the final line. We have realized that we have to look at -- the state of the equipment. And if it failed for reasons other than those, that the manufacturer should be held responsible for, we're going to, you know, make those decisions and make that information known.

Our purpose is not to make it seem as though every failure in the field is, indeed, related to the manufacture of the device, but it is an overall program of trying to find out again what's being used, how well is it, in fact, being maintained, what the status of respiratory equipment is, is it providing protection to the users.

It's a program, I think, to make all of us better aware of what's out and how well is it working, and I can't emphasize too much that we're aware of maintenance problems and things like that, and we'll take those into consideration.

Now, what the program intends to do is to say at this point in time with that data -- I'll let Jim respond to that.

MR. DUFFY: No, I agree with you. You know our feelings on that, and I think there has just been a misunderstanding of what actually the used equipment will be tested for, to the audience here and to the record.

We find lots and lots -- there's a lot of junk out there. There's a lot of equipment that hasn't been maintained. I got a phone call this morning where up in British Columbia, one respirator, SCBA, blew off of the rig. The bottle blew up.

Now, it could have been -- hasn't been hydrostatically tested in 20 years, that may be the case, but there is a real problem out there.

I go into fire stations and find breathing apparatus held together with baling wire, finishing nails, and you name it. You see equipment that has been bastardized in major cities that have equipment where one manufacturer's face piece was used, another manufacturer's bottles, another manufacturer's screws from the regulator and it's an enormous problem for us.

And I think that's one of the needs for a government agency, and we can't do it. We get requests, you know, almost -- well, since the last two years, almost daily on problems people are finding in the field, and I think it's an awful good idea for the government to look at use of equipment. Somebody look and specifically look and test equipment out in the field to see how it's holding up, to document problems with maintenance, with repair, with engineering flaws, et cetera, and I think we should try to clarify that for the record and

for the people sitting here.

DR. OPHOLD: I have got to say that I tend to agree with your comments, Rich, and certainly with what John has said.

I will add this, at the present time, we are receiving these complaints and when we -- we try to prioritize what we need to do about them. Obviously, those complaints that have to do with the immediate danger to life and health situations, we're looking into them very quickly, if at all possible.

But what we are mainly doing with those is trying to collect that information, and then if necessary, we begin to do our own investigating or tracking down to what -- if the complaint is a legitimate complaint and then begin to work with the manufacturer to say, "Is this a legitimate complaint or not?"

Whether or not it's a regulator or a hose or what, we begin to do some work on our own, bring them into the labs, check them out ourselves, and also simultaneously, work with the manufacturer to see whether he's had any complaints -- the manufacturer has had any complaints.

And just this last week, we had a manufacturer come in. Recognized -- he said, "Yeah, we've had that complaint, and we're going to take care of this."

For those of you who are not familiar with Project Fires, it's a federal agency working with fire departments developing better safety personal protection gear for fire fighters.

This particular suit here is made of Kevalar also so the fabric is tested and durable for a short duration up to 900 and some degrees. Some of the tests that we run on this have not panned out. There has been a new product on the market for reflective tape because the product that's the state-of-the-art right now after about three years of service has given us some trouble of crystalizing and burning and falling off the coat so there is a new product on the market, and we did insert it onto our prototype and it destroyed itself on the first fire.

This equipment, this reflective tape is being sold and sewn on fire coats today at a cost of $25 to $30 per fire coat, and it does not withstand the atmosphere of which a fire fighter works. And you can see, it's a lot cheaper to field test in small quantities with a few prototypes than it is to start selling it on the market and find out that it is not working.

The pants on the -- pockets on the pants are lowered so that when we put your breathing apparatus on, the straps do not go across the pockets. We can still get

And they're proceeding post haste to take care of it, and I think that meeting was held like on a Wednesday, and they said they would have all their units located and taken care of -- or not taken care of, but located by Monday morning.

And on an action plan that was satisfactory to us. We think we've come a long way in a lot of these areas.

You have to go back a year ago or a little longer. We had no field feedback system in place. We have that now. We have a way to indicate where some of the problems are and how we begin to prioritize the things we ought to look at, separately from the testing and certification program, I might add.

MR. DUFFY: And I'd also like to add that there is a great need for publishing that data, especially field audits or used equipment specifically for us so other fire fighters know exactly what's happening out there with equipment that they may use or may want to purchase, and it is of great value.

Fire fighters today are becoming much, much -- since the Lubbock incident are becoming much, much more aware of the equipment they're using, the problems associated with it, and I think this added cognizance of the fire service is certainly helping to protect their

health. And I'd like just to, you know, fully support the field audit of used equipment. Thank you.

DR. MAY: Thank you. We are ahead of the program, and I'll ask your indulgence to allow for a speaker who is on the program for tomorrow to move his talk to this morning.

It's a brief presentation as far as the way it is presented on the program, and we'll allow him to give it today because I think he has problems being here tomorrow.

So if Mr. Scallone is with us now, we will move up the talk listed at 9:30 on July 30th, and the speaker will be Albert A. Scallone, who is with Dayton T. Brown, Incorporated, Bohemia, New York.

MR. SCALLONE: On behalf of my company, Dayton T. Brown, I'd like to thank you for the opportunity you've given us to offer your comments on the role of NIOSH and testing and certification of personal protective equipment.

Dayton Brown is an engineering and testing firm which has conducted research, development and testing programs on military and civilian personal protective equipment for some 30 years.

As an independent laboratory and a NIOSH research contractor, we are particularly concerned about the subject

of private laboratory certification for the actual testing and certification of respirators and other protective equipment.

In lieu of commenting on specific elements of the Federal Register notice, we will offer as both general comments on the NIOSH program and also present our opinion regarding certain topics in the notice and consultants report.

Over the past eight or so years, we've maintained close technical contact with the members of the NIOSH testing and certification branch. Although we are not equipment manufacturers and have not been participants in the present certification process, it is our opinion that the testng and certification branch staff has been dedicated professional and technically astute in executing their responsibilities.

We feel that NIOSH, in assuming full responsibility for standards development, certification, quality assurance and enforcement, problems have been created.

It is our opinion that NIOSH has assumed too much responsibility, and that some should be transferred to the manufacturing community. In order to affect the transfer of responsibility at whatever level, we recommend that NIOSH develop and publish detailed standardized laboratory test procedures.

Such procedures should contain step-by-step testing instructions and data sheets which will produce reliable data proven repeatable through inter-laboratory correlation tests.

NIOSH has expended considerable effort in evolving performance standards for respirators. As NIOSH is the sole testing and certifying agency publishing of detailed procedures has not been necessary.

Unfortunately, without such procedures, it may be impossible for NIOSH to relinquish some of its responsibilities. It is our opinion, for instance, that manufacturers have had to rely on NIOSH to evaluate prototype respirators because this is the only way that they may be assured that their final product would pass certification.

Under the present system, manufacturers cannot be confident that their inhouse presubmission testing and evaluation will produce the same result as in the NIOSH evaluation.

We feel that this has also affected the two other areas mentioned in the notice. First, the number of requests that NIOSH has for manufacturers to witness tests is more than likely influenced by the manufacturer as being less than confident that their laboratory results will be replicated.

Second, the situation where special unpublished test requirements are used by NIOSH could not occur if published detailed procedures were required ahead of time.

The lack of detailed procedures also affects NIOSH's ability to contract for testing services in order to lighten the burden on their own staff.

This brings us to the subject of private laboratory testing. We assume here that the primary emphasis in considerating this option is for NIOSH to reduce its internal operating costs and to decrease the time required for approval.

We feel that NIOSH should maintain responsibility for field audit enforcement testing regardless of who performs the initial certification tests -- the manufacturers themselves, private laboratories or NIOSH.

We see two major problems in having private laboratories certify equipment. First, in defining what a private laboratory is, and second, minimizing the liabilities of the laboratory.

Based on our past experience, we feel that it would be very difficult for NIOSH to require that a manufacturer's own laboratory or affiliate could not be accredited to certify the equipment. NIOSH may thus be faced with a situation where they wind up with the

manufacturer's self-certification program when this may not be the desired outcome of a private laboratory accreditation program.

In terms of laboratory liability, we concur with the findings of the consultants report -- the cost of liability protection and litigation may very well outweigh any benefits derived by an independent laboratory certifying the equipment.

