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TRANSCRIPT

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List of Attendees: (See page two)

Dr. Jon R. May
Chairperson

Hearing Assistant

ABL Associates, Inc.

I N D E X

P R O C E E D I N G S

DR. MAY: The first presenter this morning is listed as Pual Siemsen, Product Sales Manager from the Environmental Process Instruments Division. Instead, presenting the discussion for Bendix will be Bob Gray who is Project Engineer, Environmental Process Instruments, A Division of the Bendix Corporation.

Bob?

MR. GRAY: Our feelings on a revised NIOSH certification program are similar to those presented by Frank Wilcher by ISEA.

We believe that a significant change in the approval process is necessary, both to expedite the process and to prevent NIOSH to spend more of its resources in administering and improving the quality of safety products standards.

Like ISEA,we would like to suggest a variation of the fourth alternative listed in the June 8, 1980 notice in the Federal Register.

However, our suggested variation will be somewhat different than that presented by ISEA. We question whether testing by an independent third party would resolve of the present problems or would actually add to them.

As mentioned several times in presentations

yesterday afternoon, the burden of engineering design, quality insurance and product liability lie with the manufacturer, not with NIOSH.

The role of NIOSH should be to establish certain performance standards and safety equipment. The role of the manufacturer should be to meet these requirements as a minimum and to certify that his product meets them with a definition of certification being a guarantee or pledge of conformance as generally associated with the word.

It would seem that reference to a NIOSH certification makes no sense since NIOSH cannot guarantee the quality of a product.

It can only certify that it tested samples supplied by the manufacturer and that they met the minimum standards.

We should also point out that 30 CFR 11 requires the manufacturer to perform complete testing of equipment prior to submittal, meaning that the manufacturer must either procure the necessary test equipment or must locate an independent testing laboratory to perform the necessary tests before NIOSH submittal.

Does it not follow that if a manufacturer has a complete description specification and he has

the facilities to perform the required tasks that he should be able to certify whether his equipment meets the approval requirements.

We believe that manufacturers are capable of performing their own tests and determining whether their products meet published standards provided that the standard is sufficient descriptive and complete.

We do not feel, however, that NIOSH must be nor necessarily should be divorced from the initial introduction of a new product to the market.

The design of a new device could be reviewed briefly, and a representative of NIOSH could be present during the final qualification testing as a witness.

We envision an approval process which would take several days and might be handled as follows. The manufacturer upon complete of his own tests notifies NIOSH of his design, test results and planned qualification test program.

The test program would be set up to cover all required testing in a minimal time.

A NIOSH representative or group of representatives would travel to either the manufacturer's facility or to an independent testing facility at the manufacturer's option to witness the testing.

The manufacturer would supply or make available all test equipment, test units, refills, recharges and test subjects.

NIOSH could specific that all testing be completed in a specified period of time based on the type and duration of the apparatus, such as within a three-day period for a self-contained breathing apparatus having a duration of 60 minutes or less.

Under this plan, the testing facility at Morgantown would remain as the test facility for field audits and development studies.

Hopefully TCL would eventually become the master reference laboratory by incorporating the best of the testing technology used at the various manufacturers' test facilities.

This plan should offer several advantages over the existing program. First, it would permit streamlining of the approval procedure without requiring additional NIOSH resources or federal allocations.

Secondly, it would permit NIOSH to concentrate the uses of its personnel and facilities toward advancing the state of the art rather than confirming the manufacturer's test results.

Third, it would eliminate pressure from

NIOSH test personnel and place the burden of compliance demonstration on the manufacturer.

In review, we believe that a self-certification program by the manufacturers coupled with witnessing of the tests by NIOSH representatives offers a desirable alternative to the current approval method.

We would like to further add that we agree with the ISEA position on the 14 issues requesting comment in the June 18, 1980 Federal Register with the following additions.

We believe that a failure mode analysis describing results of component failure would be a helpful tool to both manufacturers and NIOSH and should be submitted to NIOSH on a voluntary basis.

Secondly, witness of approval tests would not be an issue if testing were performed by the manufacturer.

Third, the duration of approval should be indefinite so long as no change is made to the approved apparatus affecting formfitter function.

The problem of having different devices which carry the same approval number should be rectified by requiring a new approval number for any change affecting form, fit or function.

We would like to emphasize the ISEA statement

concerning testing of prototypes. NIOSH should not act as an independent testing laboratory for the development of new products, but also NIOSH should not expect manufacturers to invest in tools and make production runs for the purpose of running qualification tests.

We would like to add in our statement that we too feel a need exists to provide regular updating of the 30 CFR 11 requirements.

New concepts cannot be approved because the specification does not exist. Older, out-of-date requirements remain in the schedule.

An example of this is in the case of positive pressure requirements for self-contained breathing apparatus.

For years, the only available positive pressure devices were open circuit. The approval requirements are quite liberal in that exhalation resistance is measured at a very low flow rate, and the allowable resistance is rather high.

When closed circuit positive pressure devices came into existence, they were required to meet existing requirements for closed circuit non-positive pressure devices on exhalation which are considerably more stringent that for open circuit

positive pressure apparatus and the device was required not to go negative on inhalation.

All the new requirements for closed circuit positive pressure devices have been developed. These resistance requirements are completely different from open circuit devices.

It would seem that resistance requirements for positive pressure devices should be the same regardless of system design and that references to particular types of systems should be eliminated in favor of acceptance parameters regardless of the system design.

We appreciate this opportunity to express our views on these points.

DR. MAY: Thank you, Bob. Are there any questions or comments?

It must be too early in the morning. Thank you very much, Bob.

The next presenter on the program this morning is Paul R. Bolton from Reynolds Electrical and Engineering Company, Incorporate, Las Vegas, Nevada. Paul?

MR. BOLTON: I'm Paul Bolton, Industrial Hygiene Chief for Reynolds Electrical and Engineering Company, Incorporated, in Las Vegas, Nevada.

The last few days have been a learning process for me, and, frankly, I'm less willing to defend some of the views that I'm going to present here now than I would have been when I prepared them.

However, I'm going to present my statement as I prepared it, because perhaps it reflects the perceptions of other users out there that are like me, less informed, and it does, I think, indicate the desirability that when a revised program is disseminated, I think it would warrant some explanation for support of the certain views that will be taken or certain proposals that will be made which would, I think, help education the people that would likely comment on it.

So I am going to present my statement as I prepared it.

In addition to my responsibilities for the industrial hygiene program, I have the respiratory protection program which includes specifying respiratory protective devices for procurement, servicing and maintaining the devices, training and fit testing of the users of the equipment and selection of the appropriate device for a given work application.

