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 28, 1980 Starting Time: 9:00 a.m.

Contractor: _____

Requisition Number: _____

List of Attendees:

DR. JON MAY
Chairperson

Hearing Assistant

I N D E X

P R O C E E D I N G

Good morning ladies and gentlemen. Welcome to this public meeting convened to discuss NIOSH's role in the testing and certification of respiratory protective devices.

My name is Jon May. I am presently serving as a Special Assistant to the Director of NIOSH for Testing and Certification. I am serving as Chairman of this 3-day public meeting.

At this time I wish to make several important announcements concerning conduct of the meeting and use of these facilities:

a) The times listed in the program for morning coffee/tea breaks (10:20 - 10:45) and for lunch (1:15 - 2:15) must be rigidly adhered to. If you desire to have lunch in the NBS cafeteria, please do not do so prior to 1:15 p.m. For those not desiring to use the cafeteria there are restaurants in the area, approximately 10-15 minutes away by automobile.

DR. MAY: Each day's session will begin promptly at 9 a.m., although this morning, we're promptly at 9:05. It is expected that each day's program will end at approximately 5:15 a.m., with the possible exception of Wednesday afternoon. At this time, there are no papers to be presented; however, if there is a need for further discussion or comment, we'll certainly have time to go into that on Wednesday.

The National Bureau of Standards has prepared a sheet that gives some other information that I'd like to just go over briefly.

There are two phones out in the front, and those telephones can be used for incoming calls. If you make calls out of the facility, there are pay phones out front.

Please use those phones, but anybody that may be contacting you is free to call the numbers listed in the program, 921-3330 or 921-3340, and those calls will come in through the desk.

We have a young lady out there who will take the messages and see that you get them very promptly.

As I said, the coffee breaks are listed in the morning. Because of the late lunch, there will be no afternoon break, per se.

The sheet also lists the miscellaneous services

that are available in the facility, the bank, beauty and barber shop, et cetera.

There will be no smoking, food or beverages permitted in this auditorium, and I please ask you to adhere to that.

Now, no meeting would start off right without a problem, and we already have a problem this morning, a problem that's just about sent me through the roof earlier.

We have a court reporter that was supposed to be here at 9 to make a verbatim transcript of this meeting, and I won't belabor you with the problem, but they received a notification from somebody that the meeting had been cancelled.

She will be out between 11 and 12. What we're going to do through the generosity of National Bureau of Standards, somebody will come into the room about 9:05 or 9:10 and set up recording equipment, and we will be actually recording everything said on tape until at least the court reporter arrives.

I do have to inform you that, of course, the meeting is being recorded.

At this time, I would like to just briefly mention that on September 9th through 11th in Morgantown, West Virginia, there will be an International Respirator Research Workshop held which some of you may find interesting

and wish to attend, and that's why I'd like to just mention that at this time.

There is, in fact, a program that has been brought to this meeting. Copies are available at the registration desk. Please pick one up when you get a chance. It lists the agenda for that program, and it should be a very interesting meeting.

I have just been informed that they already have set up the equipment for recording in the booth so everything is being recorded as of this moment.

It's probably a very appropriate time to enter into the record our thanks to the National Bureau of Standards for permission to use these beautiful facilities.

Anyone who has been into the Parklawn Building in Rockville would have to agree that there's no comparison.

These are truly magnificent government facilities, and it's a pleasure to hold a meeting in something as nice as this.

I would also like to express on behalf of NIOSH special thanks to Joanne Lorden and Rita Pinonne of NBS and to Peggy Cunningham and Nancy Hearst of NIOSH for their assistance in making arrangements for this meeting.

I would now like to introduce very briefly the following people from the Division of Safety Research, NIOSH, Morgantown, West Virginia. This division, as you probably

know, contains the testing and certification branch which is responsible for administering the respirator testing and certification program.

Several of those people are up front, Dr. Opold who is Director of the Division of Safety Research. I'll read them off as I have them. Dr. Donald Campbell, Deputy Chief of Testing and Certification Branch; Mr. Ralph Touch, Acting Chief, Testing and Certification Branch; Mr. Robert Shute, Special Assistant to the Director of DSR. I believe Bob is not here yet. They're coming in this morning, I think.

Ms. Nancy Bollinger, Supervising Chemist; Mr. Samuel Terry, Supervisory Chemist; Mr. Olin Defenbaugh, Chief, Physical Agent Section, Testing and Certification Branch, and, Mr. Robert Irwin, writer, editor, Office of Administrative Management who is here, and these people are here and were introduced to let you know who was running the program and if, in fact, you have any questions during the meeting that you care to address to any of these people, please feel free to do so.

The purpose of this meeting is to provide the public an opportunity to comment on the NIOSH testing and certification program for respiratory protective devices, presently conducted jointly with the Mine Safety and Health Administration under 30 CFR, part 11.

The issues and topics to be discussed at this public meeting are intended to provide the necessary focus for restructuring the testing and certification program.

This meeting is being held as a follow-up to an evaluation of the NIOSH testing and certification program conducted at NIOSH's request by several consultants, namely Dr. Morton Corn, now Professor and Director of the Division of Environmental Health Engineering of the Johns Hopkins University; Richard Breef, Director of the Industrial Hygiene Research and Environmental Health Division of Exxon Corporation; Mary Wynn O'Brian, Assistant General Counsel for the United Steel Workers of America; Robert Firenz, President of RJF Associates; and David Scott, now with NIOSH.

The report of the consultants' evaluation was made available to the public through notice in the Federal Register on February 15, 1980.

At this time, I would like to enter two documents into the record of this meeting. The first is the consultants' report and is entitled, "Evaluation of the NIOSH Certification Program, Division of Safety Research, Testing and Certification Branch." It is otherwise identified as DHEW (NIOSH Publication Number 80-113).

For the benefit of those attendees who have not received a copy of the consultants' report, we have brought

approximately 50 copies to this meeting. The second document is the Federal Register of June 18, 1980 announcing the meeting and listing some of the most important issues for discussion.

This document is identified as the Federal Register, Volume 45, Number 119, pages 41219 through 41221 published on June 18, 1980.

For those in attendance who would like a copy of this announcement we have brought additional copies to the meeting and they can also be picked up at the registration desk.

To accomplish the goal of the public meeting, we will proceed as follows. Interested persons who have advised NIOSH that they wish to present statements will present such in the order set forth in the program that you have received.

Each requestor has been given the full time requested. In addition, depending on the length of time requested, an additional period varying from five to 15 minutes was added in order to allow for questions, comments, et cetera from the audience.

In addition, depending on the need, there is time during the late morning and the afternoon of the 30th for questions, comments, supplemental or additional statements.

All written comments submitted to NIOSH, but not presented at this meeting will also be entered into the meeting record.

In addition, the record will be held open until August 29, a period of 30 days in order to receive additional comments and information.

A verbatim transcript is being made of this meeting, and along with all material received will constitute the official record.

Any individual or organization wishing to obtain a copy of the transcript must make their own arrangements with ABL Associates, the transcription service.

At this point, I'll simply ask are there any questions regarding my brief introductory remarks?

(No response.)

We will now begin with the presentations. The first speak is Dr. Morton Corn, Professor and Director of the Division of Environmental Health Engineering, the Johns Hopkins University.

Dr. Corn will discuss the findings and the recommendations of the consultants who evaluated the NIOSH Respirator Testing and Certification Program. Dr. Corn.

DR. CORN: Thank you, Dr. May. Good morning. First, I would like to express my appreciation on behalf

of the consultants to NIOSH for acting on two of the recommendations of our group, one that this meeting be held to solicit views, and, two, that an international conference be held to assess the state of the art elsewhere in the world.

The purpose of my presentation is, first, to convey to this audience the background of concern which led to the appointment of consultants by Dr. Anthony Robbins, the Director of NIOSH, to review the current testing and certification procedures of the institute, and, second, to convey the spectrum of concerns shared by the consultants which are embodied in the report submitted to Dr. Robbins.

It was not possible to accurately convey the nuances of concern or the emphases on issues in the report. I hope to do so here.

In rereading the report, my perception was it covered everything, but given the opportunity to rewrite it, I think we could have done better with the emphases. I hope that I can convey those feelings of emphases here.

The members of the consultant group which approached the task of individually reviewing the mass of materials and documents listed as Appendix C to the report were in addition to myself, Richard Breef, Robert Firenz, Mary Wynn O'Brian, and David Scott.

I speak as their representative as well. The

materials transmitted to the consultants were not the only resources available to us.

We interviewed NIOSH personnel as listed in Appendix C of the report, and we also visited the NIOSH Morgantown, West Virginia facilities, where the testing and certification facilities and staff are housed.

Although each consultant approached aspects of the program individually with evaluation in mind, the general conclusions of the report were unanimous.

In fact, the unanimity reached by the process of each of us examining different facets of the program was a source of surprise.

It is to the credit of Dr. Robbins that he interpreted the field failures of devices in the field as a possible indication of a broader, more endemic need of the user, and the possible reflection on the inadequacy of the then existing government procedures.

He appointed the consultants and gave us the directive to examine the entire testing and certification procedure.

The conclusions and recommendations in the consultant report range from the topic of adequacy of the existing NIOSH legislative mandate to the detailed testing procedures and research conducting by the T&C branch.

As our efforts started and concluded during the

summer of 1979, it became increasingly clear that it would be a bandaid approach to a larger problem if we accepted the current framework of government activity in personal protective equipment and hazardous measuring instrumentation procedures, and we only addressed deficiencies in that system.

Rather, we chose to approach our task by visualizing the needs from the user, the user standpoint, and focussing on a government program that would fully meet user expectations and needs.

We did not restrict ourselves to a critique of current NIOSH activities. In fact, because the testing and certification program had its beginning roots in the United States Bureau of Mines and was until recently performed and administered in conjunction with the Mine Safety and Health Administration and the U.S. Fire Administration, in essentially the same manner as it was administered decades ago, it is timely and appropriate to examine major changes in the program to meet needs stimulated by recent health and safety legislation including the Occupational Safety and Health Act of 1970 and the Mine Safety and Health Act of 1977.

Professional colleagues who have been associated with PPE testing and certification for many years, indeed, some have grown up with the industry, have told us that the

initial government effort was to assist manufacturers in order to stimulate the development of a very much needed national industry.

Today we were told PPE sales alone exceed $160 million per year, and this figure will probably double by 1982.

This is hardly an infant industry, one requiring stimulation for growth.

The same firms in this business originally have thrived over the years. Also, we note large organizations have entered the field during the intervening years.

In general, manufacturers have sophisticated personnel and facilities to back up their progress and their products.

In other words, the review commission by Dr. Robbins was appropriate, not as a short-term response to some spectacular equipment failures in the field, but because the needs of those in the work place have been better defined and articulated, usage has expanded, and the government machinery to address these needs was straining under a system including goals defined and implemented decades ago.

It is appropriate at this time prior to addressing the issues for discussion at this hearing to quote from page 19 of the report. Under Conclusion 5 which relates

to the then current NIOSH testing and certification program, we stated, quote, "It is our unanimous opinion that the technical qualifications and task performance of the testing and certification branch staff is satisfactory. The branch requires definitions of goals, objectives and functions, and the associated restructuring and evaluation of performance to meet these goals and objectives. In this way, the considerable technical talents now onboard will be mobilized and more efficiently utilized," end of quote.

We believe that NIOSH has a capable and committed staff. The system by which they do their work must be revised to meet the needs of the 1980's.

I will now move on to the issues which we focussed upon and for which NIOSH has requested your input at these hearings.

First, the agency approach to testing and certification. NIOSH does not explicitly in the announcement solicit comments on section 2, investigation of legal authority of the report.

The examination of NIOSH's statutory authority in that section of the report is related to the solicitation of public views on the four viable alternatives for the existing respirator, testing, and certification program.

NIOSH indicates that at this early stage, the development of a new testing and certification program

under Department of Health and Human Services Regulations where NIOSH alone would test and certify respirators is the alternative which would, quote, "provide more effective control of the respirator approval program and result in a more efficient testing and approval system," end of quote.

The consideration of ingredients of respirator testing and certification program can be considered independently of the question which of the four viable approaches is used for the program.

It is not clear to me that the certification of private laboratories to assist NIOSH with the T&C workload is not a more realistic approach.

Two, the testing and certification workload burden which can be projected as a result of regulatory stimulation of respirator requirements by users. I indicate there to assist, and I'm contrasting that with the alternative of the exclusive testing and certification by NIOSH.

The greater liability considerations applicable to private laboratories as discussed in section two of the report does not appear to be a major obstacle, particularly if NIOSH retains the final authority for certification and approval based upon contractor laboratory test results.

The latter is alternative three in the Federal Register announcement of this hearing. Alternative four, a self-certification program whereby industry would test and

certify respirators based on performance standards specified by NIOSH strikes me as a very weak alternative.

It struck our committee group, the five of us as a weak alternative.

Alternative one for doing some fine tuning of current procedures is clearly inadequate, as the report indicates. The views of those at this hearing on these alternatives is clearly of critical importance.

Whichever alternative is finally focussed upon by NIOSH in seeking to fulfill its responsibilities to those at work who require PPE and HMI, the division of responsibilities between the government, NIOSH and manufacturers must be made absolutely clear; therefore, I will now discuss the consultants' views of this division of responsibilities.

The consultants were unanimous in assigning to NIOSH the responsibility to set performance standards and design criteria for PPE and HMI. The nature of tests to assure that standards are met is also a NIOSH responsibility.

The responsibility to assure users that all, all PPE and HMI units in the field adhere to performance standards is the manufacturer's responsibility.

NIOSH must establish a schema for sampling and testing units in the field to assure users that manufacturer's units are, indeed, meeting standards and criteria for design

and performance. The approval and certification of an individual PPE or HMI is the analogue to a construction permit.

It is not an operating permit. The latter, the operating permit, is the net result of a series of manufacturing steps that leads to the distribution and sale of reliable units in the field.

The operating permit is contingent on demonstration of continued reliability of field units. I think that differentiation of the system proposed and the solicitation of views on that system is a major change from the previous procedures followed.

In the past, an approval by NIOSH was interpreted by users. A person picking up the unit as assurance that units purchased on the market were uniformly reliable. In reality, although issuing an approval, NIOSH could not give any such assurance.

As consultants, we think it is the responsibility of the manufacturer to give this assurance, and it is the responsibility of NIOSH to confirm that the manufacturer's assurances are well taken by users.

It is not in our opinion for NIOSH to approve a quality assurance program for a manufacturer. It is for NIOSH to determine that PPE or HMI manufactured in a plant with quality assurance procedures meets standards for

performance set by NIOSH. Failure of units in the field to do so in answerable by the manufacturer.

There is an analogy in our perception of the division of government/private sector responsibilities in the automobile industry.

Vehicle safety standards and emission standards are established by federal agencies assigned these responsibilities.

The automobile manufacturers are compelled to meet these standards. The EPA, for example, randomly selects production vehicles to assure that standards are met.

The necessity is greater for stringent performance standards for PPE and HMI. In the case of these units, lives literally, literally depend on the integrity of the individual device and its predicted performance in the field.

With regard to the statutory authority, independent of the four proposed approaches to exercise of this authority through a system, NIOSH was recently active in certifying six different types of HMI and PPE including three types of respirators and coal mine dust samples, sound level meters, and gas detection indicator tubes.

The authority for these certifications stems mainly from the Mine Safety and Health Act. It was projected by

NIOSH that a ten percent per year growth and request for certifications would not be unrealistic.

The consultants addressed the question of agency authority to enter new areas of testing and certification in section two of the report.

One can very briefly summarize the conclusions of our investigation into this subject by saying that only the Mine Safety and Health Act contains explicit language related to PPE and HMI testing and certification, but the Occupational Safety and Health Act in its directive to NIOSH to, quote, "develop and publish such criteria, as well as effectuate the purposes of this act," unquote, permits NIOSH to move ahead with the certification program.

Certainly by cooperating with OSHA, in that the latter in its standards enforcement activities will recognize only NIOSH certified PPE and HMI results, OSHA can be a powerful stimulus to a NIOSH program of voluntary if not required certification of devices.

The Consumer Product Safety Act also seemed to us to offer a model for product certification by manufacturers that their product meets NIOSH standards and criteria for performance.

Thus, our investigation of the legal options available to NIOSH to effectuate the presence of PPE and HMI of predictable performance in the field resulted in our

concluding that NIOSH has several alternative ways to achieve the result with the existing statutes on the books. We look forward to testimony on this question at this hearing.

Within the context of the testing and certification program, as described above, what specifically should NIOSH focus its technical in-house talents on?

The consultants were specific in their views in this regard, and I will now formulate some of their opinions.

I have already alluded to performance specifications and guidelines. With reference to PPE, NIOSH could set leakage performance standards for classes of devices under conditions of use. Thus, respirator X must perform no more than Y percent by weight penetration of aerosol Z when challenged its specific concentration and particle size of aerosol and the device is one during workload performance A, for example.

We visualized NIOSH personnel or their research agents engaging in these same tests to determine that they are feasible.

We visualized NIOSH describing in great detail the conduct of tests to permit manufacturers to set up their own test facilities to test their product and if a voluntary certification program is used, to certify them.

Of course, in the event of a voluntary or non-voluntary certification program with testing by NIOSH or by the manufacturer, we visualize NIOSH gathering production units and units delivery for usage in the field in order to test them and verify that off-the-shelf items perform as expected.

Many tests and specifications used by NIOSH until the program was placed in abeyance by Dr. Robbins were old and lagged the state of the art.

Examples of such test were the silica dust and lead fume tests. I worked my way through graduate school doing the silica test in the end of the fifties. It is really unbelievable that the state of the art for testing in the 1980's could possibly have gone that route.

NIOSH must update tests and demand technical progress from manufacturers so that users are assured of devices which are based on this advanced technology available in the United States and elsewhere.

In the opinion of the consultants, the former system of testing and certification encouraged the perpetuance of outdated technology. There was no incentive for improving a device once it was certified.

By placing time limits on valid dates of certification and by continuous upgrading of certifications, specifications and standards, NIOSH can stimulate improvement

of PPE and HMI.

The consultants believed the responsibility for researching new devices is that of the manufacturers. The device proper must meet specs and standards, research by NIOSH and must do this by performance and test developed and tested by NIOSH.

There is an area of PPE concern that illustrates the possible functioning of a new system for NIOSH testing and certification of PPE.

There is a desperate need for PPE to better meet the needs of women at work. The face fit problem of women is a major one. NIOSH could perform or contract the performance of research related to proper face fit characteristics of women and could specify dimensions of PPE classes of devices which would meet the user needs ascertained.

Manufacturers would then be required to incorporate into their products the features that would meet NIOSH specifications for face fit. I give these as examples to, if you will, flush out the conceptualization of the consultants of how this system might work.

The research role of NIOSH vis-a-vis specifications of devices is a large and formidable one. As consultants, we are aware of major questions that must be addressed. For example, with the broad array of

organic vapors that workers may potentially be exposed to, what is the predictability of usage for one vapor from tests on another or on a series, or must each be tested individually.

What is a minimum data set of test data to assure users of PPE respirator devices in the field? In the area of fitting of respirators to respiratorally impaired individuals, what are guidelines for such usage of devices by diagnosed bronchitics or asthmatics, for example.

The consultants believe these are bona fide questions for NIOS research to address and once answers are available, to distribute the knowledge to users and establish performance requirements for manufacturers.

With the areas of agency activity envisioned by the consultants, the development of in-place respirator testing methods for rapid leakage determination in the field is clearly a NIOSH responsibility.

The requirement that these tests be met on whatever statistical basis is finally evolved is the product manufacturer's burden. As I will later discuss, the rapid dissemination of failure information and stop sale issuances are NIOSH responsibilities in our opinion.

The PPE field, in general, and including respirators does not appear to use to have benefitted from the virtual revolution in new materials. We believe

this failure to integrate advances in material science into PPE products stems in large part from inadequacies in the recent NIOSH approach to testing and certification.

It is conceivable that NIOSH would develop prototype products in its research program for the purpose of demonstrating the validity of associated performance standards.

As consultants, we are not condemning all recently used NIOSH test and certification process ingredients. The total system was not effective. Parts of the system may be salvageable and integrable into a new system.

It is hoped that those appearing at this hearing will pass judgment on the strengths and weaknesses of recently used tests for NIOSH certification.

Before leaving the subject of performance specs, standards, guidelines and testing, the practice of NIOSH maintaining detailed engineering drawings of all manufacturer's products which were certified should be addressed.

The consultants do not understand the rationale for that process. It was tacitly assumed by us in approaching our evaluative tasks that NIOSH personnel literally reviewed these drawings and their updates. They did not.

Then why require their submission and submission

of all updating changes? The only test of concern to a user and to NIOSH in our opinion is the test of performance.

In the cases of failed respiratory protective devices which firemen utilized in 1979, we were informed that all engineering drawings for the failed valves were in order and had been in order since 1938 when they were first submitted for approval.

The matter of government agency involvement in manufacture design drawings for PPE and HMI was a performance procedure up to this time -- a performer procedure up to this time.

As consultants, we question its usefulness and look to the views of those appearing at this hearing to shed light on the value of the concept.

Of course, our view is based on NIOSH putting in place an effective testing scheme for units in the field and an associated system for rapid communication to use as test results for field units.

In this way, inadequate design changes will be rapidly detected. The product manufacturer will be responsible for any untoward effects stemming from design changes.

Any notification of change forwarded by the manufacturer to NIOSH should be viewed, we believe, as

a courtesy procedure and nothing more. By requiring this and filing it, the government is lending credence to the manufacturer's statement that the device is sound, because the user tacitly assumes the government is reviewing those plans.

It is conceivable, but not likely, that with the increased presence of large organizations in this business area, PPE and HMI product manufacturers will require some assistance to set up to duplicate NIOSH testing protocols.

We believe this is a legitimate request by manufacturers and that NIOSH should respond accordingly. NIOSH might also coordinate interorganization testing comparisons to be sure the test results performed by NIOSH and the companies are comparable.

Several years ago I was involved in a case of results of PPE test discrepancies between a manufacturer and NIOSH and can attest to the vexing and frustrating nature of the situation.

The manufacturer in good faith believed his product met NIOSH specs by testing on premises, but upon submission, it repeatedly failed one dust challenge test. Presumably the tests were run the same way at both sites.

My point here is that there are technical areas of performance and some sorting out between the government and manufacturer's testing in-house is a perfectly legitimate

activity. A manufacturer must invest in or purchase for usage the facilities and technical competence to document performance. If assistance is needed, NIOSH should provide some to an earnest product manufacturer.