We feel that due to the nature of the equipment being certified and the aforementioned problem areas, NIOSH should remain the sole certifying agency.

If NIOSH wishes to reduce the loading of its staff, they should do so through requiring manufacturers to supply additional test data in accordance with NIOSH, develop test procedures with their product submission or by contracting the services of independent laboratories.

Thank you.

DR. MAY: Thank you, Al. Are there any questions or comments? Everybody is sitting there waiting for lunch, and don't want to postpone it. No comments, questions? Woody?

MR. WALTERS: This basically is -- Woody Walters, Minnesota Fire Fighters. Basically, what you are saying is the way that fire apparatus -- the pumping -- the fire pumper is tested today, the manufacturer runs

the test in the witnessing of UL.

This happened to be my job for five years. The tester employed by the builder-manufacturer is under tremendous pressure by his boss because there is a $90-100,000 investment waiting to be delivered, that they are waiting for a paycheck for.

And if I am the tester under the orders of the manufacturer, I will definitely do everything --

(END TAPE II/SIDE I/BEGIN TAPE II/SIDE II).

-- piece of fire a-paratus as somebody neutral like NIOSH. I could care less what that manufacturer says, and I will make sure that that unit passed the test the way it should pass the test.

And I'm not saying that fire engines are not being tested adequately, but playing the role as a testing person employed by a manufacturer, you have tremendous pressure that an independent testing person would not have.

MR. SCALLONE: That's a difficult statement to try to answer except to first say, I don't think many laboratories would be in business if they were not objective in the way they conduct their tests -- if that's their business, testing.

If a manufacturer wants to, in some way, influence the outcome of tests, that may be his business, but an independent laboratory could not stay in business if

it did that.

I'm not totally familiar with the process that you are referring to with the fire pumper testing, but I think the issue that I was referring to was more concerned with what NIOSH was buying by going to a private laboratory accreditation program, whether or not they're going to be getting totally independent laboratories or whether they'll be getting manufacturers' own laboratories. And, in essence, a self-certification process.

DR. MAY: Any further questions or comments? Thank you, Al.

Okay, that concludes this mornings presentations, and we will reconvene this afternoon at 2:15. Please do not, as I said yesterday, use the facility here before 1:15.

(Whereupon, the hearing was hereby recessed for lunch at 1:15 p.m., to be reconvened at 2:15 p.m.)

A F T E R N O O N S E S S I O N

DR. MAY: Some of the people are definitely not here, but I assume they will come back in. The more important thing is that the speakers get their comments on the record and that is, of course, running from this point on.

I would just like to start, before introducing the first speaker this afternoon, and make a comment about the transcription. Anybody in the audience who would like to obtain a verbatim transcript of the meeting should contact ABL Associates. They are in the District of Columbia. I'll give you a telephone number.

That's ABL Associates. The area code there is 202, in case you call when you go back home -- 223-0513. Now, ask for either a Ms. Smith or a Mrs. Zamorano -- Z-a-m-o-r-a-n-o. Our preliminary contacts with them indicate that the transcript will run 10 cents a page times however many pages there are.

They will, of course, not know how many pages until sometime tomorrow, but I think you can safely say it won't be an exhorbitant fee because 10 cents a page --

The number, again, is 202-223-0513. Our contract calls for, I think, delivery of our copies within seven days, so I assume that certainly within two

weeks of this meeting, they could have a copy to you.

Okay, we'll proceed with the program. And the first speaker this afternoon is Wesley J. Kenneweg, product manager, Distributor Products Division, National Mine Service Company, Pittsburgh.

MR. KENNEWEG: Good afternoon. My name is Wes Kenneweg. I'm employed as a product manager for National Mine Service Company. We'd like to express our comments to the proposed changes to the federal certification of testing program for respirators as noted by NIOSH in the announcement for this meeting.

Number one, 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 U.S. Bureau of Mines 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.

Number two, performance specifications. We have no objection to upgrading the performance specifications for testing of respiratory protective equipment providing that these specifications are, in fact, realistic

and established through the rule-making process.

One change that should be considered is a greater emphasis on machine testing which would give the applicant end-user a more precise guideline for actual performance requirements set forth for each respirator.

Three, quality control. It is agreed that an in-depth review of an applicant's quality control plan is not necessary provided that the applicant does certify that an acceptable QC plan is in place, and is adequate to ensure product quality based on a 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 testing of respiratory protection of equipment and obtain 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 his respiratory products and modify them, if necessary, to meet the new criteria; b, resubmit all his resubmit all his respiratory products for reapproval under the new criteria; c, in the case of use equipment, be accountable for the misuse and poor maintenance of his products by the end user.

This misuse and lack of maintenance could be cause for failure during testing rather than the actual design of the certified products.

Number four, 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 a long-drawn out approval process.

The requirement for detailed engineering design failure mode analysis for each respirator submitted may be acceptable to us, 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.

Number five, 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 comments that such an indiscriminate system in the case of insignificant changes can place a burden on the applicant with no positive impact on the end user is well taken.

Under the suggested plan, however, NIOSH must define the terms, significantly revise or redesign since a cosmetic chain which does not affect the function of the respirator could be considered significant by one person and not another.

Number six, witnessing of approval tests. It first should be noted that NIOSH suggestion to bar the applicants from viewing the approval test is in direct contradictions to NIOSH's letter of June 20, 1980, attached herewith which outlines the procedures by which an applicant can view the test 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 as 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 failure. NIOSH-MSHA control of test proceedings should be adequate to ensure that the witnesses do not interfere with the testing, and if the testing criteria are conducted properly, the test personnel should not feel pressured by the presence

of the applicant.

We, therefore, would like to go on record with being in agreement with NIOSH's letter of June 20, 1980, concerning this matter.

Seven, duration of approval. NIOSH's efforts to streamline the approval program for the applicants and ultimately the end user would not be enhanced by a five-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 five years.

This resubmittal with the stipulation that the device and its component parts cannot be sold until reapproval is granted could very easily result in an increased hazard to the end user, simply due to the fact that he will not be able to obtain the necessary respiratory protection products or the 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 effect 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.

Testing of prototype respirators. Prototype testing is important as noted by NIOSH under the points of discussion for this meeting.

However, we feel that it is equally important for NIOSH to be willing to discuss the results of these tests with the manufacturer. By refusing to review the tests 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.

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 specific 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 end user of the device.

Unless NIOSH is planning to staff the approvers branch with additional people to handle the group tests and the submittals that arrive outside the designated acceptance period, we must go on the record as being against this suggested change.

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 nore 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 effects for NIOSH, the manufacturer or the end user.

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

DR. MAY: Thank you, Wes. Are there any questions or comments for Mr. Kenneweg? Hearing none? Thank you.

The next presentor is Chief R.S. Rockenbach, president, International Association of Fire Chiefs, Incorporated. And no one is rising to that introduction. Okay, we are going to -- I will exercise my prerogative as chairman, and take this opportunity to allow somebody to make a statement that had not requested so formally in writing. And I will give Mr. James Powers with Pass Powered Air Portable Air Supply Systems this opportunity to make a statement.

He did submit a written statement, and has requested a chance to introduce it into the record, and I will give him this opportunity at this time. If Chief Rochenbach appears in the near future, we will obviously give him a chance to present his statement. Jim?

MR. POWERS: Thank you. I want to make formal comments -- my name is Jim Powers, by the way, president of Portable Air Supply Systems Corporation. We're the new kids on the block.

And I want to make some comments regarding the

public notice of June 18th.

And the most significant changes from the Bureau of Mines certification program to the NIOSH control certification program were the requirements for quality control system and the submissions of the modifications to the product.

These changes were important for the users and inherently helped the manufacturers for liability protection. There was also some test criteria that were updated at that time to attempt to cover the state-of-the-art.

The conflicting fears between NIOSH and the manufacturers caused the regulations to be written to protect the actions of the regulators and the manufacturers to rebel at any indication of over-regulation or interference by federal government.

This conflict between the two factions caused the pendulum to swing to an overkill position for each side. People of NIOSH became vulnerable to attacks by both users and manufacturers. Actual vendettas began to arise between certain user groups and certain manufacturers, and TCB was caught in the middle.