As users of hazard measuring units in our industrial hygiene work and as users of significant

numbers of the full range of types of respiratory protective devices, that is the soft rescuers, air purifying, airline, open circuit, self-contained open circuit, self-contained closed circuit, breathing apparatus, we are interested in being able to obtain equipment that is identifiable as meeting stated performance standards and which will continue to perform reliably with proper use and maintenance.

Knowledge of the limitations of respiratory protective devices, such as the air purifying type, is essential for making the correct selection for a given work application.

Certification of hazard measuring instruments is primarily of value for procurement of these instruments such as the permissible or intrinsically safe for use in combustible atmospheres.

Some of the hazard measuring instruments can be tested by the users while others cannot.

For example, prior to the NIOSH testing the certification of gas detector tube units, we calibrated our own.

This had the potential deficiency of having an inventory of unusable detector tubes if their performance was not satisfactory.

We now specify NIOSH certified tubes for

those that are available, and this provides us with sufficient information as to their accuracy.

Certainly it is not feasible for us to test such items as sound level meters and noise dosimeters, but we believe there are other mechanisms for testing and certifying hazard measuring instruments, such as the construction and presumably the testing by the manufacturer to meet an ANSI standard or by factory mutual approval, Underwriters Laboratories listing or approval, and so forth.

Therefore, the need for NIOSH to test hazard measuring instruments does not appear to be urgent.

We are in agreement with the identified need to revise the testing and certification program for personal protective equipment, particularly respiratory protective devices.

Our needs of being able to procure devices that are certified as meeting a performance standard and of knowing the use limitations of these devices can be met by the development of a realistic and state of the art performance specification and testing of devices to meet these specifications.

We believe that this testing can be competently performed by either private laboratories

or industry, that is the manufacturers, which are both alternatives three and four proposed in the meeting announcement.

I do not see the need or the advantage for NIOSH to perform this testing either alone or in conjunction with MSHA even with revised performance specifications and administrative procedures.

It is questionable that the private laboratories or industry would need to be certified by NIOSH to perform this testing. I'll change certified to accredited.

It would appear that product liability potential in addition to the economic considerations for marketing a reputable product would provide sufficient incentive for assuring that the device has been tested and does conform to the performance specifications.

Among the advantages of testing by private laboratories or industry are the freeing of NIOSH resources for other obligations and needs. The manufacturers could elect to perform the testing or have it done by a private laborator.

The ready availability of testing facilities potentially more than one such facility as presently exists would aid in the development of new equipment

and in testing of prototype devices and the elimination of the problem of the applicant witnessing the test at the NIOSH testing and certification facility.

Testing facilities in some form already exist in industry and in private laboratories. It is recommended that the ANSI Z-88 Ad Hoc Subcommittee for Respirator Test and Approval be given the task of developing the performance specifications and other related specifications that may be required.

A potential problem with the testing of used respirators from the field as a part of the quality control program is the difficulty in discriminating between flaws and defects due to the design or manufacturing deficiences and those due to misuse for improper maintenance and servicing.

A product recall for the revocation of a device certification have serious consequences which warrant assurance that flaws or defects detected in used devices are truly the manufacturer's responsibility.

We feel that more latitude is needed in the area of changes to approved devices. The present system requiring the use of only those components approved for a given device can be a nuisance to the user and a potentially citable

violation of an OSHA standard.

As an example, an airline respirator requires the use of a high pressure airline that is approved for the respirator in use.

Where different makes of airline respirators are used simultaneously in one work area, it is impractical if not impossible to assure that a particular airline is used with a particular respirator.

We are in agreement with the proposal that non-significant changes in improved respiratory protective devices need not be submitted for approval.

In addition, we favor more latitude for the user in the use of components from different makes of devices, such as the high pressure airlines mentioned above, and this should be permissible rather than mandatory.

The elimination of the use of unpublished test requirements may defeat or delay some of the purposes for revising the program such as the use of state of the art performance standards and test procedures.

It could also delay the availability to the user of new and approved devices due to the time requires for public comment on standards or standards revisions.

Limiting the duration of approval to five years could be an economic burden on the user either through the need for replacement of existing devices, if not reapproved at the end of five years, or relabeling existing devices with new approval numbers.

It is conceivable that a manufacturer could elect to produce a new model device in place of an existing device and not submit the existing device for approval.

This could leave the user with an inventory of adequate, but unapproved, devices.

I thank you.

DR. MAY: Thank you, Paul. Any questions or comments on Mr. Bolton's talk? Jim? Dr. Opold has a question for you.

DR. OPOLD: Jim Opold, NIOSH. I was particularly interested in your remarks, Paul, I guess one of the reasons being that the first time we've really heard anyone speak to the health measuring instruments and trying to follow along, I think you opened your remarks by saying you're a little bit less willing to present these views as you did when you wrote them.

I'd like to have you explain that a little

bit more, maybe what your feelings are today as opposed to when you wrote this and why..

Specifically, I have a couple of questions. You said that you felt that we, NIOSH, in the testing and review evaluation of detector tubes, I think I could pick out of that that we were doing a pretty good job, and you relief upon us to do that.

Okay. Now, my question is I think that you indicated that Reynolds Electrical, for example, was capable and could do this, and I think your conclusion was that we really did not need to do this.

Now, my question would be in thinking a little bit more broadly about some of the small businesses that don't even have industrial hygienists such as yourself on staff, and others perhaps, that don't have this capability.

Do you feel that a government agency such as NIOSH ought to be involved in a testing and certification program for items such as detector tubes, because of people who can do it for themselves?

MR. BOLTON: I think, as I expressed it here, I felt it was the need for NIOSH to do the testing and hazard measuring instruments was less urgent.

To answer your question of whether NIOSH specifically should be involved in this, I wouldn't say they should not be involved, but whether they themselves actually need to do the testing or whether it can be done by others according to defined performance standards and thus be certified.

One of the views I'm less ready to defend now than when I wrote this was that in the case of some equipment that is at least marketed as meeting a given ANSI standard, for example, and I think this reflects the view or perhaps the view of many of the users out there.

We take that on good faith, that if a product is marketed, like a noise level meter, and it says that it conforms to a given ANSI standard, we assume that it does, and I understand from talking to people here, that not necessarily in the case of sound level meters, but certainly other equipment that is sold as meeting given ANSI standards, that may not be the case.

If that is, that's, let's say, one of the things I'd be less willing to defend now than when I prepared this. Does that answer your question?