The recognition by manufacturers of PPE and HMI that investment and technical capabilities and facilities is required has been slow, and some major manufacturers are still poorly equipped and staffed in this area.

The system we are suggesting to NIOSH would demand, would demand a high level of technical skills of the manufacturer, and it is fitting and proper to do so, because lives depend on the product quality.

As consultants we discussed the longevity of individual product certifications. Some comments is here appropriate.

Barring a major advance in state of the art, three or five years for a valid certification seems appropriate. In the case of state of the art, major advance, NIOSH should recall all certifications pending retest and adherence to new test protocols.

Only in this way can the ultimate potential beneficiary of all this effort gain from new materials, technology, design improvements and so forth.

While this short-term assurance to a product manufacturer may seem to some unfair, considering large

potential investments in product development, it cannot be any other way in our opinion.

This is not a game. This is a game, if you will, of life and death. Of course, the establishment of new performance criteria by NIOSH would not be arbitrary or capricious, but would occur under the rulemaking procedures of the Administrative Procedures Act.

With respect to quality control, under the recently curtailed NIOSH procedures, NIOSH engaged with manufacturers in a process designated as, quote, "quality assurance," which was differentiated by NIOSH from quality control.

Quality assurance involved direct NIOSH personnel involvement in manufacturers' product manufacturing procedures. NIOSH analyzed and literally approved quality assurance aspects of the manufacturing process.

Quality control was considered the output function, how many units were unsatisfactory as differentiated from the quality assurance procedures to minimize unsatisfactory units.

As consultants, we think the distinction drawn by NIOSH between quality assurance and quality control is meaningless. It is all quality control. The only test is the final product, and it is the manufacturer's duty to take all steps to assure that product quality is in

accordance with product performance tests.

We recommend that NIOSH withdraw from all activities related to manufacturer's quality assurance or quality control.

NIOSH rationalized its involvementin this area because of small manufacturer inability to mobilize quality control programs. This may be a valid reflection of manufacturer inadequacies. In our opinion, satisfactory product quality control is part of the price of doing business in this product market. Manufacturer inability to compete in this regard should, in our view, disqualify a manufacturer from marketing his or her product.

Let me turn now to the user reporting system for PPE or HMI. Even if the system proposed operates at a high degree of deficiency, there will be equipment defects which become apparent only after extended field usage.

NIOSH must develop a feedback system which permits users to communicate such defects in a timely manner and with particularity so that NIOSH can take effective action.

Malfunctions must be reported to other potential users as quickly as possible to avoid repetition of the unfortunate event or events. Such a system will require a great deal of the initial and continuing NIOSH effort.

It is an essential component of the testing and

certification program, not merely an addendum ingredient. At present, mechanisms for PPE and HMI equipment failures -- communication of PPE and HMI equipment failures does not exist.

We suspect that only the most spectacular and tragic failures of such equipment are ever reported back to NIOSH. Development of this feedback system will include an education component in order to sensitize users to the most probably failure modes of PPE and HMI. Also, it will include an information and distribution system to notify potential users of HMI and PPE potential problem areas.

Views on how to do this in an effective and an efficient manner are solicited by NIOSH at this hearing. In our report, we refer to this feedback system as a PPE and HMI field surveillance system, surveillance in the sense that one surveils and watches by sensitive indicators of distress and is prepared to take action upon detection of that indicator, and the choice of a field surveillance system as the wording for this feedback is a careful one.

The wheels must turn very rapidly when that sensitive indicator appears, because there may be tens of thousands of units potentially usable by others at a moment's notice.

In addition to information related to malfunctions of PPE and HMI in the field, we believe NIOSH can play a

meaningful role as the source of information related to the availability of and performance of individual PPE and HMI.

The issuance of a NIOSH report was not in our opinion a highly effective means of performing a potential user population of 100 million workers of the availability and characteristics of PPE and HMI.

NIOSH reports are not easy to get hold of or to read, for that matter.

We do not believe that NIOSH should advertise for manufacturers, but between the role of advertiser and the publication of technical reports of performance, there is a spectrum of activities, available to NIOSH to promote.

NIOSH is soliciting views on this role at this hearing.

It was a relatively difficult task for the consultants to determine the current responsibilities and procedures used in the PPE and HMI certification program. A large effort was devoted to gathering and then digesting materials in memos, Federal Register publications, laboratory procedures, even letters of transmittal between manufacturers and NIOSH.

We believe the government agency charged with testing and certification has an obligation to explicitly state its procedures and that these procedures should be

readily available--(End Side 1)--compendium of materials which taken together explain all facets of NIOSH testing and certification program operations.

Approval testing. NIOSH should engage only in testing of devices formerly submitted for approval. That is, submitted according to the published procedures governing such submission and testing, informal submissions, unpublished test results, prototype testing, in our opinion, all are inappropriate to a publicly financed agency concerned with assuring the availability of satisfactory devices to users.

The product manufacturer has the responsibility for bringing the product to the stage of development where it can be submitted for testing.

If NIOSH decides to exploit new and novel ideas and/or technology to foster new examples of PPE and HMI it should do so by sponsoring research by capable investigators with the results of such research subsequently available to the entire public, including the manufacturer.

Prototype unit testing and unpublished results of such testing was in our view NIOSH underwriting of individual manufacture research.

NIOSH has solicited public views on this issue at this hearing. Other views are certainly possible. I have reiterated the concensus of the consultants on this

subject. I hope that sets the tone, the stage for the hearing, and also indicates to you some of the more deeply felt divisions of responsibility in this area.

We believe the government is fully capable of working out the detailed procedures. There's a great deal of technical talent there. The reordering of the system is, if you will, switching from cartesian to circular coordinates.

We are recommending a very large change in emphasis, and that's the thrust of our report, and perhaps another stage of consultants working with NIOSH can assist them with the technical ingredients.

We did not focus upon that. I will be here for the next hour. I'd be happy to answer at this point any questions from the audience or from those affiliated with NIOSH, for that matter.

DR. MAY: Thank you very much, Mort. As he said, he has about one hour to remain with us. If there are any questions for him or the consultants, please feel free to raise them. Before you speak, there is a microphone at each end of the auditorium. If you have any questions or comments, please make them into the microphone, identify yourself by name and affiliation and then make your comment. Thank you.

MR. POWERS: My name is Jim Powers. I'm President

of Corbal Air Supply Systems Corporation. My question now is in your study -- I have many questions, but the one I want to bring up at the moment is in your recommendations for improved product specifications to update according to the present state of the art, my question is has the human body changed, and those products deemed as safety devices and life-saving devices over the years, even though it's been through a slow process has been thoroughly tested, and most cases, thoroughly used in the field and proven to be satisfactory.

The human body, in my opinion, has not changed that significantly so that those products are no longer valid products.

Now, if you in your new product specifications want to start on with new categories to allow greater diversification of design so that you can permit wider varieties of products on the market, I'd say this would be great.

My question is, is it necessary at this point to void out those lifesaving devices and now regulate luxuries into the products.

DR. CORN: The answer to that question has several facets. Let me try to take them one at a time. First, the assumption that there are highly satisfactory devices available,, I do not think the user network could

attest to that. The, quote, satisfactory device has been certified in most cases under conditions not totally representative of conditions in the field.

One of the types of tests that consultants felt was very much needed was stress testing for PPE, and there is no current stress testing.

I mention the use of PPE by those not qualified to use them, people with an impairment. I don't know how good, and I say this with all honesty, how good currently approved devices are for the spectrum of uses that they're used for.

I think we are absent a great deal of information on it. Now, I'm sure there are areas they're quite good for.

To get to the second point, they are good. Should the government be the stimulator of better, and I think our group felt, yes, that is the government's role. Let us take non-PPE and HMI equipment, the human eye certainly hasn't changed, but you and I have looked at spectables of 100 years ago.

They have certainly been used by people. I have been intrigued by the glass quality that was considered good 100 years ago. You may recall they had a handle, you held the handle, and you looked through them, and the advance came with using the ear as the support. The glass

quality improved. I don't think you'd want to wear spectacles of 100 years ago.

I think the government in this field can stimulate development, and, indeed, it should. Remember the person picks a device up off the shelf. I do a great deal of work in the factory.

The person that goes to work assumes the employer and all mechanisms available to the employer are working to assure them of a safe work place. I did it as an 18 year old.

I worked in a logging camp, and I went in there very naive. I thought it was a safe place, and I watched people getting hurt everyday, and it dawned on me that it wasn't a safe place, and some very fundamental safety precautions were not being taken, and that was a revelation.

Somebody employed me and was not taking those precautions, so I believe the stimulation, if you will, through the charge to NIOSH and to OSHA is to try to assure to the user that the work place is safe, and the worker that picks up an approved device, that approval should say something about that particular device.

Now that's the consultants feel very strongly about that point, and if it's picked up in a hurry, you're on your way to a fire or to a closed vessel entry or

whatever it is, that user should feel that it's going to do the job that that label says it's going to do, and the job it should be able to do should be at the state of the art of technology, and that's what our report is aiming at.

Can I answer any other questions? I'd be very pleased to. In fact, I'm anxious to discuss this report. The group realized we were recommending major changes. We were very pleased that Dr. Robbins has acted upon them and has this hearing, and we are anxious to share our views and certainly to hear other views. Yes?

PARTICIPANT: Dr. Corn, could I ask you to repeat very briefly the views of the consultants on the four alternatives?

DR.CORN: We did not articulate the four alternatives in the announcement. The report was digested by the agency, and those alternatives were explicit and articulate in their present form by NIOSH.

We certainly discussed the seeds of all those alternatives in the report. I spoke for myself in not excluding some independent laboratory involvement. I'm worried about the workload.

There's a little less than 2 million going into this program now. There was some 60 people, and it was staggering under the work load with the old system.

With the system we're envisioning, it could be even a heavier burden, and I'm not ruling out the possibility of some sharing of testing by independent laboratories.

The voluntary testing I expressed skepticism for. I think that the assignment of this responsibility to the government is an assignment, and that cannot be transferred in total, but there can be some sharing of the testing and reporting with the total responsibility for action on the part of the government, and that was the wedge, if you will, that I put in the remarks here.

I'm trying to remember if that was not stated in the report at any point, but I suspect the other consultants would not differ with what I've just expressed.

MR. KELLEY: Bill Kelley of ACGIH. I would have preferred to not take this comment out of context, but since Dr. Corn will not be here this afternoon, I'm forced to.

In part of the testimony which I will be giving, the statement follows. The make-up of the panel of consultants charged by NIOSH to review the testing and certification program is distinguished by the competence of the members in their fields of expertise and in being without credentials in the field of product quality assurance, page 44 of the publication. I think Dr. Corn

re-emphased his dilemma in his comment that says quality assurance and quality control in its distinctions are meaningless in that all is quality control.

I don't personally hope to it, but one could perhaps make the same statement in regards to PHDs and regards to doctors.

I think there is a very real distinction, and I think it is unfortunate that this very distinguished panel did not have representation by someone who was knowledgeable in the quality assurance field, and I would certainly hope that in the future that NIOSH would exert some effort to get such representation, because I think it would very positively contribute.

DR. CORN: I accept the criticism as valid. We are not experts in this area. My remark on the lack of differentiation between quality assurance and quality control was not in the sense of the technical meaning of the terms to those involved in that field.

I certainly accept the criticism that this may be an invalid statement. It was in the sense of the goal of this testing system that the differentiation is meaningless.

The goal of the system is to assure on the market a high degree of reliability of the device, and for NIOSH to break down an approval for an internal assurance system of the manufacturers' methods and to take that out of the

umbrella of quality assurance and quality control and say anything that happens now in the field is quality control, that to the consultants was most puzzling.

The only test to the user is does the device work, and it's in that sense that I'm using the umbrella of quality control.

MR. KELLEY: I think when one gets into quality systems and the components in the quality assurance/quality control area, I think there is a very useful distinction, and perhaps the role of NIOSH or whatever agency would assume responsibility for this program would be in the quality assurance area or what should the characteristics, what should the performance characteristics of these devices be.

Quality control aspects is more of an operational activity, and that is how the manufacturers get to those operational characteristics, and there is no question that the quality control in that context would be a manufacturer's responsibility, but NIOSH or whatever agency acting for the users, the purchasers and the ultimate users, the workers, I think, must assume that responsibility for quality assurance, and, therefore, I think, in those distinctions it's necessary.

DR. CORN: Permit me to rephrase what you said. It must not assume the responsibility for quality assurance.

NIOSH must only confirm that the device works. It does not assume the responsibility for the device working. That's where the consultants seem to differ from what you're saying.

There's only one person that answers for a failed device, the person that went into the market for the device. The government must be very clear to divorce itself from sharing that responsibility.

MR. KELLEY: When the agency sets up the performance requirements, those performance requirements is the quality assurance, what the device must do. If NIOSH or whatever agency sets up the criteria for performance, it must be responsible for those criteria.

DR. CORN: We call them performance specifications, not assurance. They are not -- assurance -- we're defining words here, and I think we're probably not arguing, but we're confusing each other with our terminology.

Criteria, standards, specifications are the measures by which a device will be judged. Anything contributing to the device being judged satisfactorily, anything leading up to that point of testing where failure or past counts is not the government's. It's the manufacturer's. That's what we're saying.

PARTICIPANT: I didn't want to get into this, but this happens to be my field. Most people here know

me as --

DR. MAY: Please identify yourself.

MR. POWERS: I'm sorry, my name is Jim Powers, and many of the people here know me formerly as the quality assurance specialist. I'm now the President of Corpal Air Supply Systems Corporation, but I could give you a lot of history of why some of the quality control requirements came to be and are here today, but that's not important at this point.

What is important at this point is that when a product meets the product specifications that you're saying for the certification program, NIOSH or any certifying agency must have some reliance that the product is representative of a series of that line of products coming off the line.

Without a quality control system, that can't be assured. Now, you're saying, okay, the manufacturer must have this quality control program. They must say they have this quality control program, and they'll be glad to say that.

DR. CORN: No, no, what would you say to my requesting before and phrasing it to the manufacturer, before your first production run, we want to be there to randomly select for testing your first production run, and we will be back for subsequent production runs?

MR. POWERS: I would say you would be bringing yourself back to the decasser method of quality control which in my opinion is no good, but the system that -- I'm not saying that NIOSH could have the expertise to go into anybody's plant and tell them the way to run their plant.

I never did think so, even though I've been there, but you'reproposing a field audit program which is a measurement of reliability, and there is no way that any field audit program could ever hope to be successful without some system within the manufacturer's operation to maintain consistency.

DR. CORN: Of course, of course.

MR. POWERS: And you're saying the only thing that's important is the final test, and I'm telling you the final test is only a spot in time.

DR. CORN: I could not agree with you more. We are removing, we are saying if that final test is satisfactory, the manufacturer must have what you refer to as a quality assurance program in house. All we're doing is keeping NIOSH out of that.

We don't want NIOSH in there working with the manufacturer on that quality assurance program and then stating we approve it.

NIOSH approved the quality assurance programs of the devices that failed in the field. Those were

approved quality assurance programs, but people died, so what's the point?

I want to test the device so people won't die, and then if you're interested for educational purposes and out of curiosity, let's go back and see how they did it in the manufacturing process. That's the difference.

It's a shift in emphasis. I think the EPA wants vehicular emissions tests met, but I don't know if it's going around certifying how Ford manages to do it or GM. They're testing what's coming off the line.

MR. REVOIS: William Revoid representing the ANSI Respirator Test Approval Ad Hoc Subcommittee.

I want to have the record show that three years ago NIOSH held a series of hearings or actually a three-day hearing on requesting advice to improve the respirator test approval system.

At that time, ample time was given for people to prepare for the hearing which is not the case this time.

I'd like the record to show that many people in government agencies, technical societies, user organizations, industrial trade associations and respirator manufacturers spent considerable time preparing for these hearings and presented many recommendations for the improvement of the state of the art of respiratory protection.

Unfortunately, NIOSH seemed to ignore all of this, and we hope that this hearing is not going to be another waste of time. Thank you.

DR. MAY: Thank you very much, Mort. I would like to respond to that, Bill, by simply saying that neither I nor anyone else presently knows exactly why that program did not produce fruitful results with the exception that after those meetings considerable thought was given to the comments made.

Those reports were analyzed, and, in fact, groups within the institute and without were trying to develop a response to that, to come up with a new basic set of 30 CFR 11 requirements.

At the stage when that reached some level of possibly going further, NIOSH was beset with considerable problems in the program.

That necessarily is not a bona fide reason for ending it, but problems did arise. We realize the program had major flaws. Another reason is that at that time, the present director of the institute, Dr. Robbins, was not in command, so to speak, of the institute.

There was a different individual who had totally different ideas about where the program should go.

I have no idea what those ideas may have been,

except to say I guarantee you this time there will be not letdown of this procedure to modify the program.

There is a commitment made by Dr. Robbins to either revise this program into one that is going to provide the protection for the users that Dr. Corn addressed or the institute will get out of the business.

We are not going to continue to operate the program the way it has been operated, and we are not going to drop this commitment after this meeting. I can say that from now until the end of Wednesday.

Please regard that as sincere, and there is a commitment from the institute to do that.

We are going to take this record, and we are going to examine it, and we are going to make a new stand on this program, and we need a lot of help on that. That's why we're holding this meeting, and you can be guaranteed we'll proceed, and hopefully out of it will come a program that NIOSH will continue its involvement with new performance criteria and in a manner that we think will be best for the user of the equipment.

If, for some reason, that is not possible, the the institute will adopt another alternative, but the commitment is there.

In that light, I would like also to take a minute to say that I'm aware of the ad hoc committee that

ANSI has formed. It's a very prestigious group representing some of the leading experts in the country, and we will look forward to the recommendations of that committee which we think we can use in turning this program around.

Are there any other comments at this time, any last comments or questions for Dr. Corn?

If not, I would again like to thank you, Mort, very much for setting the tone for the meeting. 10:20 is listed in the program as a break.

Please return by 10:45 when we will start the rest of the program.

(Whereupon, a breif recess was taken.)

DR. MAY: The next speaker on the program is from the Occupational Safety and Health Administration. The program you have lists R. Hays Bell, Ph.D. as giving the presentation. Their presentation will be made by Frank Tipton who is a safety engineer, Office of Physical Agents Section, Occupational Safety and Health Administration. Frank?

MR. TIPTONL Thank you. I am speaking today on behalf of the Occupational Safety and Health Administration on substitute basis for Dr. Perswell. There are some copies of my presentation available on the table over there.

It's a restricted number. I suspect that's

somewhat fortunate since I've discovered there's a few typographical errors in it.

The Occupational Safety and Health Administration welcomes this opportunity to provide testimony concerning the improvement of the NIOSH testing and certification program for respirators.

We have long believed that several changes to the testing and certification program are necessary to insure that this nation's workers can have confidence that the respirators they wear are adequate and reliable.

As I am sure you already know, OSHA standards prescribe the use of respirators only when engineering controls are not feasible, during installation of engineering controls or in emergencies.

At this time, a large worker population relies on respirators for protection, and as more health standards are promulgated by OSHA, the number of workers who must rely on respirators for some period of time will of necessity increase.

The recent standard regulating exposure to lead specifies a period of ten years before primary lead production companies must reduce exposures by engineering controls.

This means that all employees of these companies must rely solely on respirators for protection from lead

until February of 1989.

It is thus obvious that good respiratory protection is now and will continue to be a very important element in protecting worker health.

Up to now the NIOSH MSHA respirator testing and certification program in 30 CFR part 11 has been the only assurance of adequate quality and performance of respirators.

OSHA believes that it is now necessary to broaden this respirator testing program and deal with recognized deficiencies.

At this time, OSHA does not wish to state a preference for any of the four program alternatives described in the notice of this meeting, but rather to focus on the necessary criteria for an effective respirator program.

It is our feeling that if specific program operational criteria are developed, any of the alternatives can be effective provided that funding is available to implement the program.

OSHA believes that the current 30 CFR part 11 must be revised to establish state of the art performance testing procedures and criteria.

It will also be necessary to modify the performance testing procedures and criteria to keep pace with technology.

However, in view of statements in the Federal Register notice for this meeting, an important distinction must be drawn.

The purpose of research is not to reflect the current state of knowledge or to discover the state of the art. It is to advance the state of the art and to improve on current knowledge.

Therefore, there need never be a delay awaiting research results to develop performance specifications that reflect the current state of the art.

Additional research is always laudible, but some of these respirator testing issues have awaited resolution long enough already.

We need to proceed promptly with an improved testing program. In those instances where rulemaking is necessary, there will, of coure, be the usual procedural delay, but we believe there are improvements which can be made to the existing program immediately in that they will not require rulemaking.

First, we feel it is necessary to increase inspection and testing frequency of respirators. According to current practice, NIOSH purchases approved respirators on the open market and tests them to determine whether the devices are, in fact, in an improved condition.

Because NIOSH has indicated that they have a

limited budget for purchasing such equipment, only a small number of respirators can be tested each year.

To alleviate this situation, respirator manufacturers could be required to provide a specified number of their respirators as part of their application for approval.

To preserve the randomness of choice of units, the approving agency must be able to choose which specific units are to be tested.

One method of doing this would be for the manufacturer to reimburse purchase coupons to the approving agency which would then obtain samples for testing from any distributor it chooses using the coupon as payment.

OSHA's field staff could assist the approving agency in securing the respirators for testing by making these purchases at distributors throughout the country.

To increase testing by getting the maximum use of existing testing equipment, NIOSH could hire part-time help and in-house contractors to test respirators, or some of the testing could be expanded to a two-shift basis.

Respirators that have had the approval certificate amended should be completely retested. If the modified respirator qualifies for approval, it should receive a new approval number.

There are several changes to 30 CFR part 11 that

OSHA believes are desirable and that do not require additional supporting research.

For instance, duration of respirator approvals can be established without waiting for new testing criteria. Under the current program, a respirator approved 40 years ago can still be used today.

This practice curtails incentive for innovation and technology and can also, as you point out, result in confusing situations.

The duration of approval should be specific but varied with different types of respirators. Longer durations should be granted for more complicated or expensive equipment since users are not likely to replace the equipment as often.

An alternative is to limit each approval to five years, and after that period, subject each approval to yearly reviews to determine whether an extension in approval should be granted.

This alternative, however, appears administratively untenable. We would like to point out that the situation described in the section of the notice on duration of approval represents a violation of the basic premise stated under changes to approved devices that continued approval would only be for modifications that do not affect form, fit or function.

Dissimilar diversions of a device surely must incorporate some change of form, fit or function with the exception of different colors.