TCB's reaction was to use less and less judgment for which they had the capability. Reduced their voluntary assistance to expedite better products reaching

the users.

As a matter of pure self-preservation, the so-called black hole was created. This resulted in increased time lags between submission and approval. Now it appears evident that a change in procedure is necessary to maintain user protection and simultaneously calm down the various factions.

The solutions we see proposed in the June 18, 1980, notice are reactionary in nature and treat for the most part only the symptom rather than the disease.

The problem areas are listed, but I won't go through the list. I'll take them one at a time.

Performance specifications. The current performance specifications were established on what was required to use a unit and survive or remain healthy. Has the human body changed its requirements to fit the state-of-the art? No.

What is needed is a new category to allow new concepts, new designs that permit comfort and safety beyond that of basic survival. Thus allowing basic economical survival units as well as more expensive models with extra features.

Why burden the user to pay for regulated luxuries they may not need or cannot afford? These new proposed dynamic rather than static requirements might be met with

less opposition by manufacturers if the manufacturers were not forced into expensive revisions of products already deemed as reliable, life-saving devices.

Quality control. The detailed quality control plan submitted by NIOSH were never any guarantee the quality control system existed at the manufacturer's plant. Usually, however, on-site inspections revealed that the system was either being followed or that the system being followed was equally or more effective than the one submitted.

In this industry, to operate without a complete documented quality control system is suicidal. The cost of losing a liability lawsuit far outweighs the cost of an effective quality control system.

Quality is not free, but once the decision is made to be a quality producer, the most economical way to do so is with an effective defect prevention oriented quality control program.

Maybe the need for the regulatory agency to be as deeply involved as it has in the past in the structure of the manufactured system has been greatly reduced, but the need for the manufacturer to have a system is not, in any way, decreased.

If the proposed field audit has any chance at all of detecting what is representative of what a

manufacturer is producing, then the manufacturer must have a system to produce products that are consistent.

The starting of purchasing products that have been used appears to be somebody's idea of measuring reliability of certified products. While the need for reliability requirements for respirators has been discussed at least six years at TCB, it has not had either the budget or the time for its employees to properly study what the requirements should be.

Now, with no proposed accelerator life tests with reduced emphasis of design specifics, and with quality control to be on an honor system, a used or abused unit will be picked up from the field and tested. Based on these results, all such units by that manufacturer is subject to recall, stop-sale, or continued approval.

This puts the manufacturer in the position of just waiting for the ax to fall. We completely agree with the idea of introducing the reliability concept into the respirator industry.

But the proposed approach is like shooting somebody to show you that guns are dangerous.

Engineering drawings and dimensional tolerances. When the submission of a 12-pound unit requires 27 pounds of paperwork, it is evident that a reduced staff

of TCB would never review every dimension. We would believe, however, that a complete elimination of all drawings would be a handicap to TCB. We believe that one set of drawings of manufactured parts and subassemblies, including a top assembly drawing, would be helpful in the certification process.

These drawings would appear to us to help identify the unit components and analysis by the TCB personnel would be easier made.

Changes of approved devices. We would question the necessity of using the time required by TCB for a new approval just for one major modification as the suggested solution proposes.

Witnessing approval tests. We don't have any particular comment. I have written here the present solution sounds appropriate.

Now, this is obviously not a popular stand to take. I happen to know the people involved. I know their capabilities, and I know they are very capable. And I was a little amused yesterday when everytime somebody would say something to the effect that the test was going to be run wrong or the test was going to be misinterpreted or they ran the wrong test, Dr. Ophold gets up and says, "Cite me an example."

And nobody cited an example. I wouldn't either,

you know. You don't tell the cop that stops you on the street off, you know?

So you're not going to cite the examples. But I can remember some. But for the most part, they were disagreements rather than actual errors, and there were sometimes test procedures corrected over those disagreements, but it's not due to lack of confidence, and it wouldn't have changed if they'd watched the tests being run from now to Kingdom come.

Duration of approval. Unless the user can pay the manufacturer a reasonable fee to refurbish the units in their possession after five years, this proposed regulated antiquity, regardless of condition or circumstance, could be prohibitively expensive for large users or limited budgets.

Product quality requirements. AQL's are not guidelines for establishing the allowable percent of defective units as a noticed -- as a notice mistakingly suggests.

AQL or accepted quality levels are the foundations for sampling plans which are scaled up and down according to the seriousness of the defect and the risk of making an error in sample measurement.

The effort of any manufacturer is to have no defective units. The use of AQL's have proven to be

the most effective way to accomplish this.

The suggested alternative of allowable percent defective works from the other end of the operating characteristic curve. Any realistic criteria of allowable limit would be the basis for excuses of failures and a criteria impossible to measure by the regulatory agency from the standpoint of logistics or budget.

This alternative is completely incompatible with the proposed field audit.

Unpublished test requirements. This problem and solution is a prime example of the reactionary thinking. In spite of the generally friendly rapport of various manufacturers with each other, they are serious competitiors and dislike any loophole which would allow a competitive edge to their competition.

The proposed solution appears to be the result of such pressures.

When 30 CFR 11 was written, there were types of respirators both self-contained and air purifying that were not yet invented, but they were subsequently presented to NIOSH for certification.

Some of them were good, and they deserve special consideration. to serve the public and a market that the company had the foresight to accomodate.

Let us not loose sight of the fact that the only

reason for the existence of a regulatory agency is to protect the public from harm and not for the purpose to stifle original thinking and competition. We are not suggesting an uncontrolled free-hand by the testers' whom for the day, but the solution must allow room for innovative designs for unique industrial applications that cannot wait a year for proven test requirements.

Testing of prototype respirators. The use of NIOSH laboratories as an extension to the -- as a research and development arm of the manufacturer was never the intention of prototype testing allowed in 30 CFR 11.

Approval testing, the ability of TCB to test -- a pretested prototype made in every way like the production model with the exception of using machine parts instead of moldings and castings has permitted manufacturers to bring a variety of respirators to the public at affordable prices.

If these molds and castings were made before the certification, and a problem should arise during the process, thousands of dollars would be wasted in revising molds and tens of thousands of investment dollars would be tied up for excessive periods of time.

A large company would pass this cost to the

users, and the small companies would simply go out of business. In either case, the public loses.

We totally agree that a retest of the crucial characteristics should be made on the production model. After all, NIOSH can revoke a certification if it did not perform satisfactorily.

Group testing of respirators. This notice states that this procedure would be more responsive to the user and applicants' needs.. There is no way to respond to this statement since the frequency of the acceptance periods were not stated.

We cannot know the status of our competition, but as near as we can calculate, the waiting time costs us about $30,000 per month per model in lost engineering time and allocated overhead.

What we would like to see is a bigger portion of our tax dollars allocated to increase the qualified staffing sufficient to handle the overload that's existed for years and appears to be progressively worse.

In fact, it is our opinion that if the government properly funded the certification program with sufficient personnel and travel money instead of trying to fit the program into a mold suited for research doctors and technicians, we'd not be meeting here today.

User maintenance and manuals, we agree there should

be. NIOSH system manuals, we agree with the proposal.

Publication of test data. NIOSH already has the power to pass, fail, instigate recalls, stop sales and so forth. And now they want to bring back the public whipping post. The psychology is sick.

Submissions to NIOSH are simply nobody's business but the applicants and NIOSH. When the unit is certified and the test data is available through the Freedom of Information Act, if it is so important for somebody else to have.

The publication of field audit data will show the failure of TCB's ability to do enough field testing to have statistical confidence in their sample data. This would be true because of their lack of -- not because of their lack of ability to run the test well, but because there is not enough money in the whole NIOSH budget to properly conduct such a program let alone TCB's.

The program of field audit is valuable to detect problem areas, and it works quite effectively as long as it is kept on a low profile for quick response. We believe that better communication between NIOSH and the manufacturers that it regulates would be the best way to serve the public.

The barriers of distrust on both sides of the

fence has been the precipating factor for most of the things listed in the problems of the notice.

We have never believed that the purpose of TCB was to potshot and punish, but to try to serve the industry in getting to the -- getting to the respirator users the best possible protection in the most efficient and economical manner.

Thank you.

DR. MAY: Questions? Jim, you're going to have to learn to really say what's on your mind instead of beating around the bush.