DR. OPOLD: Yes. The next question that I have on page two of your presentation, you mention

that there are other mechanisms for testing and certifying health hazard measuring instruments and that whoever does it should relay upon the ANSI standards.

Then, on page three, you say it is recommended that the ANSI Z-88 Ad Hoc Committee for Repirator Test and Approval be given the task of developing the performance specifications and other related specifications that may be required, end of quote.

My question on that, Paul, where does, and maybe this is a past and also present type of question, where can the Ad Hoc Committee go to get information for performance specifications for such things, and I use this as an example, corrosion.

We recognize that's an area that we need to probably develop a test. Flammability, we've heard that mentioned from some of the firefighters throughout this meeting. What is the temperature?

Where would the Ad Hoc Committee get this information other than in a group of intelligent people sitting around trying to think what that might be.

I'm a little bit lost, so could you explain that please?

MR. BOLTON: I'm not sure that I clearly

understand your question. I would think that the Ad Hoc Subcommittee would get their information the same place as if they were a group of people not so identified.

I recommend that on the basis that I visualize this particular subcommittee as being made up of knowledgeable people on respiratory protective devices, and hopefully would include representatives from OSHA and NIOSH.

You know, I think that's where they would get their information, by sitting around as that subcommittee, and I only recommend that because it's a committee that's already formed, and I think they'd get it through the same place as if they were a committee made up by NIOSH.

DR. OPOLD: I'll just pursue this one step further. My point, maybe I didn't make it clear from the first question, is that what do we do, and I'll put ourselves into that, what do we do when we don't have the answers, and I used corrosion, for instance.

What should we do then to develop those specifications? I think it boils down to, if I go a step further, that somebody has to do the research, and are you advocating that the private universities, non-profit organizations, industry and others do this

after we recognize we have to set up the performance specifications, or would it be better for a governmental agency such as NIOSH to take the lead in developing these performance criteria.

MR. BOLTON: I would say that I certainly don't have any strong feeling one way or the other in regard to the research on it. It certainly may be appropriate for NIOSH to do research on necessary or necessary for developing the necessary test procedures.

My recommendation here has to do with once the performance standards are agreed upon and the test procedures are agreed upon, my recommendation is that either the manufacturer or the private laboratory be permitted to do the testing necessary to verify that the devices do meet the required performance standards, and, of course, that the tests would be done following the final agreed-upon test procedures.

Research prior to that in order to develop the necessary test procedures, performance standards, if it's appropriate for NIOSH to do that, I have no objections to that, or if NIOSH would elect to have a private laboratory do it for them under contract, I would have no objection to that.

DR. QPOLD: One last question then, Paul.

If you had to give me a yes or no whether or not NIOSH ought to stay in the business of testing, and we'll use the word certifying health hazard measuring instruments, such as ionizing radiation, survey meters, sound level meters, explosimeters, gas detector tubes, you can go on down the list, would you say we should or we shouldn't?

MR. BOLTON: To answer that yes or no, I'd say yes, I think that is an area where NIOSH can be involved in with certifying approval process. Whether they actually do the necessary testing of new devices or whether that's done by others, I think that could be satisfactorily done either way.

DR. MAY: Any other questions or comments for Paul? Thank you, Paul.

I'd like to add just one comment at this time, and that relates to a statement that Paul made and also to Jim's response.

One thing I've heard over the past seven months from everybody, both from within the program and outside is the fact that 30 CFR 11, the test requirements are grossly inadequate and are archaic antiquated and come from the 19th century, and we certainly have limited resources in the institute at this point to deal with updating those requirements,

and I, for one, would be strongly in favor of, and I'm sure the program would be of utilizing every available resource to help us as quickly as possible no matter which mode we adapt to to update 30 CFR 11 to the state of the art.

To me, from what I've heard, at least, there are things in 30 CFR 11 that we could change today, tomorrow or next week, simply move the state of the art up to what it is in 1980 from where it was when it was adopted.

There will be a lot left over that will require research, and certainly we have to get that research underway and ultimately produce a set of test requirements, again regardless of who essentially does that testing in the future, move it along to the point where all of the test requirements are meaningful and are oriented toward the environment for one that the equipment is put into use.

So I think a comment was made yesterday by Bill Revoir about the ANSI Ad Hoc Committee, and I certainly think that the institute will not ignore those resources and that we will use not only their committee to an extent, but anyone else who can provide some input to updating 30 CFR 11 to something more meaningful than what we have today.

Our next presenter, and we are running ten minutes ahead of the program exactly, because yesterday Albert Scalone from Dayton T. Brown gave his presentation, and, thus, will not be on the program this morning, so if Kenneth Vaughan is present from Racal Airstream, we will go ahead.

Our next presenter then will be Kenneth V. Vaughan from Racal Airstream Incorporated right here in good old Rockville, Maryland. Ken?

MR. VAUGHAN: Good morning, ladies and gentlemen. Can everybody hear me? Obviously not.

Racal Airstream is a manufacturer of powered air purifying helmets, products which are approved by NIOSH as permissible respirators.

However, I feel no obligation to be here today to present a mandate from the manufacturing sector of this industry or to be here as a delegate from any lobby group.

From what I've heard of some of the opinions expressed in the last few days, the opinions I'm going to express may well be considered to be radical, perhaps even heretical, perhaps even lunatic.

But we present these opinions, I present them here as judgments, very mature, very considered judgments, not solely as manufacturers, but as people

part of this particular society who need to behave in a responsible manner, particularly as a manufacturer, in a responsible manner towards those people who use and depend upon our product.

So we offer these comments in a constructive and a considered way, in fact as a direct reaction to the process, the remarkable process that has brought about this public meeting.

I think we should consider that for just a moment. It was a wise and a courageous decision to commission the independent consultants report, and to make that report public, positively public.

It was also wise, and it was necessary to offer this public forum as a means of obtaining relevant inputs, and I think this whole process, the whole process is a commendable example of responsive, responsible and open government.

I welcome too the supplementary information as it was presented in the Federal Register. This is a professionally and generally very objective identification of the options available to the institute.

In fact, NIOSH has brought to us, its constituents, its management options in a way which is clear, precise and, at least to me, very understandable, and I welcome that, I welcome that very much.

Any restructing of the NIOSH test and certification program that is to be done must be guided by one principle, and that principle is the need to protect end users.

It's the end users of our equipment that need to be protected. I believe this to be the principle that has led NIOSH to bring out this re-evaluation procedure, because after having studied the proposals and after having been involved in the background and some of the activities that led to the report, it's clear to me that these proposals are guided by the principles that the end user is the most important person in this very complex interaction between government, manufacturers, employees and employers.