Clearly with no difference in form, fit or function, there should not be any danger regardless of which unit is chosen for use.

Respirators as different as described in that section should be separately approved if they pass the requisite tests.

A stop sales and recall procedure should be formally established. The current regulations have neither provisions for halting the sales of a respirator nor for a recall of defective devices.

Thus, these procedures appear very open to challenge by manufacturers.

A stop sales and recall regulation should require a statistically significant number of respirators to be tested to determine the extent of the defect.

Recalls should be limited to those cases that pose some immediate hazard to the wearer. If testing reveals defects which lead NIOSH to believe that the respirator should not be used, the approval should be suspended until the responsible defect is corrected or a more suitable unit is developed.

A panel which consists of government officials

and independent respirator experts should review every case to determine whether stop sales, recalls or decertification is necessary.

OSHA does not agree with the position stated in the meeting notice that quality control requirements should be eliminated from 30 CFR part 11.

In fact, we recommend that 30 CFR part 11 be revised to establish uniform quality control plans. Under current regulations, the manufacturer is allowed broad discretion regarding the stringency of the quality control plan and choice of factors to be inspected.

Instead of this discretion, each manufacturer of a given type or style of respirator should be required to test the same qualities, items and functions.

OSHA agrees that product quality control is inherently a manufacturer's responsibility . However, if NIOSH were to establish a set of test criteria to use in monitoring a manufacturer's adherence to effective quality control and to insure that the percent effective rate is less than a given value, NIOSH would, in essence have its own quality control program.

The criterion for each quality item or function specified by NIOSH for its monitoring would by necessity be adopted by each manufacturer. Such NIOSH criteria would be important enough that they should be established by

rulemaking in 30 CFR part 11. In this context, it is relevant to point out two essential uses for an analysis of dimensional tolerances.

The tolerance set by a manufacturer would influence the mechanics of the sampling and the interpretation of the sampling in a quality control program.

A consideration of manufacturing tolerances is a necessary part of designing the NIOSH monitoring. In addition, an analysis of the dimensional tolerances may affect whether respirator design should be approved.

Variations in dimensions of a face piece or harness parts will affect the consistency of fit on any person and will affect the range of population that can expect to be fitted.

We see no reason by filters, cartridges and other components of respirators should not be interchangeable between different models or even between different manufacturers.

Such components could be separately tested and approved. At the same time, there should be a small challenge for manufacturers to use standardized fittings, threads, sizes, et cetera, or make adaptor fittings so that interchangeability is physically possible.

We believe that such interchangeability would promote competition and product improvement. In general,

the revision or improvement of 30 CRF part 11 should be evolutionary rather than revolutionary, so that change can begin promptly.

We do not expect radical overnight changes, but gradual improvement and updating of testing criteria as new research findings become available is essential.

We hope that the Department of Health and Human Services will set a high priority for and provide more legal assistance to the revision of 30 CFR part 11.

Revised rules should include consideration of respirator designed criteria. Engineering design is not synonymous with failure mode analysis, and the terms should not be used interchangeably.

The three elements of the evaluation suggested, sound engineering and scientific principles, construction of suitable materials and evidence of good workmanship are unacceptably vague.

Because performance is the only arbiter of acceptability requiring sound engineering and scientific principles in design is unnecessary.

Construction of suitable materials and evidence of good workmanship can be expressed in explicit terms of dimensions, test results and exact qualitative parameters.

A hose clamp serviceable after X number of hours

in an acid environment is an example of a test result.

Respirator design should be based on the physiological limitations of the wearer. The maximum breathing resistance and air flow permitted for each type of respirator as specified in the 30 CFR part 11 may not have a scientific basis.

Under heavy workload, a 30-minute service life air cylinder or an SCBA may only last 20 minutes. In addition, some approved air purifying respirators may be physically unbearable to wear.

The design of a respirator should be wearer oriented and economic considerations should govern the design of the respirator unit.

Design criteria should accommodate the various geometries of the human face, especially concerning face size and features.

The face piece should have a relatively comfortable fit. The respirator should accommodate the wearing of eyeglasses.

The location of filtering elements and breathing tubes should minimize the restriction of vision and permit normal range of motion.

Components which need frequent servicing should be readily accessible. The respirator should be easy to clean and inspect for potential defects. When selecting

materials to make the various components, the environment in which the respirator is used must be considered.

The respirator should withstand temperature and humidity extremes and should resist corrosion, impact, vibration and abrasion.

Several changes should be made to the filter testing criteria. The chemical cartridges should be tested at 80 percent or higher relative humidity because a major portion of the chemical industries are located in the high humidity Gulf Coast areas.

The silicon mist test should be replaced with an oil mist challenge and a chromic acid mist challenge to more effectively reflect the actual use performance requirements of filters.

The lead fume test should be replaced with one that is more predictable and stable in fume concentration and particle size, such as the use of lead acetate from a liquid generator.

Quantitative fit testing studies indicate that negative pressure, atmosphere supplying respirators offer much less protection than their positive pressure counterparts.

It is a waste of limited resources to test such expensive, low performance respirators. Consequently, the negative pressure units should no longer be approved.

The test methods for filter media for particulate materials must be reconsidered. The method used currently to test particulate filters only determines the integrated penetration over the testing period for the very high aerosol concentration.

Considering the trend of setting lower permissible exposure limits for toxic substances, this method becomes less and less appropriate.

During employee use, the filters may not load up and improve the filtration efficiency. Employees would then end up exposed to much higher than predicted levels of the fine particles which have penetrated through the filter media.

A test method determining the initial penetration through the filter and rate of penetration fall-off should be developed.

Concerning the sorbants for gases and vapors, it is well documented that the break-through times vary greatly.

Respirator cartridges should be tested against a specified number of gases or vapors but not just a single one.

In reference to special use air purifying respirators, current testing methods for paint spray, pesticide and mist respirators employ testing agents which

have no relation to the real substance.

For example, if a respirator passes a lead fume and in an organic vapor test, it can be certified as a respirator for pesticides.

Another example, there are no testing criteria for mercury vapor cartridges. More realistic testing methods for such substances should be developed. Under current regulations, a disposable respirator that is subjected to a single test which is a silica dust test is approved for protection against asbestos, a known human carcinogen.

Electrostatic filter media for particulate filtration is known to be severely degraded by high humidity and exposure to oil mists. It also loses its efficiency during storage.

Since mechanical filter media, such as fiberglass are available, electrostatic media should no longer be considered acceptable.

There are other now obvious program changes which must await the results of further research. This research should begin as soon as feasible. The shelf life for filters and sorbants must be considered.

Most respirator filters are made with electrostatic elements which degrade upon storage. Furthermore, the service life of sorbants, such as activated charcoal,

may be shortened if they are exposed to humid environments. Tests should be conducted to determine the shelf line of future and sorbants. Filter elements should be labelled to indicate when they are no longer serviceable. Many respirator manufacturers provide only one size of face piece. One size is not likely to achieve proper fit for individuals with widely differing facial characteristics.

At the present time, we have no way to predict adequacy to fit based on any facial measurements. Research must be conducted to determine distribution of facial dimensions of the American work population.

There's a very serious need to find a facial dimension that is a good proxy for face piece fit. Such a proxy measure would allow the selection of better panels for fit testing and also permit the selection of a meaningful series of panels specifically for various size categories.

I would now like to address items discussed in the notice not already covered.

At the present time, there is no uniformity in the user instructions provided by the manufacturers. A proper instruction manual should contain at least an explanation of the capabilities and limitations of a respirator.

Proper fitting and use should be explained as well as methods of inspections, cleaning, storage, trouble shooting and simple repair of each particular unit.

Finally, spare parts should be listed on a simple diagram provided. Respirators should be field tested, especially in the case of initial approval testing.

Even if the respirator has been well designed and has passed all performance testing criteria, problems can still become evident during field use.

NIOSH should issue a conditional approval for a respirator which has passed all performance criteria pending satisfactory field testing results.

Initially, field testing should be conducted on high protection respirators, such as SCBA, supplied air and powered air purifying respirators.

Later on, all approved respirators should be subject to field testing. OSHA agrees that approval testing should be performed on regular production units. Prototype units may not fairly represent the final regular production units.

If testing is done on preproduction units, then only a provisional approval should be granted. Securing used respirators for testing should not be equated with quality control.

The manufacturer is never responsible for defects of use and abuse which are the result of user actions.

Only in response to a new performance criterion on durability of respirators or their components would this type of testing be legitimate.

However, establishing a single criterion

applicable to all uses of a respirator type would be very difficult.

OSHA has often received variance request concerning the use of limited production, special purpose respirators.

OSHA cannot determine the effectiveness of those respirators. NIOSH often claims that the respirator user must submit detailed quality assurance plans which are not feasible for the small number of respirators involved.

NIOSH should give special consideration to the realistic and practical testing and certifying of limited production respirators.

If an innovative respirator design has been developed and submitted to NIOSH for testing, sometimes NIOSH cannot test and certify the device because there are no criteria available.

Special provisions should be made in the revision of 30 CFR part 11 to accommodate new designs in respirators. OSHA does not believe that group testing of respirators would be an improvement.

Fundamentally, it is inconsistent to claim that a system based on waiting until a time in the future will make a program more responsive.

The relative time of testing different units

of a given class or type should have no influence on the speed of testing and evaluation process itself.

Air purifying and atmosphere supplying respirators are tested by different personnel anyway. The test equipment is designed for a specific type of respirator.

Therefore, there should be little problem in testing any respirator as it arrives without waiting for batch processing.

The publication of test results would serve little purpose under present circumstances, because the test methods are not really meaningful.

For example, air purifying respirators are only tested for filter efficiency. A respirator can provide very efficient particulate filtration, yet be very uncomfortable to wear, and not fit a majority of the wearers.

We do think that full publication of actual test data values for all approved respirators can be very beneficial if the respirators are thoroughly evaluated by complete realistic test regimen.

Many of the 18 questions raised by the consultants have already been answered, but a few remain for comment. Provisions should be made for user comments. At present, there is no mechanism for action based on feedback from the respirator users to NIOSH.

One way to do this would be a user comment card

attached to the instruction manual so the user can notify NIOSH if there is a real or potential defect found in the design and construction of the respirator.

NIOSH should require registration with the manufacturer of any high protection factor respirators or device which is to be used in environment immediately dangerous to life or health.

The user could then be notified by the manufacturer promptly if a potential defect were discovered. The consultants posed a question of further research. OSHA believes that respiratory protection is too important to employee health not to be a very worthwhile topic of more research to improve what is in many respects a fairly basic technology at present.

One factor in respiratory protection is relatively new and of uncertain impact on the use of a respiratory protection program, including the need for testing and certifying respirators.

This new factor is quantitative fit testing. Quantitative fit testing promises to give individually tailored evaluation of the effectiveness of any respirator for any wearer.

This would appear to drastically alter one of the present basic concerns about respirators, that is assuring a minimally protective respirator in a predictive

manner. The class protection factors, the quality control program and unit certification are in large measure an effort to confidently predict that a respirator will protect.

We hope these remarks will be useful to you in evaluating what changes to make to the testing and certification program.

There are many changes that OSHA believes are very necessary. This concludes my prepared remarks. Thank you.

DR. MAY: Thank you very much, Frank. Are there any questions for Frank? That's a lot of material to digest in a short period of time.

I personally feel if I had a couple of hours, I'd probably have one million questions for him, and on the light vein also, I think his talk proves that anything you might have heard about OSHA and NIOSH being very close together these days is not necessarily true.

(Laughter.)

MR. BRENNAN: Excuse me, sir, Bob Brennan, Scott Aviation.

In your presentation, I found many points that I feel are valid, one of them concerning the manufacture of respirators is the ability to notify people when a defect is found.

In your page 17 in your presentation, you've got the suggestion that NIOSH should require registration, I assume you mean of the user with the manufacturer on any high protection factor respirators.

At present, as I understand it, NIOSH not being a regulatory body could not require the user to register the use of the device with the manufacturer, but it strikes me that OSHA being a regulatory body could, in fact, step in and require the user to register his use with the manufacturer and in that way implement what I consider to be a very good thought here.

MR. TIPTON: Thank you.

MR. DUFFY: My name is Rich Duffy. I'm with the International Association of Firefighters.

Regarding the previous remark, there was one major problem in that firefighters, one of the main users of self-contained breathing apparatus were not covered under the statutory requirements of OSHA, thereby your particular scenario wouldn't work for us.

MR. TIPTON: I'm sorry, I don't quite follow the point you're trying to make.

MR. DUFFY: Well, if OSHA required user registration for use of breathing apparatus, self-contained breathing apparatus would fall under those, dangerous to health. Since the firefighters are not covered under

provisions of OSHA, they have been excluded because they're public employees. OSHA would have no authority requiring a firefighter user to be required to register.

MR. TIPTON: Unfortunately, well put.

PARTICIPANT: Excuse me, sir. Ibelieve that we have reached an impasse which I'd like to point out that OSHA apparently can't require registration as was pointed out by the members of the fire community, and it appears that NIOSH cannot require and enforce the requirement for registration either, and I suggest that other people look at this as a good idea.

The question appears to be how does one implement it realistically.

MR. TIPTON: I think I can make one comment about that. The contradiction is not really total. He was only referring to a small subset of the users of respirators, and, in fact, I believe that under the state plan that those employees would be covered.

MR. OPOLD: I'm Jim Opold, Division of Safety Research, NIOSH. I guess I'm breaking a little bit of a precedent here in asking a question of Frank, but I think for the record we'd like to know what are the concerns of the compliance officer and what kind of citations are being delivered in the field when it comes to the findings of personal protective equipment? Are they following

regulations? Do we have adequate regulations, and this type of thing? I think we would like to have that answered.

MR. TIPTON: Well, the one part of your question, I think it would be a little inappropriate of me to say that our inspectors are not following the current regulations. I certainly think that they are.

The types of citations issued are going to depend on the facts and circumstances of each of their inspections, so there's no way to really say anything very definitive about that here.

As far as some feedback from the compliance officers about the current respirator situation, I've recently sent a letter out to the field, and the answers haven't been returned yet.

MR. WALTERS: Woody Walters, Minnesota Firefighters. With the units that are on the market now, several components sometimes are changed. You mentioned the face pieces. One fire department might have a particular type of mask and a particular individual firefighter feels another brand fits his face better so he purchases it himself or a particular brand of mask does not have an off mode for pressure for donning, and so he purchases a regulator to put in the other type.

All of the masks being NIOSH approved, but as

soon as the modifications were made, NIOSH approval no longer exists.

If a firefighter was injured with this modified mask using all components from NIOSH approved masks, would the city or fire department be cited by OSHA by mixing these units up?

MR. TIPTON: That's a lot more complicated question than you may think. The jurisdictional question is in there as well.

I think NIOSH had better reserve the right to correct me if I'm wrong, but, in essence, I addressed some of your concern in my prepared remarks, but I think under the situation the way it is now, each of those devices that you described would not be the one approved by NIOSH and, therefore, would not be an approved device.

MR. WALTERS: Does OSHA cite a citation because that unit was modified?

MR. TIPTON: That depends on a few other things as well.

MR. POWERS: I want to address my comment to the same general area. I want to go on record saying that I took a lot of exception to a lot of your speech, but to generalize what I'm taking exception to is the standardization idea.

Whenever you start standardizing the components

and you start standardizing the quality control systems that you recommended both, then you are opening up a bag of worms that you'd never be able to administer.

As the fireman just said, he's going to put a face mask on this unit and a regulator from that unit and a tank from another unit, and he's going to build himself a unit out of various certified units, and because of that, the industry has almost deliberately not standardized because the liability involved, when the fireman goes in there and dies because he mixed it up and didn't work right is beyond any manufacturer's ability to handle.

I want to say on the quality control aspect, where you say you want to standardize what's to be checked by the manufacturer, then I think that is unrealistic.

I don't see how OSHA who goes in to various manufacturers' plants could ever recommend a standardization that wouldn't fit.

There's no way that any standard system is going to fit every manufacturer's plant, and I know it.

You have to have versability both in your design characteristics and your quality control system, so I would like to take much exception to this standardization idea on either concept.

MR. TIPTON: Thank you for your comments.

MR. BOLTON: Paul Bolton, the Reynolds Electrical

and Engineering Company. As I understood your recommendation there regarding standardization is that it would be permissible, not mandatory, am I correct?

MR. TIPTON: I think what we were saying is that there should be an opportunity available there, and essentially the purposes here would be to highlight areas that we think should be explored.

DR. MAY: Are there any other questions for Frank? I'd like to just pose one, and that relates to your comments about self-contained breathing apparatus, negative pressure, and that they should -- I think your comment was they should essentially not be -- we should not continue to use them because of their limited utility and switch to all positive pressure units.

I guess my question really relates to those from the industry who manufacture such devices and what their comments would be on that comment OSHA made or any further comment you'd care to make on that point.

No one wants to tackle that one? Okay. I thank you very much, Frank, on behalf of OSHA for your comments. I'm certain you'll be hearing more from us on some of them also.

I think since we're only roughly five minutes away from the next presentation, I'm going to go ahead and get into that paper, and if, in fact, we end prior

to 1:15, as I said this morning, please do not utilize the cafeteria, but if there are any in the audience who want to go outside and eat, it might give you a little more time.

The next presentation will be by Randy Watts, fire training coordinator for the Cumberland County Volunteer Firemen's Association, Carlisle, Pennsylvania. Randy?

MR. WATTS: Thank you. Before I start my prepared presentation, I would like to go off the record as a training coordinator and speak for myself as a fire-fighter and make it part of the record that in my opinion the fire service is a vital market portion. It should be a vital concern to OSHA, and we should not be considered insignificant, and that our problem should be addressed in greater detail, that we should be set aside from industrial regulations and considered as a separate part.

I did take offense to the OSHA comment that we are a small part of the market, and I don't think that's a fair way to treat us.

I don't speak for the International Association, I don't speak for any other group in the fire service, but I did personally find that one point offensive.

Now I'm back on the record, and I speak today

as Fire Training Coordinator for Cumberland County, Pennsylvania, and my concern is the people of the fire service in that county.

Prior to assuming this position, I did work in the commercial fire equipment business inspecting and maintaining self-contained breathing apparatus in the field, and I guess that's made me a little bit opinionated and I'll get into that in a minute.

Cumberland County covers 555 square miles in south central Pennsylvania. It's just across the river from Three Mile Island. We used to say it was near Gettysburg or it was near Hershey until Three Mile Island almost melted down. It's become a better landmark.

We provide fire and rescue services to 187,000 people, 37 independent volunteer fire departments. We are not the career service. We're the volunteer service.

We have a total of 376 SCBAs in our county, and they are approximately 50 percent MSA, 50 percent Scott and four percent other brands. They are about 50/50 pressure demand.

We are not the most important area for any manufacturer nor do we set any trends in the use of self-contained breathing apparatus that make us authorities.

We must rely on manufacturers and approval agencies to provide us with breathing apparatus that is

properly designed, properly manufactured and is designed and approved by people who understand the nature of the business we conduct.

We do not operate in controlled industrial conditions with one known toxin where so many parts are allowable that we can monitor for, we're assigned breathing apparatus.

We operate in unknown environments under conditions of stress, emotion and under difficult condition. Our breathing apparatus is a little bit different probably than what you all are used to in an industrial application.

To the best of my knowledge, and this was just brought out in a little greater detail, the fire service, at least in Pennsylvania, is not covered by any approval agency.

OSHA has no jurisdiction, NIOSH, and Pennsylvania Labor and Industry does not cover us, so that whatever breathing apparatus we choose, whatever we do decide to use and however we go about using it and maintaining it, it's just fine.

As a result, it's a haphazard approach. Any recommended practices or standards that are followed by progressive people are done so on a voluntary basis. The rest is left to chance, and this is where the problem

comes in for the fire service. Equally important, as you're considering your new standards, should be a requirement for user selection, some jurisdictional control over what we do, in fact, use in the fire service, but most importantly, two other areas, the training of the people that wear the self-contained breathing apparatus.

I've seen firefighters on the fire ground read the box lid, put the mask on for the first time and rush inside a burning building to, I guess, rescue the beautiful lady.

That's not the way we should be trained. We've been lucky in the county so far that nobody has been killed, but as I say, typically what happens, a man will read the box lid, put it on, go in a building, he'll develop some user competence, some understanding and capability of the unit at that fire.

Three weeks later, he's exposed to it again, the process starts over. Over a period of years, if he lives, he becomes proficient in the use of the breathing apparatus.

It's not a desirable system. I'm not being critical of ourselves, but telling you realistically what does happen, and I think there should be some way that we can overcome that.

We have got to impose standards on the fire

service. We don't seem to be able to do it from within. We must impose some standards for training and use from without.

Another thing that poses a problem to us is the cost of breathing apparatus. For 7, 8, 900, that's a lot of coin cards we have to sell, a lot of bingos or a lot of ham suppers, so we can't afford to continually change our breathing apparatus the way an industry can.

You mark up profit margins and mark ups above cost to generate income to pay for the expense of your personal protection programs.

We go out and bum money from other people and have limited resources to deal with, more so than what you would imagine, so your new technologies that you want to introduce to breathing apparatus are going to be very slow to be implemented in the fire service.

I'm sure we could go places we still have the old chemox mask, and it's frightful. It's not that we're too dumb to know any better. We are, but we oftentimes too can't afford it.

What I'm trying to say is first of all the fire service must be made aware of the need to provide proper breathing apparatus.

I believe wholeheartedly with total adoption of pressure demand breathing apparatus, but how are we

going to pay for that, and how are we going to get to the backwoods fire chief to make him aware of what pressure demand is.

That's a problem we've got to consider. We've got to train the people properly in the use, and in my opinion, it's my understanding that the controversy that stirred up these hearings today was the death of fire-fighters, and it seems to be an indication from what I've heard and read that the maintenance of those units was the cause of the problem.

Someone in my opinion should be able to arrest a fire chief who lets mildew grow inside regulators, stores units with water in the regulator or converts 20-pound carbon dioxide fire extinguishers into use as breathing air cylinders, and it happens.

Again, I'm not trying to cast stones at the fire service. I'm part of it, and I love it, but we're not industry.

We don't have industrial hygienists. We don't have Ph.D.s who can quantify everything that we breathe and everything that we do.

We have some fire chiefs, at least in Pennsylvania, in eastern Pennsylvania, that virtually can't read or write, and these are some of the problems that you're going to have to address, I think, as an approval agency, as a

watchdog. When you approve a manufacturer's unit, that's fine, and it should be good quality and it should be controlled and approved, but when it goes out of that manufacturer's plant, you lose control, and we have to have some mechanism to take care of it, to follow up on it and make sure that it is maintained properly.