Are there any questions or comments for Jim? I think it will take the program awhile to respond to them, and probably not respond today, but there is certainly a lot of data and information you've given us, much of which I'm sure we would like to address at this point. I will not address any of it myself, although there are many things that I would like to.

Are there any other comments? Dr. Ophold?

DR. OPHOLD: Jim Ophold, NIOSH. I have to ask Mr. Powers the same as I did yesterday and the answer may be that I'm the cop and nobody is going to identify the wrongdoings.

I think that, as I said to Rob Sere this morning, I think that we're in a business here that is very

important to all of us. We are in a business that is not built directly on friendship, and we're in a business that so often we forget what is important for the user -- the worker in the United States.

So I have to ask my question just for the record. Show me, as I said yesterday, where we did not follow the procedures established in 30 CFR 11 or where we misinterpreted our test results?

MR. POWERS: Well, like I said, I know some examples where there was conflict of opinion. Since I am now a manufacturer and those people are now my competitors, I'll not cite them.

At the time I was working at TCB, and I could have and would have but I am not there now and won't.

DR. MAY: Any other comments or questions? Has Chief Rochenbach arrived? Okay, we will then go on with the next presentor who is Einar Horne, technical director, Occupational Health and Safety Products Division of the 3M Company. Einar?

MR. HORNE: Thank you, John. For many years, 3M has been a manufacturer of certain types of respirators. For example, 3M manufactures chemical cartridge respirators, particulate filter respirators, powered air purifiers, and supplied air respirators, all of which can be used for protection against nontoxic dusts, toxic dusts

toxic vapors.

Consequently, 3M is directly affected by the 30 CFR 11 regulation related to respirator testing, certification, selection and use. Further, as a manufacturer,of respiratory devices, we are acutely concerned that changes to existing standards, policies and practices improve the quality and effectiveness of personal protective devices.

Therefore, in response to the invitation for interested parties to submit comments concerning the consultants report and possible amendment of 30 CFR 11, we offer the following views for the purpose of aiding in the development of an appropriate and feasible regulation that would adequately protect employees who are required by OSHA standards to use NIOSH approved respiratory devices.

My testimony today will address those areas identified in the notice for these hearings published in the Federal Register on Wednesday, June 18, 1980.

Specifically, I shall discuss both the proposed changes to 30 CFR 11 that were outlined by NIOSH and the consultants report. One of our major concerns with the existing 30 CFR 11 regulation is that the respirator approval system is based largely upon the test methods developed in the 1930's that were designed

to measure the effectiveness of respirators during that era.

NIOSH simply took the Bureau of Mines' tests, personnel and philosophy into the decade of the 1970's. Even the approval numbering system was continued. In recent years, there have been significant scientific discoveries and developments within the respirator industry.

Today, new and innovative respiratory products having the ability to greatly improve employee respirator protection and acceptance are ready for the market place. Nonetheless, because the current approval system in 30 CFR 11 is technically outdated and inapplicable to todays' respirators, these new and improved products are not receiving NIOSH approval.

3M has testified in two previous hearings in 1977 that the entrance of new respiratory products into the market place is being restricted.

Continued adherence to this old approval system tends to have a chilling effect on the incentive to continue to design and develop new and better respiratory products. Why design a new product if it cannot possibly receive NIOSH approval?

Further, the advent of new and more encompassing regulations by OSHA, EPA and other governmental agencies

restricting employee exposure to potential or known toxic substances has increased the use of respirator protective devices to protect employees.

The need to amend, update and repromulgate the testing and certification process of 30 CFR 11 to reflect the current state-of-the-art in the respiratory industry is obvious.

A new approval system must contain the flexibility to evaluate innovative products with the ultimate goal of providing the American worker with the best respiratory protection available.

It is on this basis and with this goal as our incentive that 3M has developed and submits the following comments.

The consultants are to be congratulated for their excellent analysis of the present NIOSH testing and certification function. They have established a base from which a workable system of certification and field audit of respiratory protective devices should be rapidly built.

3M and other respirator manufacturers have had discussions like this one with NIOSH before. While this is the first one held since Dr. Robbins took over as director, the idea and the need are not new.

He is to be congratulated for his approach

to the regulation analysis through the use of a panel of experts. We were pleased to see the recommendations of the experts that Dr. Robbins assigned because they once again brought forth an opportunity to recommend much needed changes to the methods presently used for approving respirators.

The consultants report went into great detail in regard to the subject of liability that NIOSH shares with the manufacturer, and a concern was expressed about the liability and the responsibility of NIOSH certified laboratories.

The liability argument that the NIOSH consultants puts forth is persuasive but incomplete.

Manufacturers of NIOSH approved products get sued, and I suggest that there are many cases outstanding today as a practical matter. NIOSH is not sued for giving approval.

The NIOSH approval certification is not looked on as 3M as a sharing of product performance. I'm confident other manufacturers of personal protective equipment would project similar feelings. The approval is looked upon as a market place necessity due to recommended OSHA respirator program requirements for the use of only NIOSH approved products as outlined in Chapter 3 of the Industrial Hygiene Field Operations Manual

of OSHA.

If the personal protective equipment manufacturer takes the profits and gains from the sale of a personal protective device, he should be liable. But then no manufacturing company should obtain marketing advantages because of design specifications in the law as is the case today with the existing 30 CFR 11 regulations.

Let me repeat that if personal protective equipment manufacturer takes the profits and gains from sales of a personal protective equipment device, he should be liable. But then no manufacturing company should obtain marketing advantages because of design specifications in the law as is the case today with the existing 30 CFR 11 regulations.

In late 1977, public meetings were held in Washington, D.C., with respect to amending the certification requirements for respirator protective devices as contained in 30 CFR 11.

At this meeting, extensive testimony was elicited from governmental agencies, users of respiratory protective devices, manufacturers of these devices and academic institutions.

All parties testifying agreed that extensive changes in the certification procedures were desparately needed in order to assure that the American worker has

the most advanced and best occupational protective devices available.

Nevertheless, in spite of the overwhelming need expressed for changes in 30 CFR 11 at these hearings, the controlling governmental agencies stated in their conclusion that promulgation of the amendments would require the normal three to five years.

To date, no action on that hearing has occurred, and almost three years have gone by.

We submit that it is inconceivable that delays such as these in issuing regulations can be allowed to occur.

We ask to have included as part of this testimony all 3M testimony that was submitted to NIOShduring the last hearing in 1977.

In order for positive changes in respiratory protective device approvals be consummated, the negative aspects of the existing system must be identified and brought forward.

To do this, we have thoroughly studied the history of the respirator approval system in the U.S. as practiced by the Bureau of Mines and NIOSH. One fact stands out -- NIOSH continued the Bureau of Mines tests, approval numbering systems, personnel and philosophy without modernization. This includes tests for approvals

that are not accurate, not reproduceable or adequately defined.

These tests have been established without a determined test variation and our 1930-1940 era instrumentation. The paint spray test, lead fume tests and silica dust tests -- silica mist tests are all examples. Even more disastrous for innovative new products has been the carry over in use of the design philosophy of respirator approval rather than performance oriented philosophy.

Designations by design-class such as reusable, replaceable and single use is even more obscure because of the lack of acceptable definitions. Under the present system of testing and approvals, manufacturers are forced to submit products that will pass tests that may or may not guarantee protection to the user.

It is possible that the existing NIOSH testing does more harm than good based on the fact that the tests have little, if any, correlation to actual field conditions.

One might ask why an innovative respirator manufacturer would want to submit his product into this existing NIOSH system voluntarily. Manufacturers do it today because of OSHA health standards and OSHA enforcement.

If OSHA inspectors do not see NIOSH approved devices, they cite and propose a fine for the employer. Submission for approvals is not done because NIOSH testing guarantees worker protection, reduces or eliminates liability of the manufacturer or is timely.

Existing NIOSH approvals are a marketing device having little or true -- or no true merit.

3M markets both approved and unapproved respirators successfully and aggressively. We do this because our thorough laboratory and field testing data tell us that the product protects the worker when correctly used.

We sell nonapproved products because market studies and field evaluation show that the user-need exists even though the design specifications and tests in the existing 30 CFR 11 regulations do not allow certification.