Also, my perception of the proposals as they are presented is that NIOSH have a desire to be consistent, and, therefore, although I do have some disagreements with some of the options presented, I support, and I support very strongly, those aspects of this proposal that are the most significant and the most important aspects, and I think there are three.

There are three fundamental statements of philosophy in this document which is before us, and these three are much more important in my view than

some of the details which are scattered throughout the proposals, and I'd like to address each one of these three separately and to give you my opinion on them.

The first question is, should there be a NIOSH test and certification program, and our answer is yes, definite, positive, unequivocal yes, there should be.

In the Federal Register, there are four alternatives listed, and I'm sure if I refer to them as the four alternatives, everyone here will know what I'm talking about.

We support alternative two that NIOSH develop a new testing and certification program making major revisions to the existing program, leading to regulations where NIOSH and NIOSH alone would test and certify respirators.

I would support NIOSH being able to contract certification testing to other laboratories provided that the laboratories concerned were truly independent and provided that the laboratories concerned were known captive.

I'm sensitive, as I'm sure other manufacturers would be, about my product being put into a potential competitors laboratory for certification purposes.

I do not support a program that would allow other laboratories to approve respirators directly.

I do not support a program that would allow manufacturers to sell certified products.

The second basic question is should the tests, the certification tests, as we now know them, should they be replaced with performance specifications, and my answer is again a definite yes.

The change in emphasis is vital at this time because it relates to the users' environment, not because it's convenient for manufacturers and not because it's convenient to NIOSH, not because it's convenient to employers, but because it relates to the end use of our equipment.

Technology is improving. Applications are changing. Requirements are tougher, and users are becoming more aware of their needs, and all these factors lead to a requirement for increased end user assurance which would be achieved by a move to performance specifications away from engineering specifications.

A third major question is, should a field audit program be a major part of the NIOSH involvement in product monitoring.

Again, my answer is a definite yes. An

audit test program could provide real continuing assurance of product performance in the real world, and, of course, it's in the real world and not in the laboratory where end users live and where end users are exposed to occupational hazards.

Now, I support these three major principles that the test and certification program should be operated solely by NIOSH, that the engineering specifications should be replaced by performance specifications and that NIOSH should operate the field audit program.

However, the procedures and the details must be worked out, they must be technically sound, practical and effective, and, of course, we have no proposals here today on procedures and details and systems, and so we cannot comment on any proposals as such.

It will not be easy to define performance tests. Performance at the end user level is a function of various characteristics including filtration efficiency, face fit, wearability and comfort, and all these product characteristics need to be considered in performance specifications and in the revision of the NIOSH certification program.

Field audit results again would be very

difficult to obtain, very difficult to assess correctly, because field performance is a function of outgoing quality, reliability, maintenance, use or misuse and environmental stresses, and the audit program will need to consider all these aspects in a way that is statistically meaningful.

Perhaps NIOSH should stratify its audit effort placing a much greater emphasis on equipment whose failure would cause death or injury than on other items.

Now these concepts and the programs and the formats to be used should be arrived at by enlisting the use, the aid of outside specialists and outside consultants and outside opinions and must obviously be open to public comment before being adopted.

They are my views on the major philosophical matters, as I see them presented in the Federal Register and in the consultants' report.

I would like to offer the following comments on some of the more detailed proposals, and I'll do this very briefly, because I don't think at this state of our proceedings it is worth dwelling on.

I welcome the requirement that the applicant should certify that an effective QC plan exists rather than the existing rather cumbersome and probably

ineffective evaluation of procedures and documentation.

I agree that NIOSH did not need and should not require detailed dimension drawings. I think a parts list and an airplane drawing will certainly serve to control the configuration which is the purpose of this particular requirement.

I agree that non-significant changes do not need NIOSH reviews, but that redesigned items should be resubmitted.

I believe strongly that applicants do have the right to witness certification testing, but that this right must not affect the correct conduct or the scheduling of the tests.

One light moment. It took me four years to learn how to say scheduling and forget how to say scheduling (English pronunciation). I can even say aluminum these days.

I have some difficulty with the concept of approvals being for a fixed period of time only. If the field audit program is effective and regular acceptance tests are being performed by NIOSH, the sunset requirement is not necessary.

Again, perhaps NIOSH should require resubmission of life supporting and life preserving devices while relying on the audit program to control other

types of respirators. The NIOSH requirement too would have to be for a resubmission date, not for a reapproval date, since the NIOSH workload should not be allowed to penalize an applicant.

For example, if my sunset date is the first of January 1985, and I submit on the first of July 1984, if the test program is not completed because of a workload at NIOSH, I do not see why I should be penalized for that.

I agree the AQL's, acceptable quality levels are not good guidelines for quality control. A sampling plan for inspecting a lot to an AQL of one percent is statistically arranged so that if the lot is one percent effective, it will almost certainly be accepted and not rejected.

However, the AQL tables are very widely used in a more precise guide to the use of AQLs would help to improve the theoretical outgoing quality.

Now, we at Racal, like I'm sure many other manufacturers do, we have a 100 percent test and inspection stages at various points in our assembly operation including the final stage.

I believe that prototype testing is a very important activity. Some of the NIOSH test procedures are very difficult to duplicate, and manufacturers, us

among them, are reluctant to invest very large sums of money in tooling and in processing equipment without the final assurance of success in the NIOSH laboratory.

It is likely too that the products that need prototype testing are those that are new, have unusual features and those are the very ones that might bring new benefits to the end users.

I believe that prototype testing should be accepted and scheduled by NIOSH as if it were a normal application requirement.

I find the proposal for group testing of respirators to be commercially unacceptable, technilogically inhibiting, and possibly discriminatory. I don't like that.

Several aspects of the present program were not covered by the report or by the proposals, and I'd like to mention two of them briefly.

I belief that communication and interaction between NIOSH and its constituency is important, both at the management level and at the techincal level.

I would support regular conferences to develop understanding and technical cooperation. Finally, the progress of applications, the certification, is a concern for manufacturers. I believe the

manufacturer is entitled to regular progress reports from NIOSH. I believe applications must not be bumped to the bottom of the pile because of some kind of minor non-conformity, and I also believe that NIOSH should have a fixed time from the date of application for its evaluation.

I thank you for this opportunity to present my particular perspectives to this meeting.

DR. MAY: Thank you very much, Ken. Questions or comments regarding Mr. Vaughan's presentation?

MR. POWERS: Jim Powers again. I want to take exception to your comment on AQLs.