We've all got to work together. A couple of specific comments that I would make, and I'm sure that you're aware of them, but there's a big difference between breathing apparatus in an industrial situation where temperature, humidities are somewhat constant versus the fire services.

It may be 68 degrees in the station. We respond for ten minutes into a rural situation. It's 20 degrees above or below zero, and suddenly we throw that unit inside a structure that's 2, 3, 400 degrees temperature.

It doesn't always work. We have examples where the high pressure hose connection on regulators is blowing off. The main body casting of the unit is cracking. I can cite four examples, and they occur almost in exactly the same pattern.

So we have temperature variations, humidity variations, and I think the other firefighters in the room would agree, there's no graceful way to fight a fire.

When you jump down a flight of stairs because an attic has become fully involved, you're not thinking about what's going to happen to my regulator, okay? That's the least of your concerns.

You're crawling through a narrow opening in a wall to try and make a rescue. I'm certainly not concerned about the breathing apparatus at that point. It had better work, I hope, but I'm not going to baby it like I would in maybe an industrial situation.

As was hinted at by the other gentleman involved in fire training, the pressure demand mode, and I don't mean to cast stones or be critical, but there's a new breathing apparatus just came on the market for the fire service that operates continually on a pressure demand mode with no convenient way to shut down the flow.

On the fire ground, we take our face pieces on and off a lot. We go inside a building, make a quick search, come out and tell the chief, you know, the fire is spreading vertically through the wall, and we've got to put the face piece back on.

We have to have some convenient way to control that problem. There's some unnecessary features. On the MSA 401, there's a little chest strap that goes across here, and it's tested and approved like that as a unit.

That does us no good, and it really doesn't help

hold the unit on. We've done some tests. We hold people upside down and shake them and everything. It's not scientific, but we've determined we don't need that.

So if we cut that off, we've voided NIOSH approval, so I get killed in the fire, and I have a sharp widow. She says, well, look, you didn't have the chest strap, it's not an approved unit. I'm going to subject you, Chief, to civil liability.

You know, is that realistic or not? Face straps on one unit, a lot of our fire departments, and maybe I shouldn't reveal this, the OSHA man has no jurisdiction, so I guess I'm safe, but if we remove that waist strap we void the approval.

Now the waist strap is designed to hold the cylinder on your back. If you do fall on a stairway and slide down the stairs, it's designed to hold the unit from going up and hitting you in the back of the head and knocking you out.

But the strap also rapidly becomes virtually impossible to adjust, that it helps retain the unit. The webbing material used in it just don't hold up to the fire, plaster, dust, moisture and the whole thing, so it's a good idea, but it doesn't work. Again, we violate the approval.

Another big problem that we have is interchangeabilit

of cylinders. The old fire department, about 20 years ago, the chief probably bought two masks, and they had the old 40 cubic foot cylinders that operate at 1800 PSI, and he's since gone out and gotten four more units, and they take the 45 cubic foot cylinders at 2216.

Technically, we can't interchange those cylinders, because we violate the approval. We get on a fire ground operation, we need to replenish air cylinders, we'll swap 40 and 45 indiscriminately.

The units still work, but we violate the approval. Again, is that a performance specification? It is. I understand the difference, but we've got to live with that environment.

The same way that interchangeability of different manufacturers' cylinders. It's chiseled in stone somewhere that you shouldn't interchange Scott and MSA.

I would invite you to a major fire, and you can play the role of air supply officer and try to keep 40 or 50 people supplied with breathing apparatus and sufficient quantities of breathing air without interchanging sizes and styles of cylinders. It's virtually impossible for us.

I could continue and complain about many things. Complaining will do no good. I don't think that we need to create any more antagonisms or misunderstanding. I

would like to suggest that somehow we involved the fire service more actively in the entire process, from design to testing and finally, the use and maintenance of breathing apparatus.

Keep in mind as you go through your process here that we in the volunteer fire service often lack a professionalism of the people in Boston, New York, Pittsburgh, LA, et cetera.

We are not able to train ourselves adequately. We lack time resources, we lack money resources, and we lack the facilities.

We lack so much, I guess I shouldn't sound so sad, but there's a difference between a man that works 8 or 10 hours a day for a living and then goes and fights fire as a service as opposed to someone who fights fire for a living and has the benefit of the time to train and the facilities of a fire department training officer.

This is not a critical comment against the career fire service. It's an environmental factor that you must consider in the volunteer service.

We have good intentions, but we often lack the ability to properly care forourselves. We need to be tended to.

There needs to be some agency created to oversee and control the use of breathing apparatus by the fire

service. It needs to be a supportive organization to education and promote as well as enforce.

It should be federally funded, possibly through an agency such as OSHA or FEMA, the Federal Emergency Management Administration, maybe the United States Fires Academy.

I realize it will be costing, that funding is always a problem. It's not politically advantageous to support a project like that. We're not going to find a pet senator real quick for this one today, but we're paying the price now in terms of human life.

Last year we know of at least 40 firefighters who died while wearing breathing apparatus. I don't think that's necessary.

We've just got to start, I think, all over, and maybe I'm totally off track, but I invite you to the field to look at the volunteer and the career fire services and evaluate what you're trying to regulate.

I thinkyou've got to make a distinction between industrial applications and fire service applications, approvals, use, maintenance procedures, everything.

I realize there might be a few questions. I'd welcome those questions at this point. Maybe you already did.

MR. BOLTON: Paul Bolton, Reynolds Electrical and

Engineering Company. I fail to see how the establishment of a regulatory agency would solve your basic problem which appears to me to be one of money, money to buy the equipment that is available on the market, money to provide the training that at least your volunteer firemen don't have enough of right now.

Would you care to expound on that?

MR. WATTS: Yes, it's a two-part answer I'll give you. First of all, we could work around the money problem.

We can't change instantaneously, but when you get into this kind of business where you're talking about registering users and units, it becomes impossible to deal with the fire service from a management level.

The chief officers often are not knowledgeable about breathing apparatus, if I start to talk protection factors or quantitative face fitting and that kind of thing. They won't listen, because they don't understand.

So we have to have an agency with some teeth to say, okay, chief, here's the way it's going to be done. Here's what it's going to take, here's the program, you must follow through with it. If you don't, we'll withhold. Like in Pennsylvania, we have firemen's relief funds that comes in from fire insurance tax, okay, you won't get those forms, you can't buy anything. Then the company is

going to get mad at them and say you'd better comply here so we get our money so we can buy new helmets, boots and breathing apparatus.

But there's got to be some controlling factor rather than allowing -- for example, in my county, we have 37 companies. Anything that I do with the chief is voluntary on his part.

I can suggest programs. We've contacted manufacturers to buy flow testers and implement maintenance programs, but unless the chief elects to do so, we can't enforce the program.

So what we need, and, again, my opinion is some kind of federal agency to say here are the standards, here's what you're going to have to meet, we'll give you a period of grace to do it, but if you don't meet it, there will be some enforcement provision, rather than saying this chief over here will meet it, because he's pretty progressive and intelligent, but this chief elects not to, and his people don't know or don't care, so they don't have any protection.

We need to impose in my opinion a protection on the people. It's the only way I can see we'll get it. Maybe in Minnesota it works a little differently, but we have to be forced to do things, and I think it would solve a lot of problems if we were. Did I answer your question?

Are there any others?

(End Tape 2, Side 1.)

DR. MAY: Next is Jerrold L. Caplin, Occupational Health Standards Branch of the Office of Standards Development. Jerry?

MR. CAPLIN: My name is Jerrold L. Caplin. I'm a health physicist employed by the federal government in the Occupational Health Standards Branch of the Nuclear Regulatory Commission, Office of Standards Development.

The NRC staff welcomes this opportunity to offer its comments on the NIOSH/MSHA respirator testing and certification program.

The NRC has a regulatory responsibility for the protection of workers against airborne radioactive materials that are used in NRC licensed programs activities.

This responsibility is carried out in part through our regulations which require the NRC's licensees to provide occupational respiratory protection that may include the appropriate use of respirators where engineering controls are not practicable.

The NRC, therefore, has an important need to be able to assure that the respirators utilized by its licensees are capable of protecting the people who wear them again the various respiratory hazards that might be encountered in nuclear facilities.

Then NIOSH/MSHA respirator testing and certification program is one of the NRC's chief means of assuring the reliability of the respirators that its licensees use.

Our regulations generally require our licensees to use only NIOSH/MSHA tested and certified respirators in NRC approved programs. Thus, the continuation of the respirator testing and certification program is important to the NRC's interest in carrying out its regulatory responsibilities.

This program provides an authoritative, relatively unbiased governmental source to which we can refer for assuring the availability of acceptable respiratory protective equipment.

If such a program were not in place, appropriate action would have to be taken to establish an equivalent program.

The NIOSH/MSHA testing and certification program has generally been very useful and certainly has resulted in the availability of reliable equipment for use in many situations.

However, the program can and should certainly be made more useful from the NRC's point of view. It does not provide everything that the NRC needs from such a program for regulating the use of respirators, and the

NRC has developed some of the additional information that it requires through the support of research and technical assistance contracts.

Some of the areas that should be strengthened in the NIOSH test and certification program are the provision of quantitative performance requirements, broader coverage of the testing schedules, for example, for equipment such as supplied air suits or for air purifying respirators for use against radio iodines, more complete and specific test procedures for various filters, sorbants and combinations thereof, better specifications for differential pressure between inhalation and exhalation resistance, and for minimum and maximum air flow limits, for atmosphere supplying equipment, and better means for identifying certified devices as they go through various model changes.

As an aside, I'm sure that that's a very partial lista, and almost everyone in the room can come up with their favorite laundry list of many other things that need to be fixed.

However, we believe that it would be wrong for each governmental agency that has responsibilities for some aspects of respiratory protection to have to set up a completely independent program for testing and certifying respirators.

Such a course would obviously be inefficient and

might very well degrade rather than improve the overall quality of occupational respiratory protection that's provided.

Of the alternatives presented in the notice for this meeting, we favor alternative two which would focus the responsibility both for the performance criteria and the testing procedures for certification in a single agency NIOSH and by which action would be taken to revise and strengthen the current requirements, and I might add here that would include carrying out the testing and certifications.

Alternative one which would include both NIOSH and MSHA as the certifying agencies would also be acceptable. However, alternative three in which NIOSH would certify private laboratories to perform testing and certification of respirators would be much less acceptable for this sort of certification.

This alternative might be useful where a less complex set of tests on less diversified equipment were involved.

It does not seem suitable for respirator testing and certification wherein an elaborate scheme wouldhave to be developed and maintained for monitoring the private laboratories and for keeping track of the multiple sources of tests, approvals and changes to approvals. Those jobs

are difficult enough when you're dealing with just one organization.

Another important consideration involving alternative three is that the granting of certification would be under the control of several private laboratories rather than that of the federal government.

This approach would abrogate and diffuse responsibility, provide less confidence to workers and to other agencies in the assurance of the quality of the protection provided, and, thus, might be considered unsatisfactory by some individuals and organizations.

The fourth alternative which would allow the industry to self-certify respirators is the least preferable, and in our view, would entail costs that would outweigh any likely benefits.

For example, any initial savings in time or manpower would very likely be more than offset by the need for increased regulatory activity by the various responsible agencies.

My own personal view of that that I think I've expressed to some people is that it's not such a good idea to assign the fox to guard the chickens.

As to performance for specifications, perhaps too much has been made of the supposed distinction between performance criteria and test procedures. In practical

applications, these terms are closely linked. There is little meaning to a criterion for performance unless there is some reasonable way to test whether or not that criterion has been met.

We believe that—(End tape 2, side 1)--that would provide estimates of how much protection a respirator provides, and should also include more realistic testing procedure.

As to quality control, we believe that the changes in the notice, suggested in the notice on the method for assuring quality control should be reconsidered.

The suggested changes would result in checks on quality control only by after-the-fact methods such as field surveys, although such surveys are useful adjuncts to a quality control program. It seems to use that there should be a more positive method of assuring the quality of these important safety devices before they are marketed.

This is a more difficult course to pursue, and it would require a considerable commitment in staffing and other resources, but we believe that it's preferable to the alternative of allowing the distribution of unreliable safety equipment.

In these brief remarks, we will not attempt to deal with all of the important topics addressed in the meeting notice.

Most of these are the detailed procedural matters of an ongoing program. The main points that we wish to emphasize today are that we believe that the current program is very useful to us, that there should be continue to be such a governmental program, and that it should be strengthened to assure the availability of reliable respiratory protective equipment.

One topic, one other topic, that we feel is important, but was not addressed in the notice is the need for closer coordination of the interest of the various governmental agencies that have responsibilities in occupational respiratory protection.

The need for such coordination has been recognized before, but no formal mechanism has yet been established to meet this need.

NIOSH' planned revision of the testing and certification program presents an opportunity to initiate action to provide such a mechanism.

One way to establish a coordinating group might be by agreement between the agencies at appropriate management levels.

I would believe they would be a pretty high management level within the agencies. This approach has proven to be effective in the test and certification program for personnel radiation dose symmetry processors

for which a group of this type was formed and shared by the National Bureau of Standards.

Whatever the form of the group, we believe that it would have a beneficial effect in enabling the testing and certifying agency and the user agencies to better understand each other's need and to take coordinated action for improving the quality of occupational respiratory protection.

We would like to work with NIOSH and other agencies toward that goal, and for now, we thank NIOSH for this opportunity to present our views.

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

(No response.)

Okay. The next speaker in the program is listed as Thomas Ratliff from R&R Associates, but I was informed a short while ago that he would not be making a presentation this morning. That came to me out of the blue.

I was not informed by Mr. Ratliff that he had apparently not been able to make the program, so what we're going to do is Mr. Kelley, Executive Secretary of ACGIH who is on the program this afternoon at 4:55 has agreed to move his presentation forward. That will allow us to make use of this time and possibly end

the program at a more civil time of the day, so without any further ado, I'll introduce Bill Kelley who is Executive Secretary of the American Conference of Governmental Industrial Hygienists in Cincinnati. Bill?

MR. KELLEY: Thank you, John. I am William D. Kelley, Executive Secretary of the American Conference of Governmental and Industrial Hygienists.

The ACGIH is a professional society of occupational health and safety professionals employed by governmental units and universities in this country and over 30 other countries.

Our sole goal is worker health protection. This goal is achieved through the mechanisms of any professional society.

We are here today to positively contribute to this NIOSH public meeting. I have been employed in positions in nuclear safety, radiological health and occupational health since 1962 and for NIOSH and its predecessor organization from 1967 through 1978.

During my employment at NIOSH, I served as assistant division director for the Division of Laboratories and Criteria Development with specific responsibilities for the coordination of the division's quality assurance fforts including the analytical laboratories at Cincinnati and Salt Lake City, the

chemical reference laboratory and the testing and certification laboratory.

I will not attempt to address the relative merits of one, NIOHSH, or, two, NIOSH Mesa, or, three, NIOSH in private laboratories, or, four, the industry's self-certification programs.

However, since 30 CFR, part 11 is only one of a family of some 18 sets of regulations used in underground coal mines, a commonality of approach and requirements would seem to have merit for effective and efficient health protection.

Would a testing and certification program without MSHA be accepted by MSHA, for instance, in the area of instruments used in gaseous coal mines?

I will attempt to focus on the elements of such a program as outlined in the federal register notice of June 18 and the consultants' report.

Performance specifications have been the goal of the program for years with some considerable sums of money and effort expended in this area, for instance, in fit testing panels.

Performance requirements cannot be static, but neither much they be changed for reasons that will not make significant improvements in worker health protection. Otherwise, resources which could be better used for other

worker health protection activities will be spent on an annual new model respirator replacement program.

Quality control, no evidence was presented in the consultants' report or in the Federal Register notice to substantiate the statement, the detailed in-depth review and approval of applicants quality control plans as presently specified in 30 CFR 11 needs to be eliminated.

Either from other input here or from a NIOSH follow-up investigation it will become clear that the population of personal protective equipment and hazard measuring instrument manufacturers will show a wide diversity of experience and ability to establish a formal quality system.

To assume that manufacturers can readily implement a self-certification program is fraught with danger. I am shocked that NIOSH is now considering a field audit program.

Such an off-the-shelf purchase program was developed for NIOSH a number of years ago by its consultant, Mr. Thomas A. Ratliff, Jr.

The plan was based on work done by the National Highway Traffic Safety Administration. An application involving detector tubes was first worked up.

Three reliability cost sampling plans of the same type were worked up for the 3M whitecap and two

other representative types of respirators.

The basic approach was documented by Francis Armstrong of the NHTSA in the ASQC transaction of 1972 in pages 225 to 236.

Mr. Ratliff made a formal lecture presentation to the TCB staff and officials on the reliability cost sampling plans developed for NIOSH.

I would suggest that the TCB records be studied or Mr. Ratliff be asked to refresh NIOSH's memory.

NIOSH needs to decide what NIOSH role in the personal protective equipment and hazard measuring instruments area would best insure worker health protection.

It may well be that NIOSH should assume the role that equipment purchasers and users would exercise if they could act together.

The generic guidelines for quality systems is a new standard developed under the auspices of the American Society for Quality Control as ANSI/ASQC Z1.15 1979.

These guidelines would be useful in setting up any such system. If it is NIOSH's intention that the level of product quality is to be determined at the manufacturer's site, then it would be evocating the proper use of AQL, acceptable quality level sampling plans with appropriate OC or operating characteristic

curves so that the proper protection for individuals lots is present for the customer or consumer.

ANSI/ASQC Standard A2 1978 for term symbols, definitions for acceptance sampling can be consulted.

Approval tests. I'm sorry, engineering drawings with dimensional tolerances. If a number of suppliers of personal protective equipment and hazard measuring instruments have great difficulty in developing and implementing a quality assurance system, as my knowledge would indicate, is it really feasible to expect these same people to prepare a detailed engineering design, i.e., failure mode analysis for each respirator submitted for approval.

I fear that NIOSH would be trading in one set of declining headaches for a new set that would make their former problems miniscule.

Change to approve devices. The intent of this section to allow non-significant changes in respirators without modification of the certificates of approval seems to counteract the intent of the duration of approval section.

It would be most informative to hear the quantitative definition of insignificant changes, non-significant changes and significant changes.

The statement that significant would be defined

as any change which may place the performance, et cetera, does not help, because may place must then be quantitatively defined with a level of variance of the performance tests involved, included, et cetera.

Product quality requirements. It would be most informative for this meeting to see the documents or hear the rationale behind moving away from the AQL concept.

Has NIOSH through a quality control expert reached these conclusions? The make-up of the panel of consultants charged by NIOSH to review the testing and certification program is distinguished by the competence of the members in their fields of expertise and in being without credential in the field of product quality assurance, per page 44 of their report publication.

The discussion on pages 17 and 18 in the consultants' report is not reassuring. How many plant quality control audits have the consultants performed?

How much input to their report came from people knowledgeable in product quality assurance? I'd like to follow up on the discussion this morning in regards to quality control with a few comments, if I may.

The first, a bromide, if you will, is that you can't inspect quality into a product. Modern acceptance

sampling exerts more effective pressure for quality improvement than is possible with 100 percent inspection.

A practical difficulty in devising an ideal sampling plan is that it is not possible to change the laws of chance.

All lot by lot sampling plans are certain to pass some of the lots containing defective product if such product exists in many of the lots submitted for acceptance.

This fact needs to be faced by all who specify and use acceptance sampling. It follows that the selection of an acceptance sampling plans requires a decision on the risk that the user of the plan is willing to face all things considered.

This is an economic decision that depends on a number of matters.

In lot by lot sampling by attributes, the risk of acceptance of submitted lots containing any stated percentage of defectives are given by the operating characteristic curve of the particular sampling plan.

It is, therefore, appropriate to give careful consideration to the operating characteristics curve in the selection of a sampling plan.

Some definitions, if you will for the record. From ANSI/ASQC Standard A3 1978, in terms of general

quality systems terminology, one, quality, the totality of features and characteristics of a product or service that bear on its ability to satisfy given needs.

Two, quality system, the collective plans, activities and events that are provided to insure that a product, process or service will meet given needs.

Three, quality assurance, all those plans or systematic actions necessary to provide adequate confidence that a product will satisfy given needs.

Four, quality control, the operational techniques and the activities which sustain a quality of a product or a service that will satisfy given needs, also the use of such techniques and activities.

Using this framework of definitions, one might be drawn to the conclusion the NIOSH is responsible for quality assurance, and the manufacturers are responsible for quality control.

Quality system audit, a documented activity performed to verify by examination an evaluation of objective evidence that applicable elements of the quality system are suitable and have been developed, documented and effectively implemented in accordance with specified requirements.

The consultants' report, in particular, indicates that quality audit is nothing more than a handholding

operation. In a related activity, in the MSHA quality assurance program out of about the last 90 companies audited, 62 had grades of less than passing, that is of 70 percent, and the average score of all 90 companies audited, the average score was 55 percent.

A quality audit program is not necessarily a handholding operation.

The concern that has been expressed here, I think, goes beyond quality assurance or quality system into that area of reliability which is defined as the ability of an item to perform a required function under stated conditions for a stated period of time. As has been pointed out by other speakers, this is an added dimension beyond the current scope of the program.

Witnessing of approval tests, we have no comment. Unpublished test requirements. Unless priority is given to the publication of new tested and proven and subjected to public scrutiny test requirements, improved worker health protection will be seriously jeopardized by freezing a state of the art technology and stifling all innovation and research.

Testing of prototype respirators, no comment. Approval tests, approval tests only on production samples on initial testing may be counterproductive. If a manufacturer has to gear up a production line, buy raw

materials and subassembly materials in production-size lots, train production people, inspectors, et cetera, to turn out a few devices for approval, the financial risk will be greater which will stifle newer models with improved worker health protection.

Such approval -- should approval not be granted, the cost will ultimately be borne by the worker in one form or another.

Even if approval is granted, the worker will pay for the plant, equipment and personnel costs of production capacity lying idle awaiting the receipt of an approval.

Essentially it will be in the price of the product.

Perhaps, a contingency approval pending the first production lot being submitted for formal approval could minimize risks and cost to the worker.

Group testing of respirators, no comment.

User and maintenance manuals, some balance between the intent of this section and the intent of the changes to approve devices section must be achieved.

NIOSH systems manual, we agree. Publication of test data, performance results reporting by NIOSH will require consideration of their advertising value by manufacturers of competitive devices.

It would be hoped that insignificant differences in certain performance tests will not leave purchasers to less than optimum buying decisions.