In addition, in many cases, there is no approval schedule for the specialized respirators required by workers for their protection in specific environments. Discussions with NIOSH and the Bureau of Mines officials have made it obvious that they feel that they cannot legally change or add to 30 CFR 11 any approved devices that fall outside the existing design criteria in a reasonable time frame.

For these basic reasons, we think that NIOSH should develop performance criteria for respirators. NIOSH respirator standards intended to insure the achievement of specific goals should be based on performance criteria and not on design specifications.

NIOSH should specify the problems to be solved and not the detailed prescription for solving them. For example, face fit protection level should be specified instead of four point suspension but NIOSH must include valid quantitative means for determining whether the required performance has been achieved.

By specifying the performance criteria in functional terms for the user, the purpose of 30 CFR 11 will be clear as will be the level of respirator performance required to schieve it.

The manufacturers trying to meet the need can then search with minimum restraint for innovative solutions to respirator user problems. The restraints on technology are then only limited to those that are actually relevant to the user.

Performance criteria are also less prone to serve as obstacles to a fair competitive market place since they are less likely to protect established technologies against potentially more productive and new ones.

Evaluation of performance is necessary. Therefore, NIOSH should publish detailed procedures for well-defined tests. A few of the valid tests now in existence in 30 CFR 11 should be retained, but in every case, complete equipment descriptions and test procedures, as well as test variabilities, require definition.

It will also be necessary in defining tests for performance criteria to leave the system open ended so that as innovative technology or unique new equipment comes along, new means for evaluating product performance effectiveness are permitted.

NIOSH and the private sector must work cooperatively in developing and publishing appropriate detailed performance tests of known reliability. One usable means to control product performance is the ability of one competitor to test another's product with methods that are reproducible and of known variability. Only then can subsequently discussions be meaningful.

If field audits are ever to be useful, tests must be as uniform as possible so that disputes can be resolved based on truly parallel data.

The quantative fit test controversy presently being encountered in industry with OSHA on the lead standard is the example of a need to have NIOSH publish detailed performance tests.

There is no defined fit test method that can be used by industry. Yet, if NIOSH had followed up on their sponsored Los Alamos research with test protocol, a system might exist and fit factors could be assigned to each respirator by the manufacturer if he so desired.

NIOSH must be able to adapt new tests regardless of operational approach to approve new devices that cannot be tested and approved under existing specified design oriented test methods.

It should not be the intent of NIOSH to require unnecessary tests or to include new devices or to exclude new devices from approval, consideration because an existing specified approval test or requirement is not directly applicable to that new device.

Once NIOSH has defined performance criteria and reliable test methods to compare performance to the criteria, manufacturers should conduct the tests and certify that their products meet the published NIOSH requirements.

NIOSH should audit field samples to verify manufacturers claims. At this point it is obvious that 3M recommends alternative number four described in the June 18, 1980, Federal Register.

We reject the others for reasons I will discuss later.

Option number four, the self-certification alternative would combine the best of the listed alternatives. 3M recommends the following: NIOSH would develop and maintain performance criteria using the best state-of-the-art methods.

These would be promulgated and published in the formal rule-making procedures. Manufacturers would use these performance specifications and test methods to evaluate theirproducts.

Products meeting the appropriate specifications would be manufacturer-certified as meeting the minimum requirements.

NIOSH would allow manufacturers to submit samples to validate tests between NIOSH and the manufacturer, but NIOSH audit of the manufacturers' facilities is unnecessary.

NIOSH should have a continuing program to develop improved test equipments and testing methods. It is important that NIOSH replace current testing techniques and equipment. NIOSH should keep manufacturers informed of any improved techniques.

Prior to distribution and sale, the manufacturer would notify NIOSH of its intent and the geographic area into which the product would be sold. The manufacturer would include a description of the

product and its intended use.

This notification would allow NIOSH to exercise its option to purchase theproduct and perform its own evaluation if it is felt necessary to verify that the product, in fact, meets the performance requirements. If NIOSH finds problems through its own evaluations or based on user complaints, we feel adequate provisions exist in the last today to handle enforcement of the findings.

After discussion of its findings with the manufacturer and agreement of fact, NIOSH could request voluntary action such as correction of the problem, stop-sale, recall or whatever, depending on the nature of the problem.

If the manufacturer does not take acceptable action, NIOSH could use legal procedures to prevent distribution of the substandard product.. OSHA would accept the manufacturers' certification of devices as labeled.

The field audit by NIOSH would allow sufficient response time to a manufacturer to correct any problems discovered in NIOSH evaluations. If NIOSH does conduct field audits and desires to distribute tests results, only conformance and nonconformance should be stated. Not numbers, as numbers can often be misinterpreted.

Manufacturers must be informed of nonconformance prior to any date of distribution. As a cross-check on the system, NIOSH must be required to present evidence of controlled testing before a nonconformance publication is distributed. A system to handle failures should be proposed and debugged.

NIOSH should not undertake to widely publicize negative results of tests performed for anything but major hazard defects, and only after consulting with the manufacturer.

Bad press by NIOSH for a poor, but insignificant test result could cause irreparable damage to all manufacturers, and could wipe out a small manufacturer. NIOSH policy should be structured so NIOSH personnel participation on concensus standard-making committees, such as the American National Standards Institute, is encouraged.

It will help get improved criteria into the system faster. Broad participation by all effective parties is essential in the selection of the strategy for solving user problems and the choice of the level to be required.

Much is lost when NIOSH personnel are not part of the reasoning for establishing concensus criteria. NIOSH need not sponsor research on new devices.

With the number of manufacturers in safety and health, market forces will bring needed products for so long as performance criteria are not so confining as to prevent innovative products entering the market place. The private sector is better suited for research than NIOSH.

The self-certification method would allow frequent assessment of the product in he field by NIOSH. It will correctly place the burden of designing and producing and testing reliable devices on the manufacturer. by placing the primary responsibility on the manufacturer for certification.

NIOSH could use its resources to help develop better, more pertinent performance specifications and test methods to evaluate them. NIOSH has not performed this function adequately in the past, and the self-certification alternative would allow resources to be diverted, concentrated and utilized in this manner.

Some of the advantages of option number four are: it reduces the need for continued expansion of NIOSH facilities and personnel as the number of approvals grow.

It brings new products to market earlier. It allows NIOSH to concentrate on the audit of products that may be more representative than selected submitted

samples.

As manufacturers accept the responsibility for testing, their resources will be used to develop new and more realistic test methods. It prevents NIOSH from being used as a development laboratory by manufacturers.

Changes to a product won't need submission as long as the manufacturer certifies conformance to performance criteria. As approval time and submittal expenses reduced, manufacturers would be encouraged to produce a wider range of specified products that would afford the end-user a better selection at reduced costs.

It increases productivity as it reduces costs of approvals, both to manufacturing and NIOSH. It will improve the working relationship between NIOSH and manufacturers. Innovation, comfort, efficiency and economy would be encouraged.

In the case of a major defect being discovered in the user's product, it is the manufacturer's responsibility, not NIOSH's.

The responsible manufacturer must locate and inform their customers of the problem.

Option number four has the further advantage than an element of trust, and maturity must be established

among NIOSH, OSHA, and the manufacturer that needs of the user will best be met with this type of system.

Those that sow seeds of dissent and misinformation about the manufacturer's true intent will be forced to bring forth their data that can be examined on the basis of technical fact, not through endless, expensive legal controversies that serve no good purpose or as has been the case, without any data from their own experience.

Discussions of the other certification options that NIOSH has presented is important. All things being equal, continuing as we presently are doing but with revised administrative and test criteria area is completely unacceptable.

The present system has been and is being abused by those evolved in the certification process. 30 CFR 11 as it is being administered appears to be autocratically designed to establish an adversary role between the approving agency and manufacturers of devices.

This is a role that neither the U.S. manufacturer, government or user can allow to continue. I might add that only in the U.S. does this adversary role exist. In many other countries, governmental approving agency cooperates with local manufacturers of equipment, even to the level of cooperation that it makes it almost

impossible for imported products to be approved.

Further, the present system of MSHA and NIOSH approval of a device does not guarantee end user utility or safety. As we have testified in the past, the fact that a respirator meets a test requirement is only a very minor part in an effective user-respirator program.