AQLs are not in any way a measurement that one percent defective come out of the product line. They never were, they never will be, and no matter how the subject is misread, statistically that is not sound.

AQLs are based on a sampling plan basis for which percents of lots can be rejected and not a basis of any given lot of the percent defective within it.

MR. VAUGHAN: I agree with that response. I think perhaps you misunderstood what I said in which case I probably said it very badly.

What I tried to say was that the AQL method

which is presently listed in the NIOSH regulations simply says that for critical factors you should use a certain AQL and for major factors a secondary one and for minor factors a third one which is a method that is broadly used throughout industry, and the method is not good.

The reason is, and if you'll bear with me, I'll see if I can explain it from this curve that I've sketched very roughly on the board, this is the thing that's called an operating characteristic curve which describes the power of a statistical sampling plan.

You can see the shape. This scale on the lefthand side is the probability of accepting a particular lot of a given quality in that this is a high level of probability of acceptance, and this is a low level of probability of acceptance, and a horizontal scale is the lot quality as submitted to that particular sampling plan.

On this side you have a very good quality, and as you go along this scale, the quality gets bad.

Now the way in which the term AQL is used in the professional QA and in the statistical sense is to say that the AQL in any particular even, the event being defined as submitting a sample lot to a

particular sampling plant, the AQL is at a point which is sort of up here, so if I write one percent defective right here and I throw this up, then this number at the top is usually either 90 percent or 95 percent depending on the particular system that you use, so I repeat my basic comment that if a lot is one percent defective, and if it is then submitted to a sample plan for, quote, one percent AQL, then there is a 90 percent probability that that particular lot will be accepted.

There is a very low probability that the particular lot will be rejected.

Now, the point is, of course, that this particular AQL concept is meant to be part of an ongoing quality system. It's not meant to be used in one shot activities.

The truth is that in industry, and I know because we are as guilty at incoming inspection stations as most people are, that we use this because it is so commonly used.

Now, the onset, and what I've tried to suggest is not that we should go on a massive campaign to education people away from using a point at this end of the curve which is called the AQL down to using a point say at this end of the curve which would be

the lot tolerance percent defective or whatever you want to call it, we shouldn't do that, because if we try to do that, we lose.

What we should do is to insure that people use this system in a way which is meaningful, and that was my basic point. I hope that answers the question.

MR. POWERS: I'll agree with that one.

MR. VAUGHAN: Thank you.

DR. MAY: Any other questions for Mr. Vaughan? Thank you very much.

Now, we have at the present time listed a break, but we're running ahead, so what I'd like to do is I believe that Mr. Burd is probably sitting there.

I think we'll go ahead with the presentation listed at 10:45, and if we run past the 10:20, we will break at that point, and try to keep the program moving along rather than keep you here later in the day.

So at this time, the presenter will be Mr. Donald H. Burd, also from Racal Airstream in Rockville.

MR. BURD: Thank you very much. This is the first time I've ever had the opportunity to essentially appear at a meeting of this sort where

in essence it's kind of testimony in one way or another, so I'm a bit cautious, so if you'll permit me to, I'd like to read pretty much what I've written.

In that way, I am consistent with what I said before, last week, yesterday morning or this morning.

I'm Don Burd, Manager of Quality Assurance for Racal Airstream, Inc, Rockville, Maryland. We're manufacturers of devices which have been classified by NIOSH as powered air purifying respirators.

I'm intimately familiar with the present requirements for documentation and quality plans. I do it.

Racal Airstream, Inc. and I welcome some of the recommended changes as proposed in the Federal Register of Wednesday, June 18, 1980.

We eagerly await these changes as a means of making life easier for those of us involved in the preparation of the submittal documents without reducing the quality of our product to the end user.

Reduction in the number of detailed drawings, detailed quality plans and procedures and detailed control of incidental changes all worked to the betterment of the product as effort can be oriented

toward product excellence instead of documentation overkill.

From this standpoint, the whole process of certification and approval will become more efficient permitting the product to reach the end user in shorter time without making the testing and certification process less effective.

It is, however, most important that we who are intimately involved with testing and certification be informed that the progress of NIOSH changes well in advance of implementation dates so that we may offer our comments prior to final proposal implementation.

I'd like to introduce a new problem, one not covered by the consultants' report nor these proposals. The problem deals with multi-purpose protective devices, a phenomenon of the technology of the present and a reality of the future.

The unit we at Racal Airstream, Inc., manufacture is a combination hardhat, face shield and respiratory protective device.

Presently the respiratory protection component is tested by NIOSH and when certification is complete, we put on labels showing that the unit has been approved by NIOSH, et cetera, period.

Our product also meets the OSHA requirements by fully complying with applicable ANSI standards.

There are, however, combination devices for sale in the marketplace today which apparently offer face and head protection and carry NIOSH certification.

For technical users knowledgeable of NIOSH responsibilities, this presents no problem since technical users understand that NIOSH approval only represents approval of the respiratory protection function.

Less sophisticated users may believe, however, that NIOSH approval extends to and includes head and face protection.

This can be as a minimum misleading, and there's an extreme danger.

As an example, let me take you through the testing preparatory to permitting a Racal Airstream helmet to be used in an underground coal mine.

First NIOSH tests and approves the helmet as a respiratory device. Second, MSHA examines the helmet for intrinsic safety as it applies to use in gassy coal mines. That's not the same as the NIOSH/MSHA approval for respiratory protection.

An independent testing laboratory then

tests the helmet for head protection against ANSI 89-1, 89-2 and against -- and for face protection againt ANSI 87-1.

Now that's to get it into the mines. A similar sequence of testing and certification goes on for using Racal Airstream helmets in grain elevators, that is NIOSH takes care of respiratory protection. The independent laboratory takes care of head protection, face protection and intrinsic safety.

Because of a move in technology to combination devices, it's necessary that NIOSH consider programs to certify multi-purpose combination protection devices.

In fact, NIOSH should consider the need to certify standard hardhats and standard face shields. Head and eye injuries still persist in injury and can be as deleterious to health and welfare as respiratory injury.

TE certification of respiratory protective equipment in non-IDLH situations is considered important by NIOSH, then it's also important to other personal protective equipment.

This suggests a very close linkage between NIOSH requirements and requirements of other applicable standards of organizations such as ANSI.

Now when these criteria are being developed, let's not overlook the impact these standards will have on overseas standards for technical and leadership reasons.

Wherever possible, attempts should be made to be compatible to these overseas standards and requirements, and if I may add just one thing, we're talking about where are we going to get the information to do certain things.