Of course, NIOSH will be able to replicate and validate any reported performance differences because they may be forced to do so.

The consultants' report, it is unfortunate that the obvious dedication and many hours of work of the consultants was negated to a great extent by the lack of a professional quality assurance competence in the group.

The inconsistencies are exemplified by the statement on page 28. An industry of this size is no longer an infant, and does not require assistance for quality assurance.

Yet on page 21, the report states, "They must also teach manufacturers how to perform performance criteria tests if the manufacturers desire such instruction."

I would recommend that in subsequent deliberations NIOSH should provide some quality control and input into the process to better reflect the appropriate role of quality assurance.

Summary, ACGIH wishes to work with NIOSH, to strengthen and refine the testing and certification

program. It will require a priority of resources, both staff and money which heretofore have not been evident on a long-term basis.

We stand ready to assist in any way we can. Thank you.

DR. MAY: Thank you very much, Bill. Are there any questions or comments for Bill? Jim, as much time as you like.

MR. POWERS: I'm Jim Powers. I'd like to refer to the field testing comment you made about that Tom Ratliff submitted to NIOSH.

It's true, he did. It came from the quality technology -- from ASQC. When it was submitted to NIOSH and taken at the minimum sampling level that would be statistically significant, it went beyond the entire budget of the whole TCB, not only just the testing program, the whole TCB, so how could they follow that program when there is a significant budget?

The main question that I would like to direct to Him, we said earlier that there would be a response from this meeting. Is the response going to be enough budget to operate the TCB program?

I doubt that we would be here today had that TCB program been properly budgeted initially, and I wonder if that's going to be any different.

MR. KELLEY: I'll defer to that. Maybe both Jim and I will try to respond to that. It is my opinion that the answer is yes, there will be a commitment, and that the commitment would have been in the open now if we weren't faced with cutbacks in government spending, hiring, et cetera, due to this economic situation we're in.

Dr. Robbins has made a commitment to get the resources for this program. It is in the planning stage, a very large increase in staff for Morgantown, West Virginia is in the planning stage.

If they can convince OMB and everybody else that released those purse strings, yes, we will get those resources.

Now, if that doesn't work out, there are those of us working both in the program and operating in the area of the edges of the program that will try to get internal reorganization to get personnel assigned to Morgantown to enable us to carry on this new program.

Our commitment is there, but it translates down to sometimes we don't have the final say in whether we're going to get those resources, but my position, at least, is to make the people that do allocate those resources internally, make them aware of what the consequences are if they don't make the resources available.

They're faced with either this or that. As long as they're aware of that, then we've done our job, but our commitment is to get all the resources we need to go on with the type of program we think is necessary in Morgantown.

MR. POWERS: Well, referring to Bill's earlier comment about the lack of response from the previous session, I think that the lack of response at that time was probably not for the lack of intention to respond.

You don't hold a three-day meeting and have this many people sit all day and listen to rhetoric because they are not industry.

The industry and the users and the government alike has put in an awful lot of money and personnel sitting here right now, and yet every time, they have one of these meetings, everybody leaves the room with great intentions and no budget to do it.

I hear what you're saying. You have great intentions, but I also know you don't determine the money. You know, the Department of Health, Education and Welfare, are they going to put out the money?

DR. MAY: If I could answer the question, I wouldn't be here today, Jim. I'd be in the White House or somewhere else.

I think everyone has to appreciate the fact I will

not be held accountable for what happened in 1977 at that three-day meeting.

No one in this program necessarily likes what might have followed up as a result of that meeting. Times changes. This is 1980. This is not 1977. There were three firemen dead in Texas after 1977.

There are a lot of things that have happened that indicate this is not then. The environment has changed. The time has come to do something with the program.

There was an atmosphere in 1977 where it was very easy probably for a lot of different reasons just to let that meeting go by.

Actually that's not what really happened anyway. A lot of work was put in to coming up with some new ideas, but it was very easy to dispense in a way with that whole effort.

There were no fires consuming the program. There was no great publicity outside. This is different. This is not going to go that way.

Now I'm not going to stand here and tell you that they're going to release 75 new positions and $50 million for Morgantown, West Virginia. We're going to try to get those resources. Again, if we don't get those resources, then those people that make those decisions know what they're dealing with, but the message I've made to Dr.

Robbins all along and from what I've heard in Morgantown is we don't want to continue to operate the program the way it's been operating, so somehow, somewhere there is going to be a change in the program.

Either we'll move it along the way we want or there will be some totally different program, but there is a commitment on Dr. Robbins' part to change that program and to make it totally user oriented so that, as many people said this morning, they can rely on the NIOSH MSHA or NIOSH certification level, and that the equipment has been subjected to meaningful tests.

If we can't do that, then in my opinion, we ought to get out of the business.

Dr. Corn?

DR. CORN: I'd like to make two clarifications, the first with respect to Mr. Kelley's detection of what he thinks is an inconsistency which is not a minor point.

Our group views the role of the government as one of cooperation with the private sector in this field. It is not our intent to exacerbate what apparently are some difficult relationships.

If anything, we'd like to see the relationships between government and manufacturer improve. We think that improvement will come when roles are defined. It is our believe that current manufacturers have the

financial capability to hire the talent and build the resources that will permit them to do testing in accordance with government specifications.

However, these are detailed and difficult tests which I can attest to having working with some of these.

With the best of intentions, there are going to be opportunities for working out these protocols together. We are saying if such requests come to the T&C branch, the proper role of government is to assist and not to turn away.

The proper role of government is not, as we observed, to have a staff member assigned to a manufacturer as one was assigned to develop a quality control program for the manufacturer.

That we don't believe is proper, but that person could have been available for consultation with a quality control counterpart on the manufacturer's facilities.

It's that type of distinction we were trying to draw in our report.

DR. MAY: Any other questions or comments?

CAPT. SHIRTZ: I'm Captain John Shirtz. I'm the staff bioenvironmental engineer for the United States Air Force Space Division located in Los Angeles,

and to define a few terms a bioenvironmental engineer is basically an industrial hygiene engineer. The Space Division is responsible for the majority of our space program, so we end up working with chemicals such as most of the hydrozine family, Erfna, inhibited red nitric fuming acid, and nitrogen textroxide.

There was one point you brought up, sir, about publication of results, and I really would like to stress that I really think that NIOSH should public results of all certification testing.

Did I get the impression that you were saying that the publication of those results were unnecessary?

MR. KELLEY: No, not at all. My statement is that it would be hoped that insignificant differences in certain performance tests will not lead purchasers to less than optimum buying decisions and that, of course, NIOSH will be able to replicate and validate any reported performance differences because they may be forced to do so.

We are not at all against reporting of results. The reporting of those results should accomplish something other than just providing perhaps advertising value which is not going to contribute to good purchasing and use decisions.

CAPT. SHIRTZ: I do agree with that. As you know,

being in the Air Force, most of our equipment is tested by the United States Air Force.

We will pick up NIOSH certified equipment if it's necessary to stay in compliance with an NRC license; however, in most cases, we do all of our own certification.

We did run into a problem with a few air capsules which were NIOSH certified to do a certain job; however, we found that those air capsules would not work within our environment, and we had a great deal of difficulty obtaining the test results as to how these air capsules were tested, against what chemical materials and in what operational environment.

I really think if we had been able to get that, we might have avoided somewhat of a financial loss.

DR. MAY: Any other questions for Bill?

(No response.)

MR. KELLEY: Thank you, John.

DR. MAY: Thank you very much. I think Bill's presentation and the homework he did indicates NIOSH lost a valuable man when he left us to go with ACGIH.

We're running slightly ahead of our program. Is Chief McGary presently here? No. Okay. It's time to try to adapt then, and I haven't discussed this with Bill earlier, Bill Revoir, but I was wondering if he would have any objection to making his presentation now? He left?

Okay. Is there anyone in the audience who would like to take this opportunity to make a statement, someone who has not presented anything in writing or made such a request? We certainly want to get as much comment as we can.

You can come up front if you like. That would be fine. Why don't you do that?

MR. RYMERS: My name is Steve Rymers. I am President of Rymers Consultants which is an engineering service house that among other things we make breathing machines and do third-party test work.

Several years ago, I was the engineering officer for the Navy's Experimental Diving Unit, and, as such, I did personally most of the approval testing that the Navy did for underwater breathing equipment, and I have also written most of the procedures that are still in use.

I have several comments. I'm ad libbing this off of some very, very short notes, so if I stumble a little bit, please forgive me.

The first area that I'd like to talk about is that of performance testing, and I would suggest that the NIOSH people that are responsible for this take advantage of the testing procedures that have been worked out specifically by the Navy and also by the Air Force.

The Navy puts underwater breathing apparatus through a test regimen that makes what's in the current issue of 30 CFR 11 look like child's play.

The procedures have been tried over several thousands of hours, and they've gotten them to where they give quite good and quite reproducible results.

Specifically, the Navy has its procedures now to where their machine test predicted durations on CO_2 count stand up very well to what you get in actual use which is, if you've tried to do that, somewhat of a neat trick.

So I would suggest that the NIOSH people contact both the people at the Experimental Diving Unit and the appropriate groups within the Air Force and NASA that have done their own inhouse testing.

As far as the areas of unpublished test requirements and testing to prototype, respirators on the part of NIOSH, these are touchy areas, and, as a general rule, unpublished and unofficial test reports have a way when done by a government laboratory, have a way of putting a government laboratory in competition with private business, and if the availability of unpublished testing or prototype testing on the part of a government laboratory becomes widely known in the industry, it makes it very difficult for someone in industry to convince a

manufacturer that he ought to pay for something that if he gives it to the government and waits a little while he'll get done for free.

That may not be a problem in this industry. It is in the diving business.

The last area that I would like to address is the publication of test data, and, again, I will indulge and go back to some of my Navy experience. Navy test reports on equipments submitted for Navy approval, and I might add that as far as diving equipment is concerned, approval for Navy use is also the key for approval by use of almost all of the country's police and fire departments.

There was a time when Navy test reports were classified FUOO.For Official Use Only, but we got so tired of seeing our data appear in advertising, FUOO or not, that we finally came to the conclusion that there was only one way to do it, and that was if a piece of apparatus was submitted for official testing, the results were published, good, bad or indifferent.

I think that the passage of time there's one other factor that's involved, and that's the Freedom of Information Act. As a general rule, if somebody wants a piece of information on hand by the government, and they want it bad enough, they can get it, so as far

as NIOSH and the industry is concerned, I think it would be to everyone's benefit for NIOSH to do two things: one, all the testing that NIOSH does should be official; and, two, if something is done for official testing, the results should be published, because they have an unfortunate way of becoming public by bits and pieces if they're not public to start with.

There's a lot less heartburn for all concerned if the rules of the game are known ahead of time. That's the end of the remarks I have at this point. If someone has some questions, I'll be glad to answer them.

DR. MAY: Any questions, comments? Okay. There will be another possibly short presentation that is not listed on the program.

The Mine Safety Health Administration submitted a very brief letter to the institute this morning representing part of their position, and it was, as I say, not to be presented, but Murray Jacobson stated that he would be happy to read it into the record at this time, so that if anyone has a question regarding MSHA's position or present policies that we operate under or any question along those lines, you can do so.

Murray Jacobson.

MR. JACOBSON: I'm Murray Jacobson, Assistant Director for Health, Technical Support, MSHA. We have

the responsibility at the present time for the joint approval under 30 CFR part 11 and also 30 CFR part 74 and the authorities for our own approvals for all other devices that are approved for us in underground mines.

Presently we have approximately 100 people working at our approval and certification center at Dallas Pike, West Virginina, or try Adelphia, West Virginia.

This is for a single industry, underground coal mining and those non coal mines in which there is gas present.

I'm going to read into the record a letter which we prepared from MSHA to NIOSH routed to our position of MSHA responsibilities.

In accordance with the June 18, 1980 notice in the Federal Register, I am transmitting MSHA's comment concerning the NIOSH role in the testing and certifying of personal protective equipment.

In the notice you list four possible alternatives for restructuring the testing and certification program. At this early stage in the review process, MSHA cannot totally support any of the alternatives outlined.

MSHA believes in an alternative which allows the continuation of the joint MSHA/NIOSH approval program for equipment use primarily in mines and during mine emergency operations would assure greater effectiveness

and better serve the safety and health of the miners.

Specifically, we would want to continue the joint approval program for self-contained breathing apparatus of the type used in mines and by miners and a filter and self-contained self-rescuer devices.

Although MSHA favors a program retaining joint approval for the above-specified equipment, we agree that even under such a program, the administrative and test procedures and criteria would need revision.

We look forward to working with you in this effort. In addition, over the next several months, we will be looking at MSHA's role and the joint approval process in assessing the resources needed to maintain a viable joint approval program for mine emergency equipment.

At this time, for all equipment currently covered under 30 CFR part 11, other than those specified above, MSHA would not oppose a laboratory accreditation program to test the equipment; however, if this alternative were explored further, it would have to be built-in mechanisms which would assure that, one, the laboratories would be certified by NIOSH; two, NIOSH would monitor the test; and, three, only NIOSH could issue the final approval.

We share your concern for developing a program which provides for more efficient testing of respirator protective equipment. Towards that end, as mentioned

earlier, we are evaluating our resources and hope that you do so also in an effort to assure that they are adequate to support whatever program is proposed.

I appreciate having had the opportunity to comment on this program at this early stage in the NIOSH review.

I along with other representatives of this agency will be available to discuss your proposal further.

In addition, I will be forwarding our comments to you on the specific topics listed in the Federal Register very shortly. Please do not hesitate to call.

Thank you. Any questions?

DR. MAY: Thank you, Murray. No comment and no questions for Murray?

(End tape 2, side 2.)

DR. MAY: No comment and no questions for Dr. Jacobson? We have another comment from the floor prior to proceeding with the printed program.

MR. FERGUSON: My name is Jim Ferguson with Climax Milibdinum (phonetic), a Division of AMAX, and I just had a couple of comments to say.

One is that of the alternatives described in the Federal Register, number three looks most desirable to us, and I'm not very well versed in the Underwriting

Laboratories approach towards testing their equipment, but it seems like such approach might be of value in the testing of respiratory protective equipment.

We think also there ought to be special procedures which will incorporate the erganamic considerations which are appropriate to the mining industry.

We feel also that there ought to be some type of an endurance specification. We have had some problems in the past with the respirator face pieces not holding up to the mold that they came out of, and the lack of a good fit caused our respirator program a tremendous amount of credibility with the nearly 5000 workers that we have working underground.

Thank you.

DR. MAY: Thank you very much. Any questions? Okay. If not, we're pretty much on track, and according to your printed program, the next speaker, the last speaker before the lunch break was Chief Roger A. McGary, First Vice-President of the International Society of Fire Service Instructors, Takoma Park Volunteer Fire Department. Chief McGary?

CHIEF McGARY: Good afternoon. As he indicated, my name is Roger McGary, First Vice-President of the International Society of Fire Service Instructors representing that organization at this meeting.

I'm employed by the Takoma Park Volunteer Fire Department and have spent 24 years in the fire service, 15 of those parallelling industrial fire protection positions, the last nine as fire chief and fire protection engineer for Murk and Company Incorporated in Rahway, New Jersey.

Although representing the society at this session, my comments reflect my personal observations, and I'm sure some of those of my fellow society members.

We in the Instructors Society have a vested interest in the welfare of those using respiratory equipment, in particular the firefighter.

In the last few years, we have ridded the number of firefighters who have died in the line of duty, in particular with great alarm, those who have succumbed while wearing breathing apparatus.

Relationships between field maintenance and that certification process, as completed by NIOSH, should have ties that will help eliminate injuries and fatalities inthe field.

Unfortunately, there appears to be little preventive concerns from NIOSH until, and we emphasize until, an incident occurs.

We further recognize that you might be quick to state that maintenance and training have failed, or

we might have eliminated these injury fatality producing scenarios.

We as the predominant fire service organization with an interest in the training, including maintenance, wholeheartedly agree with you. There is a lack of training and maintenance in the field, and that's one of our objectives, that is to improve those areas by way of our seminar series on breathing apparatus and the likes and through workshops presented at conferences that this organization runs.

My own expertise is not in the certification criteria. Therefore, it's difficult to second guess the statements placed in the Federal Register announcement.

We urge NIOSH to consider those factors that will help eliminate the potentials for injury and fatality of the users of respiratory protective devices.

We as instructors wholeheartedly support the concept of performance specifications. We advocate behavioral objectives in training, and in my opinion, the performance specification will provide a similar concept for the breathing apparatus field.

We support the auditing of equipment in use, but we caution that the audit must also consider the maintenance program used by the user.

The respiratory equipment, we have found will

in most cases perform as spedified, but the key factor will be the field maintenance, and in many cases, poorly done if done at all.

I think the experience of fire service instructors in the field will support that comment that we find that the respiratory protective equipment used in the field lacks maintainance, extremely poor maintenance programs overall.

In your comments related to testing of prototype respirators, I have some concerns in that area, and that being for the manufacturer who develops a new process, one not presently used by a manufacturer, where does he fit in.

He may well have a product that could revolutionize the breathing apparatus field, but with a lack of ability to introduce it to you for certification or testing, as a prototype, it may never reach the potential user.

Further, we might ask what provisions are being made to enable a manufacturer to develop a new concept. Is there a testing field for him.

As I noted a few minutes ago, I do not consider myself the expert in the testing and certification field, but as an end user, I look at the ability to use the equipment, maintain it and have optimum performance for the firefighter.

Hopefully, whatever revisions are made to your testing and certification procedures will also provide the optimum in manufacturer's performance that will be reflected in the end users activities, and, therefore, we of the society support those kind of performance criterias that will better improve that breathing apparatus to be used in the field. Thank you.

DR. MAY: Thank you, Chief McGary. Are there any questions, comments?

Are there any other individuals who would care to make a statement that have not requested so to date? Okay. I have one very brief comment, and we're simply going to break early for lunch.

That is that we are considering taking all the papers that have been presented at the meeting and reproducing them and sending them to everyone who registered, everyone who came.

We would do that and mail them to you, and reproducing them would mean we would do it quite rapidly. It would not be months before you would get the actual proceedings of the meeting then.

The copies have been given to us. Ten were mentioned in the Register. They were for internal distribution despite how it might have read or been interpreted, but this way we can get all of you a copy

of every paper that was presented and will give you a chance to look at some of the comments more thoroughly during a period of time. Hopefully we could get them out before the 30 days expired. You might have a chance then to provide some other comments.

With that, we will adjourn for the morning, but I would re-emphasize please do not go into the cafeteria at this time.

Go outside, enjoy the outdoors for the roughly 30 minutes until you can use that facility or you're free to go into Gaithersburg to a restaurant of your chioce.

We'll reconvene at 2:15, I believe it say.

(Whereupon, the meeting adjourned for lunch.)

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

DR. MAY: Okay. Welcome back to the afternoon session. Before I introduce the first speaker, there's one item to bring to your attention. There's a possibility that somebody in the group lost a small green plastic coin purse.

The young lady outside the room has it for you. Good.

Okay. Our first speaker this afternoon is Frank E. Wilcher, Jr., Executive Director of the Industrial Safety Equipment Association. Frank?

MR. WILCHER: It's a pleasure for the Industrial Safety Equipment Association to participate in this public meeting which NIOSH has convened to discuss the role of this agency in testing and certifying personal protective equipment and hazard measuring instruments.

I'm Framk Wilcher, Executive Director of the Association.

While I'm here today representing our respiratory protection group which is made up of most of the United States manufacturers of respiratory protection equipment, I should also point out that ISEA is an association of 80 manufacturers representing a broad spectrum of industrial safety equipment.

Our organization comprising 12 different product

groups has been interested in the role NIOSH plans to take with regard to testing and certification of all personal protective equipment.

I would also like to point out at the outset that the Industrial Safety Equipment Association for the past five years has been urging NIOSH to adopt more modern performance standards and implement a certification program for all personal protective equipment.

In addition to urging NIOSH in this direction, our association has also gone on record in writing with the Occupational Safety and Health Administration that we would be in favor of having OSHA make it mandatory that in their regulations that personal protective equipment be certified by NIOSH.

For one reason or another, NIOSH has not been able to move forward in this direction, and, therefore, we are going to suggest today a different approach to testing and certification of personal protective equipment.

Certainly no issue is more critical than the protection of America's working men and women. We believe an important part of accomplishing this objective is through an effective testing and certification program based on realistic performance standards.

However, because NIOSH through lack of funding or for whatever reason has not been able to effectively

expand its testing and certification program at Morgantown, we would like to recommend today that NIOSH adopt a variation of the fourth alternative listed in the Federal Register notice of June 18, 1980.

The Industrial Safety Equipment Association feels that the users of respiratory protection equipment and other personal protective equipment in the long run are going to be better off if NIOSH concentrates its efforts in establishing recommended performance standards and allows the industry to establish a certification program.

Specifically, we recommend that a third-party certification program using independent private laboratories be implemented for the testing and certifying of respiratory protective equipment.

We recommend that the performance standards used by these laboratories be specified by NIOSH and that NIOSH continue its field audit testing programs which we will comment on later as we address the specific issues which have been raised by the agency.

Both NIOSH and ISEA have a common goal in our mutual desire to provide the best possible on-the-job protection to American workers be they engaged in industrial pursuits, mining or public service.

The provisions of 30 CFR part 11 were issued with

this goal in mind as far as respiratory protection devices go, but unfortunately have not worked effectively from the point of view of either NIOSH or the manufacturers.

The reasons are varied. At the outset, it must be recognized that the testing and certification procedures were developed for underground mining applications and consequently do not adequately cover other common applications of these types of devices.

As frequently is the case, government regulations, the provisions are too rigid to be applied widely in a cost efficient manner.

In addition, we feel that NIOSH's testing and certification branch has been hampered with constant turnover of staff as well as lacking personnel and sufficient expertise in the field to handle the program effectively, fairly and in a timely manner.

Delays in obtaining approvals on new devices and extensions of approval on modified devices is excessive to the extreme.

The resources of NIOSH could be more effectively utilized if the agency concentrates its activities on the development of performance standards based on adequate and suitable research.

The actual certification of involved products would be conducted by the industry itself based on a

suitable test criteria which they would develop.

Under a third-party certification program, NIOSH would develop performance standards that are realistic and as technologically advanced as the state of the art will permit.

To assure users that industry certification of this type of equipment is valid, NIOSH would on a regular basis, purchase new off-the-shelf random samples of approved equipment of each manufacturer and test this equipment either in their own laboratory or subcontract testing to a qualified laboratory.