Matching the proper device to the hazard, insuring proper fit to the workers, matching filtration performance to the real work situation should not be overshadowed by an inflexible artificial test method that prevents innovation.

The main reason an employer-user wants an MSHA-NIOSH approved product is quite simply, that they don't want a hassle from OSHA.

However, on page 13 of the OSHA Operations Manual, Chapter 3, subpart E, and I quote, "MSHA and NIOSH will provide a test schedule for any respirator against any specific contaminant. The use of unapproved respirators even in special use situations is unacceptable unless approval is pending before NIOSH."

This is not and has not been the case with the existing MSHA and NIOSH approval system. 30 CFR 11 is unworkable as it does not allow new better worker protective devices to reach the market place fairly.

Over the last 10 months, NIOSH has been doing

a poor job in communicating the status of approval testing with manufacturers than ever before.

They presently have not allowed witnessing of tests and will not discuss the status of submitted products. On witnessing of tests, NIOSH must be audited.

Errors have been made by NIOSH in testing, and so we avoid this particular question. I will give you an example of a respirator that was mistakingly tested. It's 9920, when it was first submitted, which is a dust, fume and mist respirator by 3M company.

It was submitted, tested and failed. We were not informed of when the test took place, but when we were informed of the failure, we started to ask some questions as to why it would have failed when it passed in our laboratory.

And this is one of the things that I think NIOSH has been had upon, and that is, I don't think that they have insisted that everyone always submits data on some tests before they start some of their approval testing, but on this particular case, because our respirator did not fit into the same holder as real rubber face pieces, it was taped with masking tape to the holder.

Of course, the lead fume went through the masking tape, and our product failed.

Since that time, we have had the product approved because we went through that particular activity. But, Jim, I did want you to know that there was one case you wouldn't have to ask me about, and I'm not ashamed to talk about it because I don't think you're a policeman.

From the point of view that there is no pressure on test technicians, if things are done correctly so there is not a problem to watch them test, NIOSH can establish ground rules of what a witness to a test can do and cannot do.

Perhaps the most irritating aspects of existing NIOSH policy is its position of refusing to discuss the status of certification testing. When a product is submitted and delivered to Morgantown, our experience is that it's as if everything disappeared into a black hole.

Recently, 3M experienced at least a four-month delay between the actual approval testing and QA test approval, and receipt of the letter of certification. We do not understand why NIOSH would want to delay introduction of an approved product to the market.

If and when questions arise on a submitted product, we are confident that a 10-minute phone call will often solve the problem. The problem should be solved as expeditiously as possible.

In summary, option number one shows no immediate relief that helps either the user or the manufacturer or, in my opinion, NIOSH.

Option number two, as outlined, is subject to the same objections as we have stated against the first option.

(END TAPE IIB/BEGIN TAPE IIIA)

-- at this hearing. The first one concerning stop sale and recall of products has never been subject to public review. The second, regarding an appeals procedure, has been commented on in a number of hearings with NIOSH since 1974.

Both subjects are important, and they should either be properly become a part of 30 CFR 11 with a public hearing or be dropped. These guidelines cannot be allowed to be accepted as standard NIOSH approval operating procedures without thorough comment and review.

The same is true of a process by NIOSH or by any agent of NIOSH concerning field audits of samples utilizing guidelines not reviewed publicly.

In addition to these voluntary guidelines, NIOSH uses many other test guidelines for respirators that have never been published and subject to public review.

Less, not more, power of certification should be allowed the existing MSHA-NIOSH system and their responsibilities more closely defined.

3M feels that option number three, private laboratory certification, will only introduce another level of confusion, an excuse for delay to the present approval communication problems.

Also outside certified laboratories would result in disagreement as to conformance or non-conformance. Uncertified laboratories would be worse. If laboratories are to be certified by NIOSH, manufacturers who already have the equipment and expertise cannot be excluded from certifiable status.

The Consumer Product Safety Commission was suggested by the consultants as a possible model for NIOSH to follow in the area of health and safety product testing and control. We do not agree with this recommendation.

3M experience with the Consumer Product Safety Commission in which air spill spray adhesive case occurred is evidence that power to ban a product without mandatory safeguards requiring full evaluation and critical review of the data results in severe hardship to the users and expensive financial loss to the manufacturer.

The latest of these is the decision not to approve dust respirators for asbestos, even though the respirator meets the test requirements and the law.

It is important that NIOSH personnel be required to consistently follow correct rule-making procedures. Requirements or changes to requirements for certification must be subject to public hearing and review. Any outside laboratory data system set up by NIOSH must be subject to specific cross checks for data validation and stringent published rules for information release.

Adverse data would have to be confidential and not disclosed by anyone, including private laboratories acting on behalf of NIOSH until a thorough review of the data has been held with the manufacturer.

Today, this procedure does not exist. In 1972 and 1973, early release by Los Alamos of incomplete test information from NIOSH contracted research was harmful to the 3M company respirator program. As in the case of option number one, 3M feels option number two is unworkable. To give more power or to agree to the power level of the existing NIOSH-MSHA situation that is not working is not acceptable.

In case you missed our point, the present system is slow, inaccurate, arbitrary, ineffective and inflexible.

The results of rumonious actions by federal agencies are long-term consequences. Lawsuits at 3M continue over six years after the Consumer Product Safety Commission withdrew the spray adhesive ban that was based on evidence which could not be verified.

The widely publicized Consumer Product Safety Commission national network for obtaining data on unsafe products has weaknesses that can easily result in misleading conclusions.

Any data collecting system that does not incorporate procedures for verifying information at the source is subject to question. Unverified data that are extrapolated to supposedly nationwide statistics are even more questionable.

To support our position in this regard, we reference a report to Senator John Tower from the Comptroller General of the United States Number B-139-310.

The report is undated, but is in response to Senator Towers request dated April 29, 1974. The report is attached, but will not be read.

We believe that it is advisable for NIOSH to periodically test safety equipment obtained through normal commercial channels. We also know that the results of these tests must be handled by well-structured mandatory procedures. This will prevent

embarrassment to NIOSH, unacceptable delays in correcting errors, unnecessary concern on the part of the public, and unwarranted expense to safety equipment manufacturers.

The need for submission of operating use and maintenance manuals to NIOSH does not exist. The manufacturer has the responsibility to provide the customer with technical data to effectively use and maintain specific products.

The amount of data for proper product use very considerably and must be established by professional technical and legal staff.

Some manuals require detailed assembly use and maintenance instructions. Because certain types of personal protective equipment are product specific, each manufacturer must develop his own operating and maintenance instruction manuals.

3M experience shows that a concerted effort is required to produce a manual that gives the customer what is needed to obtain satisfactory use of his product. Experience also shows that as a product is used, more is learned from field trials and customer service.

Consequently, changes to manuals, use instructions are initiated where needed to keep manuals updated for proper product use and to prevent misuse. It would be

a disservice to the users of respiratory protective equipment to be forced to wait for manual changes while NIOSH reviews and approves them.

In addition, NIOSH is not in a position to approve or disapprove a modification of a manual without consultation with a manufacturer, and without entering into development research to determine the efficacy of a change.

This is not proper activity research to solve a particular manufacturer's problem of NIOSH. There certainly would be no objection to providing NIOSH with copies of manuals, posters, maintenance and data sheets, sell sheets, et cetera, for their records, but not as a part of approval.

It seems to 3M that the literature described in this section is similar to the manuals and supporting records required for quality control plans. NIOSH has acknowledged that this requirement does not contribute to the current testing and certification program and recommends that this requirement be eliminated.

Likewise, we recommend that this proposal be dropped at this point.

In regard to the other specific areas about which NIOSH requested comments, most answers are simple. Group testing of respirators is unacceptable.as it

is, and unnecessary restraint of trade.

To force all manufacturers to go at the same pace, to make it more convenient for NIOSH testing, is not acceptable. NIOSH must either test efficiently or get more people justified in their budget if they are to continue to test.

We agree with NIOSH that they no longer try to make an in-depth review and approval quality control plans. The product quality limits that NIOSH set defined quality levels. In the real world, there are no 100 percent certainties as so many variables exist over which no controls are possible.

NIOSH must be sure they sample and statistically review field audits of products.