Well, you know, there are other countries that are doing some beautiful work. Why not talk to them and ask them what they're doing in a specific area?

Maybe that could save us a heck of a lot of time instead of having to develop new procedures here the first time out.

I understand when I was in Houston people were talking about what was going on in England, in Italy, Japan. There are other people working on this. Thank you so much.

DR. MAY: Thank you, Don. Comments, questions?

Thank you. Now, as in the previous example, I would like very much if Carol Dupraz is available, and I see her, if she would agree to give her

presentation now, following which we will have a coffee break, and the last presenter of the day on the program will be John Locke, and I have a few additional comments to make after that, and I think Dr. Opold may have a few comments to make also.

So at this time Carol Dupraz representing Racal Airstream.

She is the only repeater on the program.

MS. DUPRAZ: Is that typical of a woman, she likes to talk a lot?

I'd like to elaborate a little bit on some of Ken's comments and offer some additional thoughts on one or two areas which I don't think have really been explored sufficiently, at least in the parts of the hearings that I've heard.

I'd like to make some suggestions with respect to prototype testing. There has been some feeling that prototypes should not be accepted by NIOSH.

I personally see, and I think Racal sees, that there is an important role for a certifying agency in this regard.

I'd like to suggest that NIOSH would accept and process or test in a timely fashion at least two kinds of prototype equipment. One would be non-production items as fabricated, and after they have

been, let's say, in a field trial for which there are no certification criteria or performance test methods yet in existence; the other type would be production items as fabricated which have a successful history of use outside the United States as Don alluded to.

Submission of the prototypes, however, should be accompanied by some documentation which demonstrates that they do provide some adequate protection and have in-service reliability.

Priority might be given to products which are at least claimed to meet an emerging new or critical need as far as respiratory protection is concerned, prototype submissions for which there are no certification protocols yet in existence might even be accompanied by suggestions for appropriate approval and performance test methods.

There may be some background either within the manufacturer's house where they have done previous exploratory work, or if it is an item of foreign manufacture, there may already be some procedures in the works which would be very helpful in this regard.

Requests by actual or potential users for NIOSH examination of these classes of prototypes might also be either a condition of submission or part

of NIOSH's consideration in looking at the question of prototypes.

NIOSH might specially encourage submission of untried prototypes which purport to offer needed protection against newly identified or identifiable hazards, and, in particular, those end uses for which the market potential may be small or unprofitable if the manufacturer were to have to bear the entire productive development burden.

In accepting and reviewing product prototypes, NIOSH might also provide guidance to manufacturers in maybe trying to select one of several products to market for a specified end us, certainly input from a certifying agency with experience in testing and approving occupational health and safety products would be valuable to all concerned, both the manufacturer of the agency and the ultimate users.

(End tape.)

For new types of occupational health and safety products, NIOSH prototype testing could serve as the basis for establishing which test methods and what performance criteria should be used for developing pre-approval submission data and a functional basis on which certifications would be determined.

Finally, however, if only manufacturers and

NIOSH were to have experienced personnel and appropriate test facilities, as would be the case under options one, two and four, there would be no opportunity for a manufacturer or marketing organization to confirm its proprietary technical evaluations of product performance unless NIOSH were to accept prototype submissions for testing.

The value of product prototype testing by NIOSH would however be severely undermined if no discussion of the NIOSH prototype testing results were possible.

Furthermore, since at least some portion of prototype submissions would be products for which no certification criteria or test methods then existed, detailed discussion of the results of the NIOSH evaluation would seem inescapable as a natural consequence of the process.

The other topic is the publication of test results. There have been various options talked about and discussed, and I would like to offer a little thinking in this as a means possibly towards clarifying some of the options that may be available.

I see that there are at least three types of test results for which publication of some sort

deserves consideration. One would be publication of the result of prototype testing conducted by a certifying agency.

I think this should be voluntary and mutually agreeable to both the agency and the party making the submission and that this would cover both the content and the publication vehicle.

Since the organization making the submission may very well consider the results of prototype testing proprietary and will have paid for the service, the submitter should initiate any proposal for publication of test data, approval test data.

In the interest of providing users of occupational health and safety products, a higher level of competence and certified equipment, approval test data should be published by the certifying agency; however, applicants must be given the opportunity to review, contest and/or appeal data prior to publication.

Data publication should occur within the time frame in which product approvals are granted, but certification certainly should not be delayed until data is published.

Certifications might, however, include a date no later than which the test data would be

published. It does not appear to be any special value in automatically publishing test results for cases in which certifications are denied.

However, there may be some implications here beyond the United States market which need closer examination, and the third type of data is the field audit data.

Field audit data based on standard performance criteria and test methods should be published regardless of the outcome, but after manufacturers and/or users have had an opportunity to review, contest or appeal findings.

Results of any portions of field audits which utilize tentative test methods or proposed criteria should be handled as would the results of prototype testing, that is published only by mutual agreement.

The type of publication that we're talking about has really not been defined. I have not heard any of the people testifying at that hearing nor have I see any evidence of kinds of publication vehicles that may be under consideration.

I think the range is quite broad. It might take the form of Federal Register notices, technical journal articles. It might be in terms of NIOSH

documents or bulletins. It might be in industry newsletters, trade magazines, periodic reports from testing and certification facilities as the matter to the list of approved equipment is published.

It might even be in the form of press releases where the copy of the computer print-outs with the test data.

The publication modes which would probably best serve users is yet to be identified. Furthermore, the most appropriate publication route may also depend on whether the data relates to prototype approval or field audit test results.

In this regard, the type of publication, I think that there needs to be a great deal of consideration given here to what kind of data -- what kind of test series and where it's going to be published, will it adequately reach the audience, will it be meaningful to the audience.

On that last point, the form of the published data, publication of raw test data would be meaningful probably to a very limited number of individuals in the user segment of the population where publication of results only in terms of pass/fail doesn't really add much more to the certification credibility than

we have now. However, since certifications are issued, at least now, on the basis of minimum performance criteria, publication of qualitatively descriptive results which indicate significant differences in in-use performance could be very helpful to users in making equipment selections.

Since devices will be evaluated for certification against a battery of performance criteria, qualitative ratings would serve to highlight stronger marginal performance properties of particular products.

Qualitative ratings would also relate directly to a specified range of quantitative values obtained in standard performance tests.

I think this would be a step forward in educating users and increasing their confidence in certified occupational health and safety products. Thank you.

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

MR. POWERS: Jim Powers again. I'd like to make a comment. This field audit that everybody keeps talking about starting, the only thing that's new in the proposal is the used units in the audit.