During the transition from the current certification system to the one proposed today by ISEA, a device approved under the existing performance standards established by NIOSH would continue to be approved until such time as the applicable performance standard was revised.

Subsequent thereto, the involved products would have to be approve under the revised updated standard with suitable grandfathering being permitted for orderly manufacturing transition from one design to another and for the continued use of approved equipment in the field for a reasonable time to relieve the economic impact to employers.

Testing off-the-shelf equipment by NIOSH indicates

a serious deficiency involving reasonable potential for harm to the wearer, then suitable enforcement action or approved revocation action would be taken in line with the seriousness of the problem indicated following the pursuit of a fair appeals procedure.

Such a program would relieve NIOSH of the responsibility of the testing and certification and at the same time enable the agency to assure the users of such equipment that it was fit for use in terms of the current applicable performance standards.

We believe a program of this nature would be beneficial to the American workers using personal protective equipment and hazard measuring instruments, would be beneficial to NIOSH in their role of assuring the American workers' safety in the work place and to the manufacturer in providing reliable, fit for use equipment.

In light of this proposal, which ISEA is making today, we would like to respond to the 18 questions from the consultants report entitled, "Evaluation of the NIOSH Certification Program, Division of Safety Research, Testing and Certification Branch, NIOSH Publication Number 80-113."

Number one, NIOSH should develop performance standards for HMI and PPE and in doing so should cooperate with ANSI and other groups of stature writing voluntary

standards. ISEA recommends that NIOSH's priority for the development of such criteria be as follows: head protection, hearing protection, protective eye wear, instruments, fall protection, machine guards, emergency eye wash and shower equipment and safety clothing.

Number two, as you know, it is the preference of ISEA that NIOSH restrict its activities to the development of performance standards for product approval and leave the development of test criteria to the industry certification program.

However, should NIOSH decide to continue in the testing and certification of PPE, we favor their publishing detailed test criteria.

Some tests currently in existence should be retained while others need to be modified. If desired, we would be pleased to elaborate further on this issue.

Number three, as explained in our response to question number two, we feel NIOSH should publish only performance criteria and leave the development of appropriate detailed performance tests to the industry certification program.

Number four, recognizing the contribution of the voluntary standards development groups to technological process and the goals of the regulatory system, the Office

of Management and Budget has endorsed active participation by the federal government agencies in voluntary concensus standards activities.

This policy is clearly set forth in OMB Circular A119. Beyond any question, NIOSH should participate on concensus standard making committees.

Preferably as a voting member, but at least as a participating guest. These committees are composed of members representing government agencies, technological societies, research institutes, universities, labor organizations and trade associations which offer a much broader expertise in occupational health and safety than what is available to NIOSH acting alone.

Clearly NIOSH cannot establish meaningful performance standards which cannot be achieved by the present state of the art.

The health and safety of the American worker will benefit through NIOSH's participation in the voluntary standards development activities.

Number five, except for rare occasions, NIOSH should not offer manufacturers on a fee for service basis the testing of devices on a continuing basis or just prior to approval application.

In no case should NIOSH approve or certify a device when being tested on an informal basis. Number six,

ISEA favors NIOSH placing the responsibility for performance testing according to NIOSH developed performance standards upon the manufacturer.

Neither NIOSH nor OSHA need monitor manufacturer adherence to performance tests protocol. Proof of performance should be determined by the field audit testing program.

Number seven, ISEA favors a NIOSH developed system of random sampling for the evaluation of certification reliability.

We consider this to be the essence of the field audit testing program, and it should be based on identical tests as are involved in the certification procedure.

Inasmuch as the experience of many manufacturers indicates, the tests conducted by NIOSH personnel at the testing and certification branch in Morgantown have frequently been improperly conducted or improperly interpreted, we are opposed to the publication of any test results from the field audit testing program until after they have been confirmed by consultation with the manufacturer and the implementation of effective administrative controls.

It is the position of ISEA that NIOSH test results like bar examination test results should be announced only on a pass/fail basis.

That statutory mandate of NIOSH does not extend to the publishing of comparative test results. If a product meets the standard, it meets it, and if it fails, it fails.

Our suggested procedures for handling publication of test data appear as Exhibit 2 in our presentation.

Number eight, inasmuch as OSHA is in the process of establishing a laboratory accreditation program, ISEA believes it would be preferable for NIOSH to contract for services as described in questions six and seven with OSHA accredited laboratories rather than undertake such accreditation themselves.

Number nine, recertification of approved products should be required only when a new or more stringent performance standard is established.

There is no regulatory need for any time limit on a certification of an approved product that continues to meet the current performance standards.

When a new standard is established, suitable grandfathering must be provided to permit an orderly conversion both by users and the manufacturers.

Number ten, as indicated in response to question A, ISEA sees no need for NIOSH to certify private laboratories for the testing of PPE inasmuch as OSHA

is already well along in the development of a suitable laboratory accreditation program.

Number 11, the manufacturers need assistance in developing suitable facilities for conducting tests to achieve certification under NIOSH's promulgated performance standards. NIOSH should continue to offer such assistance. NIOSH should not continue tests for manufacturers in lieu of the manufacturers establishing such facilities in their plants.

Further, NIOSH should not evaluate the test set-up in manufacturers' facilities. Number 12, there should be no field incident reporting system because the use of unverified field incident reports as a basis for alerting the public is irresponsible.

See the Supreme Court opinion in Consumer Products Safety Commission versus GTE Sylvania, Number 79-521, halting disclosure of unverified accident reports which would both injure manufacturers and mislead consumers.

Number 13, as we indicated earlier in our response to question number seven, NIOSH could undertake to publicize the results of tests randomly sampled from the marketplace provided the following conditions apply.

A, that there has been fire consultation with the manufacturer and appropriate administrative procedures,

including an appeal have been followed.

B, tests are conducted on similar products of all manufacturers at the same time, and, C, that only pass/fail results are published without any specific test data or an attempt at ranking of products, NCR Exhibit Number 2 on this.

Number 14, under the system of third-party certification favored by ISEA, NIOSH would not be certifying products, and, therefore, would not need to be burdened with any change information.

Even under a system where NIOSH certifies, it should require manufacturers to submit changes to approved products only where such changes materially affect the fitness for use of such products.

Records relative to changes or alterations not affecting fitness for use should be retained by the manufacturer for a reasonable time.

Number 15, NIOSH should request stop sale for recall where a fair determination has established that the discovered defect or product design is either critical or major A as those terms are presently defined in 30 CFR part 11.41D, and the manufacturer refuses to implement its own stop sale and recall program, or recall program.

We have suggested a procedure for handling defects

and departures from approved designs and/or quality control plans that includes provision for a hearing where the manufacturer questions the need for a recall and provides an opportunity for an expedited appeal.

Recision of stop sale and recall should occur when the recall has been completed and the manufacturer has obtained an extension of approval or has returned to the approved design or quality control plan.

Number 16, the public notification mechanism to be implemented upon discovery of defective devices in the field should be similar to that utilized by the Food and Drug Administration as in 21 CFR part 7.50. adapted to suit the different nature of the products covered.

As part of our comments still to follow on the NIOSH Federal Register proposal published June 18, 1980, we are proposing a specific voluntary recall procedure based on the Food and Drug Administration 21 CFR part 7, subpart C, which includes an appropriate public notification mechanism.

This proposal is attached as Appendix A to Exhibit 1 of this presentation. Number 17, ISEA believes that NIOSH should restrict its research efforts to the development of realistic practical performance standards and leave the research related to product development to

meet those standards to the manufacturers of such equipment.

Number 18, ISEA believes that NIOSH should restrict its research role within its own laboratories or through contracts placed with outside laboratories to the development of performance standards.

The manufacturers of personal protective equipment have always developed products promptly to meet new performance standards or to meet new market applications as they occur.

There is no need whatsoever for NIOSH to become involved in product development in order to have suitable devices available to the American worker.

Now, that completes our response to the questions raised in the consultants' report. We appreciate the fact that the ISEA proposal for a third-party certification program is a substantial departure from current NIOSH thinking and that its assessment by the respective government agencies involved will take a considerable amount of time.

We recognize therefore in the interim NIOSH is most likely to adopt its own alternative to these recommendations or some variation thereof, and accordingly what follows is the ISEA position on the 14 issues on which comment was requested in the June 18, 1980 Federal

Register. First of all, on performance specifications, ISEA concurs that the tests to be performed in the certification process need to be replaced with test specifications that are realistic and as technologically advanced as the state of the art permit.

Obviously research by NIOSH to this end is indicated.

Quality control, ISEA favors the elimination of the procedure for NIOSH approval and surveillance of quality control plans as presently specified in 30 CFR part 11.

Requirements that the manufacturer of such equipment certifies that effective quality control plan is in place supplemented by continuous NIOSH field audits should be adequate.

However, NIOSH's field audit program should provide for only the testing of unused equipment, and under no circumstances should used equipment be tested.

No tests under this program should be conducted on used equipment, because there's no way to ascertain whether improper maintenance or abuse has damaged such equipment.

Stop sale, recall and approval revocation resulting from the field audit program should follow an agreed-upon procedure as set forth in Exhibit 1 of this presentation.

This procedure provides the necessary due process in the determination of the need for such enforcement action and provides effective mechanisms for the protection of interests of the user, NIOSH and the manufacturer.

The recall procedure in Exhibit 1, as we mentioned earlier, is modeled after the Food and Drug Administration program as set forth in 21 CFR 7.40C.

I would just like to take a minute and read for the record what this Exhibit 1 is, because it's a very important part of this presentation.

Exhibit 1 on our presentation is entitled, "Procedure for Handling Defects or Departures from the Approved Designs and/or Quality Control Plans." A, the severity of the defect or departure from the approved design and/or quality control plan will be assessed by NIOSH and classified by its potential effect on the user as either critical, major A, major B or minor as defined today in 30 CFR part 11.41D.

B, in the case of minor defects or departures, no action will be taken by NIOSH provided the manufacturer updates the documentation on file with NIOSH to reflect the revision or corrects the defect within 90 days.

C, in the case of major B defects or departures, no action will be taken by NIOSH provided the manufacturer

either, one, applies for and receives an extension of approval for the change to the affected product, or, two, returns to the approved design production and quality control methods.

D, in the case of critical or major A defects or departures, a stop sale, and, when appropriate, a recall pursuant to Appendix A which, once again, is the Food and Drug Administration procedure, pursuant to Appendix A of all affected products may be recommended by the Division of Safety Research staff.

In the event that the manufacturer questions the need for a stop sale or a recall or questions the level of recall, the Director of the Division of Safety Research will convene a hearing on these issues.

The DSR staff and the manufacturer shall make written and/or oral presentations in support of their respective positions, the burden being on the DSR staff to prove its position by a preponderance of the evidence.

On the basis of these presentations, the director of DSR will decide whether a stop sale, a recall or a particular level of recall will be requested. In the event that the manufacturer is not satisfied with the decision of the director, the manufacturer may request reconsideration by the director of the institute who shall confirm, modify or reverse the director of the

Division of Safety Research's decision. Stop sale and recall requests will not be rescinded until such time as the recall procedure has been completed, and the manufacturer has either, one, received an extension of approval for the change made to the affected products, or, two, return to the approved design production and quality control methods.

F, a proceeding to withdraw certification of the affected products may be initiated if, one, the manufacturer fails to comply with the stop sale request, or, two, the manufacturer fails to use reasonable efforts to implement and complete the agreed-upon recall procedure.

Engineering drawings with dimensional tolerances. Engineering drawings with dimensional tolerance should not be a condition of application for NIOSH approval.

Rather NIOSH should rely on the requirement for sound engineering design based on accepted scientific principles, construction of suitable materials and evidence of good workmanship.

Before ISEA can accept the potential requirement for a failure mode analyses, NIOSH will have to provide more details on this proposal.

Changes to approve devices. The present program that any and all changes made to respiratory protective devices must be submitted to and approved by NIOSH prior

to being incorporated is impractical.

Therefore, ISEA concurs completely that the current proposal by NIOSH for handling changes to approved devices.

Witnessing of approval tests. Inasmuch as the experience of many manufacturers indicates tests conducted by NIOSH personnel at the testing and certification branch at Morgantown have frequently been improperly conducted and improperly interpreted, we believe it is essential that manufacturers have the right to witness tests on their equipment only.

NIOSH agrees with this position as reflected in their appeals procedure policy which was made effective on July 1, 1980.

ISEA recommends that this new policy be more broadly applicable and equitable as reflected in our Exhibit 2 of this presentation.

Our Exhibit 2 which I'd like to just cover briefly is titled administrative procedures, and the purpose of this is -- of the procedure is to provide due process to companies subject to 30 CFR part 11 who wish to question NIOSH decisions on the testing of respirators for compliance with 30 CFR 11.

The scope covers this procedure applies to all tests performed pursuant to 30 CFR 11 for certification

approvals, extension of approval and field audits. The procedure would work as follows.

Number one, upon written request, the applicant seeking certification approval or an extension of approval will be informed of the test date or dates pertaining to the applicant's equipment.

NIOSH will provide the applicant with a minimum of five working days advanced notice of the scheduled test dates.

Two, the applicant will be permitted to witness the tests, but will not be allowed to interfere with or otherwise interrupt the tests.

Three, in the event the equipment fails any test, A, NIOSH will notify the applicant orally if he's present at the test, or if not present at the test, and in the case of an audited company, orally by telephone, and, B, provided that the applicant or the audited company has test data which demonstrates that the equipment tested has passed this test previously, NIOSH at the request of applicant or the audited company will retest this equipment pursuant to these procedures.

Four, in the even the equipment fails to pass any test applicant or the audited company may appeal the test results based on one or more of the following three reasons: A, NIOSH conducted the wrong test; B, NIOSH

performed the right test incorrectly; or, C, NIOSH misinterpreted the test results.

Number five, a written intent to appeal must be submitted to the director, Division of Safety Research, within five working days of receipt of the test results pursuant to paragraph 3A above.

Documents supporting the appeal must be submitted to the director of the Division of Safety Research within ten days after the receipt of the test results.

Number 6, when an appeal is received, the director of DSR will designate a senior experienced engineer or scientist employed by the National Bureau of Standards to serve as an appeal arbiter.

An informal hearing will be held within seven working days of receipt of the appeal documents. The appeal arbiter will provide the director, DSR, with a written decision within five working days of the hearing.

The hearing arbiter will either uphold the test results, reverse the test results or order retesting, and, eight, except as provided below, NIOSH shall not publish or release any specific test data or notice of failure concerning any equipment undergoing tests for approval, extension of approval or field audit testing.

For equipment undergoing field audit testing,

NIOSH may publish or release a notice of failure only after the appeals procedure is exhausted or the auditing company does not appeal.

Such notice shall state only that the product failed to meet the applicable performance standard. In no event shall NIOSH publish or release specific test data on equipment, whether passing or failing or any purported ranking of products based on such tests.

Duration of approval. As indicated earlier, an approval should continue in effect until new performance standards are implemented at which time new certification to the new and higher standards should be required with applicable grandfathering permitted to allow an orderly conversion by both manufacturers and users.

The contention by NIOSH that continuous approval, quote, creates a confusing and potentially dangerous situation, end of quote, is without any factual basis.

There is no regulatory need for any time limit on a certification of an approved product that continues to meet the current performance standards.

Product quality requirements. ISEA believes that because product quality levels expressed in terms of AQLs which are well established, conversion to a percentage defective would be time consuming as well as-- (End tape)--requirements should be permitted.

Rather NIOSH should only rely on test requirements that have been tested, proven and subjected to public scrutiny.

Testing of prototype respirators and approval tests. ISEA feels that NIOSH should not be expected to test prototype devices in a design stage as a research and design service for manufacturers.

NIOSH should accept for testing and approval items the design of which has been finalized but some components of which may have been run from temporary tooling subject to later confirmation with products run on production tooling.

Obviously, it is not practical for a manufacturer to buy expensive tooling prior to ascertaining from NIOSH that the device as designed will meet their approval test requirements.

Group testing of respirators. ISEA protests the group testing of respirators in that it will delay the release to the market of new and improved products which are ready for tests and approval well in advance of the next designated acceptance period.

Further, group testing will preclude witnesses of tests which is noted above, ISEA considers to be essential.

User and maintenance manuals. ISEA agrees with

the requirement that user and maintenance manuals be submitted with applications for approval. Only major manual revisions and updates should require submission to NIOSH.

It is desirable that NIOSH develop and issue guidelines relative to the content of such manuals.

NIOSH systems manual, ISEA agrees fully that NIOSH's suggestion that it develop a system manual relative to the procedure for testing and certification of PPE and HMI and that the manual would be made available to interested parties on request.

This systems manual should contain complete descriptions of acceptable procedures for, one, receiving notice of approval tests; two, witnessing tests; three, witnessing retests of failures on audit testing; four, appealing test failures on an expedited basis; and, five, prohibiting publication or release of test data other than on a pass/fail basis.

As previously indicated, these administrative procedures are set forth in our Exhibit 2.

Similarly fair procedures for handling defects and departures from approved products and requesting stop sales and recalls need to be included along the lines set forth in our Exhibit 1.

We believe that the FDA procedures for recalls

should be adopted in principle by NIOSH and provision should be made to supply information when requested by manufacturers relative to the status of their applications for approval or extensions of approval.

Also to be included in this manual is the stipulation that test procedures and values cannot be changed without prior notification to manufacturers.

Once NIOSH has established procedures, rules and policies via their systems manual, all NIOSH personnel should consistently abide by them.

Publication of test data. ISEA opposes the publication of any test data from approval tests except as an indication that a particular respirator may have passed such test.

ISEA strongly believes that the publication of failure test data from approval tests for the purposes of injuring a manufacturer's reputation as a means of reaching some internal NIOSH administrative objective is irresponsible and not worthy of further comment.

An effective mechanism for assuring better pre-approval submission tests would be to increase approval test fees.

Experience has shown that many tests conducted by NIOSH personnel have frequently been improperly conducted and improperly interpreted; therefore, no

publicity should be issued with regard to field audit tests performed except after prior consultation with the manufacturer and the exhaustion of an appropriate appeals procedure.

ISEA reiterates that it is strongly opposed to the publication of any information relative to field audit testings other than pass/fail information and that no specific test data or information relative to ranking be published by NIOSH.

We appreciate the opportunity to participate in this public meeting. We would like to summarize by reiterating that we feel it would be in the best interest of the American worker, the Department of Health and Human Services and ISEA for NIOSH to abandon its present role as the testing and certification agency for personal protective equipment and restrict its activities solely to the development of the effective realistic performance standards leaving the actual testing and certification responsibility to industry through a third-party certification program.

Thank you very much. I might mention that I have extra copies of this presentation up here in the front if somebody would like to have one.

DR. MAY: Thank you very much, Frank. I'm sure there must be many questions in the audience after

Frank's presentation. A gentleman here has a question. You're letting him off very easy. I'm sure we'll have some questions for him at a later date. Dr. Opold?

DR. OPOLD: I think we agree with many things that Frank has said and obviously disagree with some. As some of the previous speakers have -- feel the same way.

I think obviously we haven't had a chance to review all the comments, but I think a couple of questions are somewhat in order so that the record can show a little more of an explanation of some of your comments, Frank.

My first question would be you mention on page 7 in the text anyway that OSHA is already well along in the development of suitable laboratory accreditation program, and I'd like to have you explain that a little bit if you're prepared to do so.

MR. WILCHER: OSHA has had a laboratory accreditation program in effect since 1974. They went through the rulemaking at that time.

It was never fully implemented because of some objections that OSHA received from some industry trade associations.

It's my understand that OSHA now is going to republish a revision to part 1907 which is laboratory accreditation, and we'll be doing that in September of

this year.

DR. OPOLD: Okay. The next question I have is a comment that you made several times throughout your presentation, and it had to do with tests, and I'm not quoting, it's on page 11 and 14, something to the effect that tests were improperly conducted by the testing and certification branch in Morgantown and also, I think, fitting with that improperly interpreted.

I have been a director of Division of Safety Research for NIOSH approximately two and a half years now, and I have to say in all candor that it's never been brought to my attention at any time when we had staff performing tests improperly or misinterpreting the results.

I think that there have been times when our tests have not been as comprehensive as some of the manufacturers would like to have had, at least, and I would say that we would like to have carried out, but we did, as far as I know, carry out the mandate that we had in 30 CFR part 11 properly and adequately.

I'd like to have you explain that a little bit more, Frank.

MR. WILCHER: I didn't come prepared, Jim, with specific examples of where this has occurred; however, I can give you one example. In 1976, NIOSH purchased a

number of helmets in the field, and ran tests on them and issued a report that indicated a high percentage of helmets failed the applicable ANSI standard, and we subsequently learned and NIOSH people have indicated to us that one of the tests used as a basis for the report had to do with flammability and was the wrong test and improperly conducted.

That's one example I can give you right now.

DR. OPOLD: Okay. You're reaching back to 1976 which certainly we have to accept. I think that those tests on the head protective devices, we have had our differences of opinion of what was a good scientific test at that time, and I don't think we need to try and resolve our differences on that question at this point. I just raised the question for the record.

The other point that I have is the time of certification, and I think that this is an area which has been proposed. The period of certification has not been in any way decided upon.

It's just an idea that we have come up with in NIOSH, but I have this question that seems to need some discussion.

That is, how do we update, if you wouldduse that, the certified units in the field, and I think that we have a problem with new performance standards coming

into being and yet having units in the field, whether they're respirators or any type of personal protective equipment, that really have been outlined, and we have a problem of how to deal with that situation.

Do we decertify those units in the field? We thought in our deliberations that perhaps there should be a period of time for certification and then we're not saying or not indicating that there couldn't be a recertification, if there hasn't been new performance standards or there hasn't been better ways of protecting a worker in the work place.

I'd like to have you comment on that, Frank.

MR. WILCHER: We feel very strongly that as long as the performance standards are not changed that the product involved, the certified product should continue to be certified, and there's no need for periodic certification if the performance standards are still the same existing performance standards.

The other part of that question, as I understood your question, what do you do with equipment when you do change a standard, and you have the problem of equipment out there.

That becomes the difficult one. There's some economic issues right there, and you can work real hardships on the users if there isn't some reasonable

grandfathering of existing equipment. You have to come up with some happy compromise, I would think, where you do change the standards for products and hopefull arrive at a grandfathering time frame that will not work a severe hardship on the users and be reasonable from the manufacturers' standpoint also.

DR. OPOLD: That's all the questions I have.

DR. MAY: I have just one quick one, Frank, and it relates to your recommendation that NIOSH would develop a performance criteria, and that industry would essentially see that equipment had to meet those criteria before it would be so labeled, the labels meeting government specifications.