In regard to changes to approved devices, the present system is indiscriminate and places meaningless burdens on both manufacturer and NIOSH. Our views, then, in summary are: one, autocratic administrative activities being perpetrated at NIOSH and the current concept of design specification must both be abandoned.

Performance criteria for products should be jointly established by NIOSH and industry. Since neither NIOSH or MSHA has sufficient expertise within their present organization to properly draft a performance oriented regulation, Dr. Robbins should again establish

a committee of experts from government, industry and other interested parties to draft a new 30 CFR 11 regulation immediately.

Second, reproduceable test methods which can be used to judge whether products meet performance criteria should be developed and agreed upon by NIOSH and industry.

Third, self-certification by manufacturers should be employed. NIOSH and manufacturers would then have more confidence in each other. Problems of NIOSH liability and use of NIOSH as a development laboratory would be eliminated.

The removal of quality assurance plans as a requirement for certification is a good start toward the above system. The idea of manuals, et cetera, being submitted for approvals is counterproductive to the idea of eliminating quality assurance plans.

We sincerely hope that these comments will assist you in promulgating a new system which will emphasize a testing and certification program based on respirator performance, and which will be able to accomodate and encourage the introduction of new and innovative products.

We submit that these goals can be achieved without sacrificing worker protection and if not

accomplished, will ultimately have a severe negative impact upon all those workers who depend upon our professional expertise to provide them the best respiratory protection possible.

Are there any questions?

DR. MAY: Thank you, Einar. Are there any questions or comments?

MR. TIPTON: I'm Frank Tipton from OSHA. For reasons I assume will be somewhat self-evident, I'd like to pursue a couple of points that you brought up a little bit.

I'd like to request that, if you would, that you'd submit for the record information about two items: one, any data that you have that would show that unapproved respirators are, in fact, protective of the workers, and including with that, a description of the test methods; and the second one would be any data that you have that would show that approved respirators are not protective and, of course, a description of the test methods.

MR. HORNE: We will summarize some comments with those two things, and submit them to the record. We have examples of both.

MR. DEN BIEN: Gene Den Bien from OSHA. I guess Mr. Horne just raised up a question regarding the

asbestos for the dust respirators. As far as we know, the silica dust -- size for silica dust using tests, about two micrometer aerodynamic size. Asbestos fiber generally have much smaller size than two micrometers.

If any respirator manufacturer has some data to indicate that those penetration if you're running asbestos, you will have a penetration just meet current requirement.of concentration permit by the OSHA standard. I see no reason why we cannot accept the current approval for asbestos use.

MR. HORNE: I have two points I'd like to make on that, Gene. The first one is, number one, this change is being made arbitrarily without any public review, number one.

Number two, there is test data on 3M respirators that has been run by the Safety and Mines Research Laboratories in the U.K. by the Australian government that shows the efficiency of our respirators against asbestos.

And my main point on this is the fact that I do not think that it is proper for NIOSH or OSHA to arbitrarily make new rules that fall outside the guidelines that they wrote in the first place and quit using them.

MR. DEN BIEN: And if you come to point right now, everybody is putting the blame on NIOSH. They

did everything wrong. The method is bad. Right now, if they want to do something, improve the product to protect the worker, then everybody object -- you need a justification, you need that. I don't think we really have to think about which is important. Is protect the worker important or really, we just talking three days. Everything wrong with NIOSH but nobody really want to do anything right now. You know, if you want to improve regulation, it would take so many years to finish.

How about next three years? What we going to do? We going to incur a method? We have to think of some way to protect the worker.

MR. POWERS: Yes, I want to kind of back you up a little bit, Einar. My name is Jim Powers. On the new two micron requirement you're saying is put in arbitrarily.

Yesterday there was a paper presented by OSHA saying they wanted to reduce the electrostatic filtering system, and now they'retalking about mechanically filtering two microns, you know. This doesn't seem to me to be compatible.

And so when you start looking at a two micron which has in the past been considered respirable, I agree with you, Einar. These things should be a little more

carefully considered before they are just arbitrarily put in effect.

DR. MAY: I have a comment I'd like to make -- I feel compelled to make, really, in light of one part of your comments, Einar. I think it would be good to set the record straight as far as my involvement in this program because some of you are not aware of it.

I've been involved with the testing and certification program for about seven months now, having been assigned by Dr. Robbins in January of 1980, to act on his behalf with the program, try to keep him and Dr. Freunds aware of what was going on day to day before they have a lot of other things to worry about in the institute, and to get involved with Jim and the group out there and try to provide whatever assistance I could, coming from Rockville and out of the office of the director.

And several things have become quite obvious to me during this period of time. One -- and we've said this very loudly, clearly and honestly.-- the program has major problems. We would like very much to change that program around to something that is totally oriented toward the user so that they can rely on the equipment.

None of us today in this room will stand and

defend a lot of things that have happened to that program over the years.

We've been very honest and aboveboard in this effort to produce changes that we think are necessary. This is an obvious area where we're going to get a lot of disagreement among people as to which is a proper course of action to take.

Now, having said, that, I'd like to introduce into the record my strenuous objection to the statement made by Einar on page 12 of his testimony which states that, "The present system has been and is being abused by those involved in the certification process."

Now, he did not elaborate on what that really means to him, but it could be misconstrued or interpreted by people who hear it as an obvious attempt on the part of the people in the program to simply do that -- to abuse 30 CFR 11 or whatever system the program operates under.

I find that to be totally 180 degrees off from the truth, and I feel compelled to say that. There are a lot of people in the program out there -- not enough people were crying for additional resources. A lot of people who are very dedicated to the program and who have a lot of expertise.

In sum total, they may not have and probably do

not have the expertise of a lot of the companies involved in this field.

They are not either consciously or unconsciously involved in abusing any power they have in this certification program. They could be accused, along with me, of being zealous in trying to change the program, in trying to change a lot of things in it that are wrong, that are improper and at times, we probably have exceeded the authority of 30 CFR 11 and made some suggested changes to the program that will, in fact, have to go through the Administrative Procedures Act and will do so in the course of the action.

It was never our intent to undermine that authority or to pass off on the part of the manufacturers or the public at large illegal acts or do things that we did not have the legal authority to do.

It was a zeal to try to correct what's wrong with the program. We need a lot of help in trying to turn this program around. I mentioned yesterday, we welcome the formation of the ANSI ad hoc committee and the people on that group who have considerable expertise in this area.

And I would, again, like to say that it is my opinion shared by Dr. Robbins that we have deficiencies. We have problems. We have lack of staff and resources,

but we don't have anybody in the program now that I'm aware of that is involved in abusing that authority.

And I wish, for one, quite frankly -- and I'll make this appeal -- that those people in the manufacturing and user communities who disagree with us, I have no qualms of that.

But as my father told me when I was growing up, I have problems with people who are disagreeable. And I would hope we could end this diatribe, one against the other, and get on with the business of trying to turn this program around. It is absolutely essential. And I think today would be the day maybe we could start doing that.

And so I would hope that anybody who presents a statement after this, if you are going to talk about abuse of any power or of the program in Morgantown, I would suggest you bring absolute hard facts with you because you're going to be pressed to provide them.

There is no way we are going to change this program around or gain any credibility if statements are made at meetings that can be misinterpreted. I'll give Einar the wherewithall to say that that might not have been what he wanted to say or that additional words would have clarified that.

The people outside of this meeting are going

to get this transcript, and I don't want them to misconstrue that we agree in any way that there has been any abuse of this power that NIOSH has in this certification program.

Now, one brief second point, and then I'll let Dr. Ophold --

On page 15 there is a statement that deals with stop-sale and recall of products. "It has never been subject to public review." The second -- and I'm reading from Einar's testimony, "The second regarding an appeals procedure has been commented on in a number of NIOSH hearings since 1974. Both subjects are important, and they should either properly become a part of 30 CFR 11 with a public hearing or be dropped."

Now, my comment will border on the witnessing procedure we talked about this morning -- the right of the manufacturer or the applicant to witness testing of his products. That is in 30 CFR 11.

If you are familiar with 30 CFR 11, there are no details provided. It simply says the manufacturer or his -- the applicant or his agent, and there are some words added, and it talks about witnessing tests.