The field audit program has been an ongoing program for some four and a half years at TCB, and

it's nothing new. It may be just coming to light, but the data has not been published. It's been a relationship between NIOSH and that particular manufacturer that was involved.

So if people think anybody, users think that the field audit program is something new, then it is not. It's been going on a limited basis for four and a half years.

MS. DUPRAZ: I don't think that requires a response.

DR. MAY: I'd make a quick response that what Jim said is absolutely true, except that I think the program has been operational, has been very minimal and in the future, we would envision when we get into this a much more dynamic program that would take into consideration the statistical implications, et cetera of samples and to make sure that we're getting some meaningful data out of the field audit program, not necessarily what we've been doing with it.

Thank you, Carol. If there are no comments or questions, I think we're going to take a morning break, and please be back and about 10:35.

(Whereupon, a brief recess ensued.)

DR. MAY: If you'll take your seats, we'll get on with the next speaker and finish the public

hearing, public meeting, excuse me, public meeting.

Our next presenter is John W. Locke who is coordinator of the National Voluntary Laboratory Accreditation Program referred to as NVLAP, U.S. Department of Commerce, Washington, D.C. John?

MR. LOCKE: Good morning, ladies and gentlemen. The purpose in coming here this morning is to acquaint NIOSH with the services available under NVLAP should NIOSH decide to pursue the third alternative for respiratory protection and testing.

We note in the consultants report, entitled "Evaluation of the NIOSH Certification Program" that, quote, "In the event the certification program is expanded to include outside labs," there was a mention of a possible use of NVLAP.

We thought it would be appropriate to describe NVLAP for NIOSH consideration should that be a viable option.

Before I discuss the details of NVLAP I think we need to talk about some general definitions, but let me conclude first with the consultants side cite of title 15, part 7A of the Code of Federal Regulations as the identification of the NVLAP procedures.

However, NVLAP also has optional procedures

covered by title 15 in part 7B and 7C. The optional part 7B procedures which were published on March 9 of 1979 are for use by federal agencies in requesting a laboratory accreditation program under NVLAP.

These part 7B procedures would be of particular interest to NIOSH.

Before I talk about those procedures, I'd like to sharewith you some background and philosophy under which the Department of Commerce operates NVLAP.

This may, in fact, answer some of your questions. We define laboratory accreditation as the formal recognition that a testing laboratory is competent to carry out specific tests or types of tests.

This definition essentially conforms to the ASTM definition, E36, a definition in the -- being development by the International Standards Organization. It's also a definition pretty much conforming to the group of laboratory accreditation systems which has been getting together internationally for about four years, called International Laboratory Accreditation Conference.

In this definition, laboratory accreditation does not include the development or promulgation of test methods or standards, and, in fact, the NVLAP procedures specifically prohibit the development or

modification of product standards or test methods.

Laboratory accreditation also does not include the act of certifying that a product meets a standard.

We define that a product meets a standard. We define certification as a process of assuring that a product meets the quality performance or safety requirements.

We find in this way certification inherently includes three distinct functions, developing and promulgating product standards and test methods which specify what requirements are to be met and how the products are to be tested, a separate function typically carried out by the voluntary standards community.

The second function is testing the product, using appropriate test methods to determine if the product tested does, in fact, meet all the conditions stipulated in the standards.

The third element of this certification, overall certification program or system, would be certification process which is often referred to as simply certification which defines how many products in a group of products must be tested to reach the desired level of assurance that each product meets the desired characteristics of quality performance or safety.

These definitions are evolving. Clearly, these are not the definitions that OSHA uses. That definition includes certification, and the definition evolving here deals only with the evaluation of the competence of the testing laboratory to perform the tests properly, so it's a limited NIOSH use of NVLAP would be limited to that specific element.

There was some reference this morning relating to a certification program which would use other laboratories for testing.

That is in the vein of what NVLAP does. Certification processing will provide the degree of assurance desired either by using statistical selection from the group of products to be tested or by making use of the manufacturer's quality control system which typically includes such statistical sampling, statistical selection procedures in evaluating components and materials from which the product is made.

Certification processing often includes provisions for recordkeeping and product labeling.

We've often been asked why doesn't NVLAP, can't that be used for certifying products. When the decision to proceed with the laboratory accreditation program was made, the complexities dealing with the certification issue were felt to be such that the

Department of Commerce was not in a position to perform those activities.

Those activities include such things as a knowledge of the production process, decisions upon how to integrate quality control programs with product selection for testing or component selection for testing and the trade-offs that go with those kinds of decisions.

It was felt that the decisions inherent with certification are peculiar to individual industries and could not be handled in a very broad sense or industry say as a whole.

So in our sense, and I think in the sense used by the worldwide community, laboratory accreditation addresses only the testing of a product.

Laboratory accreditation systems have been developed because significant sections of the community of commerce, as well as the government, have an interest in insuring that the laboratory test results can be relief upon and are obtained in an efficient manner.

It's for this reason that NVLAP was established by the department. The major purpose of NVLAP, major purpose is to provide the nation with a source of nationally recognize competent testing laboratories.

Among the objectives of NVLAP are to process new accreditation programs when the need is established, to provide an accreditation procedure which others can use in lieu of developing a new laboratory accreditation system.

To reduce the number of frequency with which different agencies and groups evaluate the same laboratory by coordinating accreditation activities.

NVLAP was formally established with the publication of the general procedures in February of 1976, the same part A procedures that I mentioned earlier.

These part 7A procedures are lengthy and somewhat cumbersome. From experience, we've found that it takes about two years to establish a program under the part 7A procedures.

This was true for our first program covering thermal insulation materials, thermal insulation test methods and for our second program covering concrete test methods.

That's primarily why two sets of optional procedures, part 7B and 7C were established in 1979. The optional procedures substantially reduce the time it takes to establish a laboratory accreditation program.

Now, just describing how NVLAP works, in order to start a program using the part 7A procedures, a written formal request can be submitted by anyone, but we operate on the basis of request.

We do not ourselves initiate programs. The request must include identification of specific standards and test methods to be included in the program.

There is no program without a well established valid set of test methods.

The requester must describe the need for a program by first estimating the number of laboratories that may want to become accredited, and, second, estimate the number of users of testing laboratories that may desire services of accredited laboratories.

Once the markets define, four questions must be answered.

Why would NVLAP accredited laboratories benefit the public? What is the national need for laboratory accreditation that is not now served by the existing programs? Is it feasible and practical to accredit laboratories under NVLAP, and why should the federal government be involved?