Do you envision that that program would be done by laboratories working as subcontractors for the industry, by industry's own laboratories, by a scheme involving all of that, or how do you envision that system operating, and how would you envision the government's seeing, in fact, that the tests were conducted, say in the case of independent laboratories conducted by groups that had the proper equipment and the personnel, and indeed, were doing work of sufficient quality to indicate that the product would meet the requirements? How would you police that type of situation?

MR. WILCHER: Well, first of all, on the testing, we would envision using laboratories, as we indicated, laboratories that are accredited by OSHA, and these would be independent outside laboratories.

We further in our thinking on this program, we also envision using a quality assurance consultants, either who are associated with the independent laboratories or are outside consultants to monitor the quality assurance program of the manufacturers that are participating, and as far as the final outcome, as far as monitoring the products, if NIOSH would continue to establish performance criteria and the proof of the pudding would be the performance of the products that NIOSH would field audit test.

I can't see where NIOSH wouldn't necessarily have to know or be involved in the test set-ups of the individual laboratories.

DR. MAY: Are there any other questions for Frank? I'll have to chase you to the mike, if you don't mind. You can come up here if it's closer.

CAPT. SHIRTZ: Captain Shirtz again from the Space Division.

The only question I wanted to ask you, as you were going over this procedure for handling defects or departures from design, now, assuming that there was

a true sample from certain manufacturers or from certain distributing outlets, and you get one or two devices and you test them, I assume this is the procedure that you now use, is that correct.

Now, if these devices are found to be defective, you have here a clause where you can then approach the director of the DSR and discuss or argue the situation or present a rebuttal to that test result, and if you are not satisfied with his decision, you can then go to the director of the institute, is that correct?

MR. WILCHER: Uh-huh.

CAPT. SHIRTZ: During this time period, and I would assume if it's anything like other appeal procedures I've seen, this could take months.

What happens to the user? How do I get the information from NIOSH to realize that I may have defective units in my operations?

MR. WILCHER: The procedure here is you're talking about something that's critical or major A?

CAPT. SHIRTZ: I would assume so, yes. Well, you have stressed the non-publication of data, not announcing that something is defective until you know absolutely sure that it is defective.

MR. WILCHER: Right.

CAPT. SHIRTZ: Would it not be wise to at least

notify the users of the equipment that that piece of equipment is in question so that they themselves could either test it or remove them from service until such time that a determination has been made that that unit is or is not defective.

MR. WILCHER: I think this procedure, if you study it carefully, and also you have to bear in mind the definitions which are not included here, the definitions of what's a major defect, major A, major B, critical and minor, are going to relate to that, but the procedures, basically what we're recommending here is the procedures used by the Food and Drug Administration, and they've worked effectively there in protecting the health and safety of the consumer.

CAPT. SHIRTZ: Well, those were the procedures that I was also referring to. I guess to make it very blunt, I didn't want to find myself in a position where a unit could be using a suspect protective equipment while lawyers for the defense and the prosecution are off battling it away somewhere as to whether or not the tests were properly or improperly conducted.

MR. WILCHER: Well, this procedure is a matter of a few days. It's not a matter of months. The appeals procedure that's tied in with this too is a matter of ten days total time.

CAPT. SHIRTZ: Okay. Well, then that answers my question.

MR. WALTERS: Woody Walters, Minnesota Firefighters. An outside independent laboratory has done considerable testing on breathing apparatus in firefighting in California which I'm sure you're aware of.

If we went from the results of that test, I'm sure you would rather that we went by the NIOSH report on the same apparatus.

I think it isn't so important as who does the testing, but what tests are they running, and are they running the tests that indicate that that piece of equipment is usable in the occupation that it's sold to, and that is not being done.

I don't care who does it. The test is wrong. When the tests are done in our atmosphere, the unit fails.

DR. MAY: Any other comments for Mr. Wilcher? Thank you, Frank.

MR. WILCHER: Thank you, Frank.

DR. MAY: We're running a little ahead of the program, but I don't think any of us will regret that.

The next speaker is John B. Moran who is with Geomet Technologies Incorporated. He is speaking today as a member of the NIOSH Mine Health Research Advisory

Committee. John?

MR. MORAN: I appreciate the opportunity to appear before you today to offer my views on the important issue of testing and certification of respiratory protective equipment.

I offer these views both as a member of the Mine Health Research Advisory Committee, a committee established pursuant to the Federal Mine Safety and Health Act of 1977.

It also contains the statutory authority upon which the NIOSH/MSHA respirator certification program is based, and as an individual with specific personal experience in many of the primary segments which relate to the subject of this meeting.

My comments will cover four primary areas: the adequacy of existing certification regulations embodied within 30 CFR 11; the real world of respiratory protective equipment application and use; general comments specific to the issues outlined in the meeting notice published in the Federal Register on June 18 of this year; and, finally, some recommendations which NIOSH may wish to consider which are beyond those covered in the Federal Register notice.

First, the 30 CFR 11 adequacy. 30 CFR 11 as it exists today can best politely be characterized as a

many times repaired, patched and modified antique which is totally inadequate to meet today's needs.

The direct result is and has been problems and frustrations for all involved, including the certifiers, the manufacturers, the purchaser, the users and the occupational health regulators.

The often-held view that the certification process is primarily one which seeks to serve the respirator manufacturing community is one which is understandable when one recognizes that the certification program is one which grew into a regulatory program out of a voluntary process which began early in this century.

Most of theproblems with 30 CFR 11 are a result of a slow transition from the voluntary certification process to a mandatory process rather than there being a clear, sharp transition triggered by major revisions to the old certification and essentially concensus procedures.

A joint NIOSH/OSHA/MSHA public hearing in November of '77 sought to address this issue, and to seek input and recommendations with regard to revisions to 30 CFR 11.

Thousands of pages of testimony were received. To review all those comments presented at that meeting today would require far too much time. It is sufficient to say that substantial information regarding the

inadequacies of 30 CFR 11 has been available to NIOSH as a result of that and other meetings, and such has resulted in no discernible change or improvement in 30 CFR 11 to date.

A few major examples regarding 30 CFR 11 deficiencies are, however, important to know. First, test criteria employed have no published technical basis.

For example, asbestos certifications are routinely issued to manufacturers on the basis of tests, not one of which involves exposure of the respirator to fibers, and respirators are certified for protection against pesticides, yet are never tested with any such product.

Many special tests are employed with the certification process which have not had public review and for which the need and resulting potential for design trade-offs are unknown to the user and the occupational health regulatory community.

Third, current quality assurance plan approvals are keyed not to a desired overall product quality goal, but rather to the size and sophistication of the individual manufacturer resulting in a wide range of manufacturer quality achievement.

Fourth, the extension of approval process for product changes is so ill defined and broadly interpreted that some manufacturers make important changes in products

without testing and approval while others have dozens of such extensions applicable to a single product.

Fifth, manufacturers must only comply with minimum performance criteria. Results of certification testing are not published, and, indeed, are not marketed. Many trade-offs, often complex in nature, are required in the design of any respirator, as there is no benefit attributable to superior performance, manufacturers seek nothing but achievement of minimums.

The real world. This meeting, previous public meeting and more formal hearings regarding respirator certifications have continued to focus upon the criteria and procedures for certification of respirators.

With the sole exception of the nation's fire-fighters, I have heard nothing which addresses that which in fact is the real issue, the adequacy of respiratory protective equipment and the protection of the worker who requires it.

As a consultant, having reviewed the respirator programs of hundreds of private companies, I can state that I have not, with the exception of the nation's very largest corporations, ever observed the proper and adequate use of respirators in an occupational setting.

Why, one must ask, is that so? There are a

number of reasons, none of which seem ever to be addressed in meetings such as this one.

Respirator reality is, in my view, as follows. Most employers in this country do not know what 20 CFR 1910 is, let alone requirements within 1910.134.

Respirator salesmen traditionally deal with purchasing agents, not industrial hygienists or occupational physicians.

Purchasing agents are interested only in place. Respirator salesmen are rewarded by sales volume, not correct respirator sales.

Purchasing agents, safety directors, industrial hygienists and occupational physicians have no basis other than certification for respirator selection, and superior performance is not marketed.

At least 90 percent of the nations employers in my view are incapable of selecting the proper respirator for the hazard.

Such employers do not have exposure data and most often do not know the exact material to which their employees are exposed.

They trust the respirator selection process to the local salesman who makes such selections in the absence of the needed data.

Employees are poorly trained in regard to

respirator use, maintenance, et cetera. Improper use, improper maintenance, improper cartridge change frequencies are the rule, not the exception.

All respirators marketed to the industrial sector are not, as is often believed, certified by NIOSH and MSHA.

Price, the salesmen, 30 CFR 11 inadequacies are the reasons for this. OSHA regulations, keyed as they are to the use of protective equipment as a last resort, are often inadequate.

For example, the recent OSHA lead standard fails to address the issue of proper respiratory equipment selection when leaded paints are used in a spray finishing operation.

I am suggesting, Mr. Chairman, that the proper use of existing respirators is an important an issue as the issue of a better certification program, and further that both NIOSH, OSHA and MSHA have responsibilities in both matters which they should seek to address.

Federal Register issues with regard to the four offered viable alternatives, before addressing the four alternatives presented, it is important to know that any of the alternates chosen would require substantial time, easily in excess of a year, to

implement due to the requirements of the Administrative Procedures Act.

It is vital that a viable certification program exists in the interim, an issue that does not appear to have been addressed by NIOSH and Federal Register notices.

Specific to option one, option one appears to be the most easily implemented, as NIOSH has substantial information in hand and clear statutory authority exists under the Mining Act.

Option two offers substantial impediments in that the statutory authority does not, so far as I am aware, exist within HHS.

Further MSHA has respirator certification needs also. How would these be met? This option appears to suggest that NIOSH would more fully focus on OSHA needs.

Clearly an important one which also offers the opportunity to meet the firefighters needs pursuant to the plan revisions of the fire brigade standards by OSHA.

Option three does not in my view offer a viable option if private laboratories are permitted to in any way act or appear to function as certifiers.

Certifications must, in my opinion, be issued by NIOSH or NIOSH/MSHA, NIOSH/MSHA/OSHA.

Option four would appear to be viable only if NIOSH established and properly funded an extensive audit program which was required to issue reports of findings and had specific authority to issue recall notices, impose fines, et cetera, for non-compliance.

Germane to all options, of course, are the performance standards against which respirators would be tested. If little improvement over the existing criteria results, little real change in respirators will occur regardless of the option pursued.

The primarily objective, therefore, should be the performance standards, not the method necessarily by which such would be enforced.

Specific to the issues in the FR notice, quality control, I fully concur with the NIOSHposition on this matter, but suggest the administrative procedures be developed relative to the testing of in-use respirators which assures that the manufacturer becomes involved in a defect or flaw analysis process prior to stop sale recall or revocation procedures.

Engineering drawings and dimensional tolerances, I concur with the NIOSH position. Changes to improve devices, while I concur with the intent of the NIOSH position on this issue, past experience suggests that a clear, precise and fully understandable definition of

changes which affect form, fit or function would be an absolute necessity.

Witnessing of approval tests, I disagree with the NIOSH position on this issue. For any NIOSH certification program to be effective, it must be able to stand the scrutiny of peers and not be conducted behind closed doors.

Additionally, NIOSH could relative to this issue assist the manufacturers in assuring that their test equipment is equivalent to that in the NIOSH reference laboratory in both specification and performance through the development of more detailed witnessing procedures.

Duration of approval. Much of the problem noted in the NIOSH position on this issue relates to extension of approvals.

Should NIOSH issue a new approval number for any change involving form , fit or function, the duration of approval issue would essentially become a non-issue.

Product quality requirements. While I concur with the NIOSH approach, the APD specified should be carefully considered to reflect the potential for health impact to the user.

Unpublished test requirements, I fully concur with the NIOSH position.

Testing of prototype respirators. I generally

concur with the NIOSH position with the exception that I believe NIOSH should discuss the results with the applicant.

I agree that direct assistance should not be provided, but NIOSH serves two purposes, the users needs and the development of new products in providing technically based discussions with such applicants.

A closed NIOSH certification environment will serve to impede respirator development, and in the long run result in the development of certification, technical personnel and staff which are out of touch with both the manufacturer's world and the user's world.

Approval tests. While I concur with the basis behind the NIOSH position, I am not aware of major discrepancies between prototype respirators and production respirators which could not be captured in the audit process.

Perhaps NIOSH should consider modifying their position on this issue to require that the manufacturer submit his certification test data to NIOSH on the production product.

This would serve to require the manufacturer to conduct such testing and would provide him incentive to correct any problem with a production product which developed prior to sale.

Group testing. My views expressed above in test witnessing precludes perhaps this option. Manuals, I concur with the NIOSH position on this issue. NIOSH systems manual, while I fully concur with and agree that such is needed, issuance of changes to all recipients appears to require attention.

Unless that issue is addressed, this important document will be outdated literally within months.

Publication of test data. This is perhaps in my view the single most important matter in the interest of enhancing effective respirator use, selection, purchase and innovation.

I fully support the NIOSH position and encourage NIOSH to develop a dissemination mechanism that assures that as many employers as possible receive this information.

Further, NIOSH should encourage respirator manufacturers to employ such data in their respective sales aids brochures and advertising.

Additional recommendations. I recommend that NIOSH consider the following additional matters with regard to respirator certification.

First, quantitative fit tested. Manufacturers should be required to submit quantitative fit test data based upon NIOSH specified criteria with each

application. This data would insure that each respirator certified meets or exceeds the minimum protection factor standards.

Such data should also, in my view, be published by NIOSH and should be an additional evaluation factor in the audit process.

Charcoal leakage, air purifying sorbant containing respirator cartridge, and, indeed, resin impregnated felts do have a particulate leakage or migration.

NIOSH should establish maximum leak rates keyed to the cartridge type and the materials contained therein. Obvious categories include organic vapor, amines, acid gases and particulate filter felts.

Compliance with this criteria should be a requisite to certification. Human use certification. Respirators are used by humans, and as a requisite to proper function come into close contact with the skin and respiratory system.

Requisite to certification should be a statement by the manufacturer that, at a minimum, primary skin irritancy tests have been performed and passed for all components which contact the skin.

Further, material safety data sheets should be required as part of the applicant's submission for all respirator materials which could be inhaled, such as

electrostatic felt resins. Electrostatic felts. Over long periods of time under high humidity conditions, such felts lose their charge, and as a result their ability to filter particulate efficiently.

NIOSH performance criteria should consider the requirement to meet special minimum penetration performance criteria for such electrostatic felts when tested under discharged conditions.

Information center. NIOSH might give consideration to establishing a national respirator protective equipment information center whereby selection information could be provided over the phone or in response to a written request to employers and employees.

At least, two major respirator manufacturers, at least offer at least a portion of such a service at the present time.

Such an information center could be publicized by the required inclusion of an address and phone number on a respirator approval label, thus assuring wide dissemination.

This condludes my formal comments. I'd be pleased to respond to any questions which you might have.

DR. MAY: Thank you, John. Before taking a question, I have one comment I'd like to make and a question.

The comment is that we are very concerned with the issue you raised about are respirators really doing the job they're intended for when they're used in industry; despite the best program that we might develop someday, are they really providing protection. Is the industry's program for selecting and requiring their use very effective.

That's one of the things that Dr. Robbins for one is very concerned about today, and I think the institute is probably going to get somewhat involved in, and that is a survey for want of a better term to look at industry and where there are supposedly good programs in force to actually see if, in fact, they are effective programs.

Are the workers being protected by the devices they're using? If some of the better industries that have good programs do not, in fact, have upon examination very effective programs, I think that's a real possibility based on some information we have, then it doesn't say much for all of the other very small industries that have very little expertise in the area of selection and use and what their workers may be exposed to.

My question -- actually another comment and a question relates to your statement about an interim program before a year or two or whatever it would take to legislative, say, a new piece, or go into new legislation

if we pursued the avenue we're recommending. We did not fail to address that. We did not list it in the Federal Register for obvious reasons.

I, for one, am not certain what that interim program should look like, what we should do from say today until a new program comes up.

I have some ideas. All of the people in the program do.

My question would be since you raised that in your talk, I wonder if you might like to introduce in the record what you would recommend that the institute do in the interim until a new improved program can be developed.

MR. MORAN: I think the problem in trying to articulate an answer to that question hinges on the choice of option.

In my view, at this point in time with regard to respirators, I think the pursuit of an option which resulted in development of statutory authority under HHS guidelines or HHS overview would be probably the best approach.

That would require in my view substantial time. However, I would offer the opportunity to truly develop new and focussed performance standards and would avoid the related syndrome we've been going through for the

last many years of continuing repatch and reamend 30 CFR 11.

I think in the interim one would be forced to maintain the current existing certification program. How one would do that particularly in the issue that Frank raised, as one got to implementing a new regulatory requirement and how does one deal with what is out there now, becomes a very important and difficult issue, and of course, it's one we've been dealing with with a number of classifications of self-contained breathing apparatus, once 30 CFR 11 was picked up by NIOSH.

We still have that problem, and even when I was in NIOSH we were having trouble dealing with that issue, so it is a complex one.

I've not spent a lot of time thinking about how one might pursue that with all four options that you've talked about, but I think it is a critical piece.

MR. FERGUSON: I'm Ferguson, and right now I'm just representing myself, not the company. I'm trying to get an idea of where you're coming from as far as your remarks, do they provide technology only?

MR. MORAN: Geomet is primarily an environmental consulting firm. My comments do not come from any relationship with that corporation which I just recently joined, but primarily are keyed to my previous experience

back in 1976 and '77 directing certification programs and in a consulting role as a user of respirators and until quite recently as an executive with one of the larger respirator manufacturers.

MR. FERGUSON: As part of my previous experience before going to my present company, I was in a field where respirators were used by a lot of small industries, and I'd like to support your comment that respirators are being improperly selected and probably not properly maintained or even utilized.

Therefore, I think it's very appropriate that you brought up the subject of a proper selection, and I think that it may have been assumed that OSHA and MSHA are going about the task of assuring that this is being done.

I think by the time they get to it, it may have been too late. The practices may have been carried out for too long a period of time.

I'd like to suggest to the committee that some kind of a product program be made a part of the certification process.

Any company making protective equipment offer some assurance that the equipment will be followed up for its proper intended use. I know some companies with other products, not personal protection, but other products,

to make sure the customer gets the best value from the product. What do you think about this?

MR. MORAN: Well, in general, I agree with you. I think we ought to pay, in essence, as much attention to certifying and developing criteria for respirators as we do to the poor guy who's got to wear one everyday, because my experience is, as yours would indicate, indicates that that is in general today a very unacceptable process.

DR. OPOLD: Jim Opold, NIOSH. I have one question for you, Mr. Moran, and you may want to answer it and you may not.

You stated that you felt like NIOSH, in one of the options in discussion, should issue reports of findings and our previous speaker, Mr. Wilcher, said that yes, we should, but only the pass/fail and that's all.

Would you care to comment on that for the record?

MR. MORAN: My concern focusses on the fact that the primary people who purchase respiratory protective products have no criteria whatsoever against which to conduct a price performance evaluation.

Until such time as NIOSH or everybody that tests and certifies respirators publishes performance data,

that process will continue to be as it is in the past.

For those people in this room who have been involved in the actual research development and production of respirators, you know as well as I do that you're involved with a number of very complex trade-offs to achieve the various performance criteria contained within the standards.

There is simply no incentive whatsoever to develop a product that is superior because of those trade-off criteria.

It's my feeling that if this information were made public that the respirator manufacturers would, in fact, be forced into marketing it, the result being that purchasers of such products would have additional criteria against which to judge the quality of that which they were purchasing.

MR. LOMAS: Yes, I'm Don Lomas. I would like to know what type of performance requirements that you feel should be published.

For instance, in a filter efficiency test, do you have any information on penetration requirements on a high efficiency filter, a minimum of 99.97 percent efficient that would you relate any experiences that you have or any facts you have that a 99.98 percent efficient filter is any better than 99.97 percent

efficient filter in actual usage?

MR. MORAN: Of course, the answer to your question requires more than a simple discussion of the difference of a hundredth of a percent in performance with regard to penetration of a defined aerosol or particulate.

The problem hinges around the following. If I can design a product to comply with a 99.95 penetration requirement and do so at one-half the breathing resistance that's required in the standard, that is, in fact, an important achievement.

Now, unfortunately, part of the discussion with regard to 30 CFR 11 revisions gets us into the issue as to what breathing resistance requirements are, in fact, appropriate and suitable and brings us back to the point that within the various subparts of 30 CFR 11 for different types of products we have different breathing resistances, and there appears to be little technical rationale for that.

Clearly that's part of the revision process or the performance criteria that needs to be dealt with. The issue I'm getting at is that we need to provide for the performance criteria within 30 CFR 11 or revisions or new procedures.

The technical rationale supports the answer to

your question. It does not now exist in my view.

MR. LOMAS: That was my point, and you answered my question. I think performance requirements in a revision of 30 CFR 11 have to become more relatable to a usage situation before publication of them can truly be meaningful or helpful.

MR. MORAN: I fully agree with you.

DR. OPOLD: I'd like to make a comment on the witnessing of tests in the laboratory. John Moran has said that he thinks that NIOSH should stand the scrutiny of its peers.

We definitely agree with that and would advocate that, and that's what we want to do. However, maybe it's an administrative type of a problem.

At the present time, manufacturers' representatives witnessing tests and in some ways when they see things not happening the way it should, it's very hard for them not to resist the temptation to interfere, and the proposal that was made was that we would conduct or have more or less a workshop at some time when all of the manufacturers could come in and witness how we did our business, not that we intended in any way to hide behind a curtain or not to stand the pressure of peer review.

Maybe you have a comment, maybe you don't on

that, John.

MR. MORAN: I think your comments, Jim, clarify my thinking on this issue, and if the institute pursues its objectives that openly, I think a lot of that issue will go away.

DR. OPOLD: I have one last thing. Dr. May had mentioned this morning the workshop that is going to be held in Morgantown the 9th, 10th and 11th of September, and I think, John, this sort of adds to what you and the other gentlemen were talking about in that we need to search out new ways of protecting the worker from inhaling toxic materials, carcinogens, whatever, and that's what that workshop is all about.

I guess I'd just take half a second, John, to put a plug in for that.

The first day of that workshop is organized totally, we think with what are some leading people in this country, to talk about the idea, where we need to go with respiratory protection, and I think that we would encourage those of you who have ideas to come to that and let it be known where you think this ought to go.