By putting out on June 20 this appeals procedure for witnessing of tests, I don't believe that there is -- that that can be construed in any way as any deviation from

30 CFR 11. We're simply saying these are the procedures we are operating under now, and spells it out very clearly for everyone involved.

So those are two parts of the testimony that I found to be -- one to be quite offensive to me, and the second to be an error where I think some -- an area where some misinterpretation may have occurred. And with that, I'll --

MR. HORNE: This is Einar Horne again. I'd like to just comment on the abuse section.

We didn't write this document for a seven-month look. We have been trying to live as manufacturers of innovative devices since 1963, and the changes to the 30 CFR 11 have not happened.

Now, I gave you some time frameworks of when the last hearing was held. Until Dr. Robbins got in office and some more pressure was applied, we did not hear a thing about any modifications to 30 CFR 11.

I feel that borders on a very, very poor utility of the work function that NIOSH has been charged with. To me, that is an abuse of the system. I will define another abuse of the system for you, and that is in January this year, we submitted a product for approval.

It was submitted on January 16th. On January 29th

it was tested. On February 14th, the QA plan was approved. On February 14th, Mr. Cook, who was then in charge of the testing and certification releases, wrote on the test document that no further action would take place on this particular device until some decisions were going to be made on single use.

Now, after that, the following things occurred. On 3/26, Nancy Bollinger completed her test report into the system. Then during this period, Don Wilmas of our QA laboratory who is in charge of approvals has made a number of calls to try to find out what the status of this product is.

We got no information. So your system is working very well, Jim, from the point of view of no information being released.

So in May, being a little frustrated, we filed for a Freedom of Infomration Act on our own product, and I think this is pretty sad. Now, the first time we were supposed to get the data, somehow it got lost in the mail so we didn't get it first trip around.

On July 22, the information was sent from NIOSH to 3M. On July 23, I received it. I looked at this particular approval procedure and, quite frankly, I still didn't have a letter of certification.

Now, it seems to me that that is as close to

abuse on a system as could possibly occur to keep a product off the market. That is my definition of abuse.

Now, we may disagree in the definition, but the fact remains that we are not expeditiously getting approvals through NIOSH.

DR. OPHOLD: Jim Ophold, NIOSH. I think that Einar expects an answer, and I intend to give him one. It's -- I think his chronology is right. I wouldn't question those facts at all.

Now, interpretation of that chronology is very important. He's right. Mr. Cook did write -- and I don't have those papers in front of me to say absolute, but in the framework that Einar was talking, he said, "Yes, we need to hold this." And then Nancy Bollinger did run the tests.

But take one thing into consideration. The answer -- the OSHA cancer policy was in the mill at that time, and sometime in the spring, asbestos was declared a carcinogen.

Now, I'll ask everyone in this room if you were in my position, would you have approved the single-use dust respirator for use as -- for asbestos and any other carcinogen or dust in general? We were in a predicament. Now, we wanted to do what was right.

I told Einar this on the phone the other day.

What we did we think is rational, reasonable and practical. We didn't give him a denial of his dust respirator for all other dust. The only thing we said and indicated was that we cannot give you an approval at this time for asbestos.

We have followed up with a memo to all manufacturers saying, "We don't know what the policy should be or is going to be when it comes to single use dust respirators for asbestos and any other carcinogen. We do know -- and I state that emphatically in a very short memo to all the manufacturers -- that we will go through the due process. And if you -- if this group tells me I am wrong, I'll consider that. I think I am right by saying when asbestos was declared a carcinogen, that I have no proof to show that asbestos -- that single use dust respirators should be used for asbestos.

Now, if somebody can give me the data to show that, I'll be glad to reconsider. We will go through dueprocess in denials or approvals.

MR. HORNE: This is Einar Horne with one comment on that, Jim, and I respect what you're saying and your ability to defend what you are defending.

You have inherited a pretty wild thing. On the

other hand, those of us who have been in the business for a number of years, we are now going through our fourth director of NIOSH with little, if any change to 30 CFR 11.

I think that if you recall, one of my main points was that I think it is terrible that respirator manufacturers are not being told the status of their product. Give us a chance to work with you. Don't make arbitrary decisions in March that I have to ask for Freedom of Information Act information out about to get in July when you're making a decision on asbestos in February.

I have a little trouble with the sequence. I hear what you're saying, but I think there is a better way to let us help you.

DR. OPHOLD: I will not pursue this any further only to say to you, Einar, that we will and have reconsidered the communications between manufacturer and our laboratory, and that's all I'd like to say on that.

I can only say in regard to the asbestos situation, we did not make any decisions in February or March. It was in June or July that we made that decision on what to do.

MR. HORNE: Again, we could keep this all week as we do on the telephone.

DR. OPHOLD: All right. I have another question

then. How are we doing for time?

DR. MAY: We have plenty of time.

DR. OPHOLD: Einar mentioned the fact that private sector, and I quote on page 11, "The private sector is better suited for research than NIOSH." I would have to say in certain areas, perhaps the manufacturers has -- are very capable to do the research. I think since research does cut across many, many lines that the federal sector should, perhaps, continue to be involved in research.

I do have a question, though, and this is something -- again, I keep going back to the International Respirator Research Workshop that's going to be held in Morgantown. But as I mentioned yesterday, the theme of that first day is the use of respirators. And I will share with you and you can share with me the experiences we've all had when we go to the work place and we see respirators hanging around our colleague workers' necks.

Now, if manufacturers are so gung ho on doing research for betterment, for improvement, I would say that we haven't done much in the last 20-25 years to get the worker to where a comfortable, usable, efficient protective respirator.

I'd just like to hear your comment on that. And

I don't think, Einar, you should take the --

MR. HORNE: I'm willing to take it on.

DR. OPHOLD: -- the whole question, but go ahead.

MR. HORNE: I think that can be answered real simply, Jim, and that is the fact that I think respiratory protection today, as compared to 1930, as compared to 1940, as compared to 1976 has dramatically improved and the easy way for you to judge that is by the number of units that are being worn by workers, and the manufacturers do respond to complaints about, in our case, respirator collapse or, in the case of other types of respirators, we can't communicate through them.

There is a lot of good work that has gone on in these areas, and if you just look at the sales of respirators now versus five years ago, I think you'll find on a world-wide basis, they are being used much, much more throughout industry.

DR. OPHOLD: I would have to disagree. Certainly more being sold -- I don't know where. I'd like to see the data if you have it, but more are being worn. If you could supply that for the record, I think we'd appreciate it.

Also I will ask you the same questions I have asked other manufacturers. Can you, for the record, supply

us the market information on the sales from the 3M Company?

MR. HORNE: That's very simple. I really don't know what that would have to do with NIOSH and the hearings, but I don't have the data.

But I really don't think that's pertinent to 30 CFR 11 changes and modifications that are necessary technically.

DR. OPHOLD: You're perhaps somewhat correct in challenging that request, but on the other hand, we would like to begin to get an idea of how many respirators are going into the work place each year, and that is why I asked that question.

The next two comments that I have are going to be very brief. In the example that Einar used as where we goofed up is somewhat correct and somewhat not so correct.

Well, it happened, and we did issue some information to the 3M Company that they failed, but they were invited in to witness the tests and the tests were rerun. This happened, as I understand it, over two years ago, and I also understand that that was the first time we ran the lid test. So I think -- yeah, we did fail. This is a good indication to admit that we maybe didn't do it right, but we also want the record to show that we

were scientific enough about it to listen, to go back and redo it.

And the 3M Company was asked to participate. The only other comment I have is that on page 16 of the testimony, Mr. Horne states, and I quote, "In case you missed our point, the present system is slow, inaccurate, arbitrary, ineffective and inflexible."

I will certainly take exception to that and for the record, and say that we are turning things around as far as the applications go, as I mentioned this morning, from a couple of weeks to not more than 90 days.

We feel we are accurate. We don't think we were arbitrary, and by God, I think we are about as effective and efficient as we can get when our staff has gone from 45 down to 34. Thank you.

DR. MAY: Any other comments or questions? If not, I thi[redacted] are going to call it a day. We'll see you tomor[redacted]t 9:00 o'clock.

(Whe[redacted]n, there being nothing further, the hearing was [redacted]y concluded, to be resumed July 30, 1980.)