We all know that the worker frequently in the coke oven environment or whatever wears the respirator around his neck, and that's no fault of the

manufacturers, no fault of the NIOSH certification program at the present time. We just think there's a big void here that the federal government perhaps ought to be working in this area.

The first day of that workshop is entitled, International Respirator Research Workshop, and we will have some international people there.

I know for sure we'll have people from England, Australia, France, Spain, Germany for sure, and that is divided into the following days a session on air purifying respirators, the physiology and psychology of respiratory use, and then the atmospheric supplying session, and then finally we have the quantitative respiratory pit session.

I just wanted to explain that. As John said earlier this morning, there are copies of this agenda, and it's a tentative agenda at this time, available on the table outside. Thank you.

DR. MAY: Any other questions for John Moran? Okay. Thank you very much, John.

The last speaker for this afternoon's presentation is William H. Revoir, Chairman of the ANSI Ad Hoc Respirator Test and Approval Subcommittee, a group that's become active relatively recently with the purpose of providing some assistance to the institute, for one, in this effort of ours to revise the testing and

certification program. Bill.

MR. REVOIR: Thank you, John. The American National Standards Institute has established an ad hoc subcommittee of the institute, the Committee on Respiratory Protection, for the purpose of reviewing the current respirator test and approval program and for the purpose of offering suggestions for the improvement of this program.

The membership of this ad hoc subcommittee has been limited to persons who have had considerable experience in respiratory protection and who are recognized to have expertise in respiratory protection by industrial hygienists, safety engineers and other professionals in occupational health and safety.

Members of the ad hoc subcommittee are persons employed by government agencies involved in occupational health and safety other than NIOSH and MSHA, research institutions engaged in respirator research, consultants on respiratory protection, industrial firms which provide respirators to workers and respirator manufacturers.

The ad hoc subcommittee has 22 members. Six are employed by government agencies. Three are employed by research institutions. Five are consultants. Three are employed by industrial users of respirators, and four are employed by respirator manufacturers.

On 18 June 1980, NIOSH published a notice in the Federal Register which announced a public hearing to be held the 28th to 30th of July 1980 for the purpose of discussion a respirator test and approval program.

This notice stated that the issues and topics to be discussed at the public meeting are intended for use in the restructuring the respirator test and approval program to increase the level of competence of respirator users that approved respirators provide adequate protection.

Inasmuch as the discussion subjects listed in the notice concern administrative aspects of a respirator test and approval program, the recommendations which I shall present today on behalf of the ANSI Ad Hoc Respirator Test and Approval Subcommittee shall be limited to administrative aspects of a respirator test and approval program.

The members of the ANSI Ad Hoc Subcommittee deplore the very short time period of only five weeks from the date of the published meeting notice until the date of the start of the meeting to permit persons to prepare for participation in this meeting.

This short time period, especially since it occurs during the summer, has made it extremely difficult for an organization concerned with respiratory protection to get its members together from all parts of the

country to develop a statement for presentation at the meeting.

Undoubtedly, if NIOSH had allowed more time for persons to prepare for this meeting, many more organizations than those listed who are to appear at this meeting would be participating.

ANSI Ad Hoc Subcommittee utilized a comprehensive questionnaire to solicit the viewpoints of members of the subcommittee on the administrative aspects of a respirator test and approval program.

The subcommittee held a meeting yesterday at which time the answers to the questionnaire were reviewed an analyzed, and a concensus of opinion of the members of the subcommittee was agreed upon.

While some members of the subcommittee may disagree with some of the recommendations, the following statements which I shall -- (end tape) -- and respirator test procedures for approval testing of respirators and granting of respirator approvals.

NIOSH alone should be given the responsibility and authority for establishing respirator performance criteria and respirator test procedures; however, the governmental respirator test and approval regulation should include provision for the establishment of a government steering committee made up of members from

government agencies concerned with respiratory protection which would develop policy for the respirator test and approval program and which would oversee the operation of this program.

This government steering committee should make use of respirator experts in the private sector for advice.

NIOSH alone should be given the authority for granting of approvals for respirators which are tested and found to meet the performance criteria; however, certain mine safety and health statutes require that MSHA jointly with NIOSH grant approvals for respirators for use in mining operations.

Second item. Modification of approved respirators. The respirator test and approval program should require a respirator manufacturer to obtain a new approval for any modification in an approved respirator that affects form, fit or function of the respirator, and the manufacturer would not be allowed to market the respirator containing this type of modification until NIOSH grants the manufacturer a new approval.

The designation number of the new approval would be different from the old designation number for the previous approval. This system would prevent NIOSH, any government agency having responsibility for

the health and life of workers, employers who purchase respirators and employees who must wear respirators to differentiate between approved respirators of a specific make and model prior to the modification and after the modifications.

The respirator test and approval program should permit a respirator manufacturer to manufacture and market an approved respirator containing a modification that does not affect form, fit or function of the respirator without having the manufacturer obtain a new approval for the respirator.

However, the manufacturer would be required to notify NIOSH of this type of modification.

The next item is product documentation. The respirator test and approval document should require that the respirator manufacturer submit copies of product documentation which means bills of materials, drawings, specifications.

Two NIOSH for each respirator to be tested for approval, NIOSH should not be required to review and approve the copies of product documentation, but should be allowed to file these copies for reference whenever tests or examinations of specimens of approved respirators obtained from the field indicate that a performance problem may exist.

The next item is quality control. The respirator test and approval document should list detailed requirements for a quality control program to be carried out by respirator manufacturers.

However, a respirator manufacturer should not be required to submit copies of detailed quality control plans for each respirator to be tested for approval by NIOSH.

Instead, a respirator manufacturer should be required to certify to NIOSH that an effective quality control program which meets the requirements listed in the respirator test and approval document will be implemented for the respirator submitted for testing and approval when said respirator is manufactured and marketed.

Design analysis. NIOSH has indicated that a respirator manufacturer should be required to prepare a detailed engineering design analysis for each respirator submitted for approval in tests, and that the analysis would not have to be submitted to NIOSH when the respirator is submitted, but would only have to be submitted to NIOSH if testing for approval or testing of respirators obtained from the field indicate that the respirator may have design problems.

The ANSI Ad Hoc Respirator Test and Approval

Subcommittee feels that it's unable to comment on this matter, because NIOSH has not provided adequate information on what an engineering design analysis should consist of.

Respirator specimens for approval testing. NIOSH should be permitted to test for approval specimens of a respirator containing materials which will be used in the approved respirator to be marketed, but manufactured with prototype tooling.

However, the approval for the respirator will not be granted by NIOSH until NIOSH has examined specimens of the respirator made with the use of production tools, production methods and production personnel, and this examination determines that there is no need for the testing of specimens of the respirator manufactured with these production items.

However, if this examination indicates that testing of specimens of the respirator made with production tools, production methods and production personnel should be carried out, the NIOSH should not grant the approval until such testing has been carried out and the tested specimens are found to meet the performance criteria.

Service of testing prototypes. NIOSH should be permitted to provide a service to respirator

manufacturers which involved the testing of specimens of prototype respirators to determine if the designs of prototype respirators have potential to result in production specimens of respirators which would meet the appropriate performance criteria.

However, NIOSH would only test specimens of such a prototype respirator provided that the manufacturer submits test data to NIOSH which indicates that the prototype respirator may have potential to result in production specimens which would meet the appropriate performance criteria, and provided that the manufacturer pays fees to NIOSH to cover the cost of testing and provided that this testing does not delay approval testing.

Assistance to respirator manufacturers in establishing test equipment and/or test procedures. NIOSH should assist a respirator manufacturer in establishing satisfactory test equipment and/or satisfactory test procedures by providing the manufacturer with copies of sketches and engineering drawings of test equipment, copies of calibration procedures for test equipment and/or copies of detailed procedures for carrying out tests.

When necessary, NIOSH should provide the manufacturer with demonstrations of the operation and/or calibration of the test equipment and/or demonstration

of the test procedures.

Duration of approval. The duration of an approval for a respirator granted by NIOSH would not extend beyond the time when new performance criteria for the particular type of respirator becomes effective.

At this time, the respirator manufacturer would be required to submit the respirator to NIOSH for approval under the provisions of the new performance criteria.

Witnessing of approval testing. NIOSH should allow a respirator manufacturer to have a representative present to witness the testing of a respirator submitted for approval.

Appeals procedure. The respirator test and approval program should include provisions for an appeals procedure which would permit a respirator manufacturer to appeal a decision made by NIOSH.

Appeals would include a decision by NIOSH not to accept an application from a manufacturer for testing and approving a respirator, a decision by NIOSH not to approve a respirator after it has been tested, a disagreement by the manufacturer that testing by NIOSH was performed properly, a disagreement by the manufacturer that NIOSH has interpreted test results properly and other disagreements between manufacturers and NIOSH.

The appeals procedure would cover matters concerning approving of respirators, the auditing of approved respirators obtained from the field and stop sale recall requests.

Arbitration of an appeal would be carried out by a panel of senior experienced scientists and engineers. An arbitrator could be a person employed by NIOSH in a division not involved in testing and approving respirators, a person employed by another government agency, or a person employed in the private sector.

Field audit, NIOSH shall carry out a continuing field audit of approved respirators in the marketplace and in the work place.

NIOSH will procure specimens of both unused and used respirators from the marketplace and the work-place.

NIOSH will examine and test the specimens to determine if they meet appropriate performance criteria. If specimens of an approved respirator fail to meet appropriate performance criteria, NIOSH will attempt to determine the causes of the failure.

The results of the field audit will be reported to the respirator manufacturer by NIOSH if the specimens of the approved respirators fail to meet the appropriate performance criteria and also if the specimens of the

approved respirators meet the appropriate performance criteria.

Time for testing respirators. NIOSH shall carry out tests on particular respirators in the order that they are submitted to NIOSH by respirator manufacturers.

Investigation of reports of alleged failure of approved respirators to provide proper protection in the field. NIOSH will investigate a report received from the field that an approved respirator may not provide adequate protection.

NIOSH will notify the manufacturer immediately that such an investigation is to be carried out. NIOSH will report the results of the investigation to the party that notified NIOSH of the possible failure of the approved respirator and will also report the results of the investigation to the respirator manufacturer.

Stop sale and recall. NIOSH shall have the authority to require a respirator manufacturer to stop sale of an approved respirator if the results of a field audit of an approved respirator or the results of an investigation of a report from the field of alleged failure of approved respirator to provide adequate protection, show that the respirator manufacturer is marketing specimens and approved respirators that have

some characteristics that cause them to fail to provide adequate protection.

However, NIOSH shall not be permitted to mandate the stop sale order until NIOSH has proven that the results of the field audit or the results of the investigation of the report from the field are valid.

NIOSH shall have the authority to prohibit the respirator manufacturer from selling the respirator until such time that the manufacturer has proven to NIOSH that the causes of the failure of the respirator to meet performance criteria has been eliminated or the characteristics of the respirator that prevents it from providing adequate protection has been eliminated.

Also, NIOSH shall have the authority to require the respirator manufacturer to recall the specimens of an approved respirator from the field that do not meet performance criteria or that contain characteristics that prevents them from providing adequate protection.

However, NIOSH should not be permitted to mandate the recall until NIOSH has proven to the manufacturer that the specimens of the approved respirator in the field do not meet performance criteria or that the specimens of the approved respirator contain characteristics that prevent them from providing adequate protection.

Stop sale and recall procedures of respirator manufacturers. NIOSH shall have the authority to require a respirator manufacturer to certify to NIOSH each time the manufacturer submits a respirator for testing and approval that the manufacturer has a detailed plan of procedures for stop sale and recall of respirators from the field.

NIOSH shall have the authority to require the respirator manufacturer to submit this plan to NIOSH for examination and approval whenever NIOSH requires the manufacturer to carry out a stop sale and recall action.

Publicity of stop sale and recall. NIOSH will publicize all orders to respirator manufacturers for stop sale or recall of specimens of approved respirators from the field.

Revocation of approvals. NIOSH shall have the authority of revocating the approval of a respirator if a respirator manufacturer violates any requirement of the approval program.

However, NIOSH first must be required to notify the respirator manufacturer of the impending revocation of the approval and permit the manufacturer reasonable time to remedy the situation.

If the respirator manufacturer refused to

eliminate the problem in a reasonable time period or is unable to eliminate the problem in a reasonable time period, then NIOSH shall revoke the approval.

NIOSH shall publicize each approval revocation. Publication of test data. NIOSH shall not be permitted to publish test data obtained in approval testing of a respirator, but shall be permitted to report the test data only to the respirator manufacturer who submitted the respirator for testing and approval.

NIOSH shall be permitted to publish test data obtained in a field audit of an approved respirator or the test data obtained in the investigation of approved respirator carried out as a result of a report from the field, only if the test data shows that the specimens failed to meet the performance criteria or that the specimens of the approved respirator in the field contain a characteristic that prevents it from providing adequate protection, and the respirator manufacturer refused to carry out a stop sale recall order.

If the manufacturer involved delays in carrying out a stop sale recall order or if the stop sale recall order carried out by the involved manufacturer isn't effective.

Use and maintenance manual. NIOSH shall require manufacturers of approved respirators to furnish with

each specimen of an approved respirator a manual which lists the applications of the respirator, describes the construction of the respirator, explains the operation of the respirator, lists the limitations of the respirator, provides instructions for donning and taking off the respirator, gives instruction for wearing the respirator, lists requirements for inspecting the respirator, gives methods for testing the fit of the respirator, provides instructions for proper maintenance or repair of the respirator, gives methods for the proper storage of the respirator and gives warning of improper uses of the respirator.

NIOSH shall require manufacturers to submit a copy of the manual for examination and approval when the manufacturers submitreepirators to the agency for testing and approval.

Systems manual, NIOSH should be required to develop and make available a systems manual that defines the authorities of NIOSH, the operating procedures for testing and approvins respirators and the test procedures in effect, the performance criterion effect, methods for handling applications for testing and approving of respirators, methods of issuing approvals for respirators, methods for denying approval for respirators, procedures for field auditing of

approved respirators, procedures for investigating reports from the field concerning alleged problems of approved respirators, provisions for ordering manufacturers of approved respirators to stop sale of approved respirators and to recall specimens of approved respirators from the field, and procedures for revocating approvals for respirators.

Research, NIOSH should carry out research only to develop new and improved test equipment, new and improved test procedures and new and improved performance criteria for respirators aimed at improving the state of the art of approved respirators.

Also, NIOSH should carry out research to develop test equipment, test procedures and performance criteria for respirators for use by persons for protection against respiratory hazards to be covered by existing occupational exposure standards being revised by various government agencies or protection against new respiratory hazards to be covered by new occupational exposure standards to be promulgated by various government agencies.

In addition, NIOSH should carry out research to determine if existing approved respirators offer adequate protection against respiratory hazards covered by existing occupational exposure standards, respiratory

hazards to be covered by existing occupational standards being revised and new respiratory hazards to be covered by new occupational exposure standards to be promulgated by various government agencies.

NIOSH should not carry out research to develop improved or new types of respirators for existing or new respiratory hazards since this type of research should be carried out by the private sector.

The ANSI Ad Hoc Respirator Test and Approval Subcommittee wishes to go on record to state that if NIOSH fails to devote sufficient resources in both manpower and equipment to develop a meaningful respirator -- to develop meaningful respirator performance criteria and test procedures, to implement an effective program of testing and approving respirators and to carry out a continuous program of auditing the performance of respirators in the marketplace, then NIOSH should relinquish its responsibility and authority to operate a respirator tested approval document.

The ANSI Ad Hoc Respirator Test and Approval Subcommittee recommends that the respirator for this public meeting concerning the administrative aspects of a respirator test and approval program remain open for at least 90 days to permit persons to submit additional comments and suggestions.

The subcommittee feels that NIOSH has not allowed sufficient time for persons to study the matter of the administrative aspects of a respirator test and approval program and prepare comments and recommendations on this matter.

Thank you very much.

DR. MAY: Thank you, Bill.

MR. REVOIR: I don't have any copies of my presentation. We had a meeting yesterday that ran till after 6:00, and I had to scribble this up last night, but I'll get a copy to John.

MR. BOLTON: Bill, I would assume that the Ad Hoc Subcommittee will have an opportunity to change their position on any one of these points upon further discussion by the committee if they deem it to be vital to do so.

MR. REVOIR: This is one reason why we're asking for at least 90 days. After receiving the Federal Register, and we get these in the mail generally a week after they're published, it gave us only four weeks to try to develop a statement on behalf of quite a diverse group of people representing government agencies, research organizations, private consultants, industrial firms using respirators and respirator manufacturers.

It's summertime. We found some of our people on

vacation. We couldn't even get in touch with them. Other people had made plans. It was impossible to get these people together in a four-week period, that is all of them together.

I sent out a questionnaire, and over 90 percent of these questionnaires were returned. We only were able to get together yesterday.

We sat here all day on Sunday, and hammered out what we feel is a concensus of this subcommittee, and we were here last night till after 6:00, and I had to eat dinner and try to write these notes up last night.

So we hope to have more time to get our subcommittee together for perhaps a three-day meeting before the record closes so we can discuss in more detail some of these things.

We had to really rush through this. I mean, based upon the study of a questionnaire, I sent out a questionnaire, I think, it was 17 pages long, quite a long document, and people had to quickly rush through that, and then I had to compile all of the results, and we had to sit and argue all day yesterday on this, so we'd like a little bit more time.

DR. MAY: At this time, Bill, I guess the only thing we can regarding the time, we certainly are not in a position to turn down any assistance we can

get with the program, and I personally don't see any problem with granting an extension so that your committee can provide some more meaningful input to us.

I won't officially say that now, but I'll have some word by tomorrow to let you know.

Any other comments for Bill? Jim has one, if you'd use that mike over there and introduce yourself.

DR. OPOLD: Jim Opold, NIOSH. I have one brief question that I think is more of a clarification. You went pretty fast, and I was only able to get so much of it, but the question had to do with you said that you agreed with our stop sale position; however, when it came mandatory, you felt like we ought to go through the appeals procedure, and only after the appeals concern is upheld would it be mandatory.

I guess my question is, Bill, how long can we wait if it's a critical or major area situation? Do you care to comment?

Maybe I misunderstood you, but would you care to comment on that?

MR. REVOIR: We did not come out and make a recommendation on details of an appeals procedure as the Industrial Safety Equipment Association did. One reason is we did not have enough time.

We feel that NIOSH, before they require a stop

sale or recall should be required to validate these test results.

In other words, they shouldn't just notify a manufacturer and say, hey, certain units are failing, or our test results indicate this, but I think they should get that manufacturer and make sure the manufacturer understands the significance of this failure and that the manufacturer is satisfied that NIOSH has carried the tests our properly.

You indicated earlier, Jim, that you did not know of any failures in the testing carried out at NIOSH.

There are a number of people in government agencies and some of the research organizations and some of the respirator manufacturers, I think, that could give specific examples.

We're not prepared to do this today, but the thing is this, truthfully at our meetings and meetings I've had in ANSI before, the ZA.2 subcommittee developing respirator use standard, NIOSH has lost a lot of credibility in this field of testing.

You've had a lot of changes in personnel. You've lost people. You've had to bring inexperienced people in. We know the difficulty of training these inexperienced people, but all this problem of using some

inexperienced people and trying to train them has resulted in some test not being carried out properly, and there area lot of horror stories out.

Maybe some of these horror stories get exaggerated, but the thing is this, in the discussion yesterday, and here is a subcommittee made up of many government agencies, half a dozen of them, and some respirator users and some research people, and almost all of these people express that they have lost confidence in NIOSH's ability to test products properly.

We feel that NIOSH should offer proof that their tests are correct before they force a manufacturer to stop sale or recall, whether you go through an elaborate appeals procedure or not, but there should be some proof that these test results are valid.

I think as Mr. Wilcher pointed out, any appeals procedure is going to have to be rapid. You can't endanger the health of the worker out in the field.

It's got to be done in a few days time or else it shouldn't be used.

DR. OPOLD: I obviously have got to carry this discussion on at least a little bit further, because I will ask you the same thing as I asked Mr. Wilcher, to show me, tell me, relate to me where, number one, we failed to carry out the tests according to part 11; two,

where, when, did we misinterpret test results, because we're on the record, and I want to know about it.

MR. REVOIR: As I said, I'm not prepared today to give specific examples, but we will do so, in the very near future.

DR. OPOLD: I understand then, Bill, that you will provide for the record specific examples where this has occurred at least in the last two and a half years and maybe beyond.

MR. REVOIR: Right.

DR. OPOLD: Okay. I think Bob has got a question, Bill.

PARTICIPANT: NIOSH . You indicated that you presentation today is based upon a concensus of opinion taken by you via a questionnaire.

Would you consider making all of the material available as part of the record of this meeting? First, a copy of the questionnaire, second, the identity of the subcommittee's members, third, the identity of the subcommittee members who met yesterday and decided on and prepared the response to NIOSH which you read today, and, fourth, some indication of any major minority opinion which may have arisen from yesterday's discussion.

MR. REVOIR: I will try to do that, Bob, yes.

PARTICIPANT: Thank you.

DR. MAY: Any further comments or questions for Bill?

MR. WEBSTER: My name in Donald Webster. I'm a senior environmental health engineer. My question is of a general nature, not for Bill necessarily.

During this session today, we've heard some comments about several years ago, many people making an effort to draw up comments about the respiratory program and submitting them, and, in essence, these comments ended up in a deadend street, so to speak.

I wonder if it would be pertinent that these comments be made a part of this record in case they might still be valuable in solving the problems that face us today.

I don't know if this is possible. I'm not sure if it's meaningful, but I would bring it up for discussion.

DR. MAY: Well, I'm not quite sure how to respond to that. If you're suggesting that, we can certainly address it.

I can guarantee you that three volumes are sitting right in the middle of my desk for one. I guess my response would be they are not lost to the institute. They have not been for the last three years, and in this mode of trying to revise the program and come up

with new performance requirements, it would be in our best interest to go back and go through all of that again, because most of that was relevant then, and a great deal of it is relevant now.

You know, I can only say again, this is a real commitment we have to change this program around, and we will do that, and if I can say anything else to convince people of that, I'd be happy to do it, but my comments I made this morning, I would just reiterate.

We are in the process of looking at that in this new framework, and what happened three years ago is not going to happen now.

The only thing you'll have to do is wait and see what happens to the program now, and I think that will show you that this is a different environment.

If there are no further comments, the meeting is adjourned for today and we will reconvene at 9 tomorrow morning. Thank you.

(Whereupon, the meeting adjourned on July 28, 1980 to reconvene at 9:00 a.m., on July 29, 1980.)