If these questions are answered satisfactorily a preliminary finding of need is published in the

Federal Register. After a 60-day public comment period, the department decides based on the comments whether to make a final finding of need, thus establishing the program or to withdraw the preliminary findings of need.

Now, once the finding of need has been established, if it is established, then an advisory committee is formed under part 7A procedures, and this committee meets to recommend criteria that the laboratory should meet for -- to be accredited.

That process probably takes about eight months, to get the advisory group formed and recommendations put forward.

I should say then those are taken by the Secretary, published as proposed criteria, a 60-day comment period, and we do not announce the program, availability of the program to the laboratories until the final criteria are published in the Federal Register.

That's what takes the two-year period or a little less.

Under the optional part 7B procedures for use by federal agencies, any agency may make a request for a program.

No separate finding of need is made by the

Department of Commerce since its requesting agencies legislative or regulatory prerogative to determine the need.

The Department of Housing and Urban Development is the first agency to use this option.

In May of 1979, HUD requested that NVLAP accredit laboratories that conduct tests as part of the HUD certification program for carpet.

The availability of the carpet program was announced in January of this year. In other words, laboratories were invited to apply.

The application deadline was in May, and we are currently assessing the applicant laboratories and plan to announce accreditation determinations by October of this year.

Based on this experience, we believe that it should not take more than one year before the request from a federal agency is received, and we begin to accredit -- we begin accrediting the laboratories.

The qualification requirements that a laboratory must meet in order to become accredited are called criteria.

Under general part 7A procedures, criteria are developed through recommendations of an advisory

committee composed of an equal number of private and government interests.

Under the optional 7B procedures, the requesting federal agency has the option to recommend criteria or to request an advisory committee be formed to develop such recommendations.

HUD chose to recommend criteria for the carpet program.

Based on the recommendations received, the Department of Commerce proposes criteria for evaluating the laboratories in the Federal Register for public comment.

After the comments are resolved, final criteria are published in the Federal Register. Once the program is establish and criteria published, any laboratory, whether it's public or private, independent, in-house, domestic or foreign may seek accreditation.

Fees paid by applicant laboratories are tailored to each accreditation request. The fees depend upon the number and types of test methods for which accreditation is sought as well as a number of programs applied for.

Significant discounts are incorporated into the fee formula for those laboratories applying for more than one program.

The National Bureau of Standards is responsible for evaluating the applicant laboratories. NBS draws on in-house expertise and hires technical experts to conduct the evaluations.

These evaluations are based on three inputs, the information provided as part of the application package, plus information provided by the laboratories, an on-sight examination of the laboratory, and the results of any proficiency tests which may be required for some of the test methods.

NBS recommends the granting or denying of accreditation to the Department of Commerce which makes the accreditation decision.

Deficiencies uncovered are fed back to the laboratory in ample time provided for corrective action before NBS recommends any denials.

Nevertheless, if the department proposes to deny accreditation, the laboratory may appeal through formal administrative procedures.

Accreditation decisions are published then in the Federal Register. A review of each laboratory's accreditation status is made annually based on periodic on-sight examinations and proficiency tests.

The frequency of on-sight visits is from one to two and a half years depending upon the particular

needs of each program.

Proficiency testing is typically scheduled about every six months; however, this may vary, depending upon the type and complexity of the test methods and the nature of the product.

So the system has quite a bit of flexibility. Accreditation criteria currently used by NVLAP are broken into two categories which we call general and specific criteria.

The general criteria focusses on the overall laboratory operation and addresses things such as organization structure, management and technical direction, professional and ethical business practices and the laboratory's quality control system.

The specific criteria are stated in fairly universal terms and derive their name from the fact that they apply specifically to each test method for which accreditation is sought.

The specific criteria address the personal competence, training, qualifications, equipment, facilities and procedures including calibration maintenance, test plans, et cetera, and recordkeeping including new data, test reports, audits, specimen handling, documentability, et cetera.

The specific criteria are tailored to each

method by what we call supplemental information. The supplemental information indicates how the specific criteria are to be interpreted and implemented for each test method or group of test methods.

This was felt necessary, because some test methods are very simple and very straightforward and do not require elaborate calibration perhaps, and so there's an interpretation which means that the criteria are lessened in those cases where there the test method does not require all elements of the criteria to be implemented.

This is particularly characteristic of some of the test method standards which are available in the standards community.

The specific criteria are tailored to reach test method -- pardon me. I think that kind of describes NVLAP.

Further details of our program are covered in the documents that I'm submitting with these comments which include basically the annual reports.

However, our 1980 annual report which I expected to be printed by today is not yet available.

Hopefully, I've indicated in general terms how NIOSH could utilize the NVLAP and design its certification program to include the use of NVLAP

accredited laboratories.

Let me make it clear that I'm not an expert in the problems of respirators, and we are not suggestiong that implementation of alternative three using NVLAP is a proper course of action to choose.

That's for NIOSH to decide. However, we do know something about laboratory accreditation and product certification, and we're willing to offer the services of NVLAP if NIOSH deems this appropriate.

So if you have some questions, I will try to answer them.

MR. JACOBSON: Murray Jacobson, MSHA. Could a government laboratory come in under the certification or accreditation program?

MR. LOCKE: A government laboratory certainly could be accredited under the program. As a matter of fact, in the concrete case, there was some consideration at Department of Transportation of what should be done with respect to government laboratories in that instance.

MR. JACOBSON: Thank you.

MR. CAMPBELL: Don Campbell, NIOSH. Your comment on page two states that there can be no program without a well establish valid set of test methods.

I'd like to ask you to expand on that just a little bit, and in particular to ask you if you mean by that that the test methods should be validated, validated in the sense that they have been demonstrated to be reproducible.

MR. LOCKE: I think the answer is yes and no. The reason that was put in was that I think the private sector was not anxious to have someone working over the standards in some way, that that really is a function of whoever develops a standard.

It could be certainly an OSHA regulation or whatever, so the intent was to make it crystal clear that we will not do that.

Now we come to an issue particularly in proficiency tests as to what is reproducible, and here we often rely on the advisory committees to address the issue of what is a reasonable accuracy and precision requirements for the program.

Now, as you may know, the voluntary standards community is attempting to put in precision requirements in all their test methods. Many of them are not contained at this point in time, so we need to do it in terms of a proficiency test program.

I would say that we do not take an arbitrary

decision, however, on the results of a proficiency test.

In other words, if someone comes in with a piece of data that is below some precision or accuracy which we have used as the basis for judgment we do not automatically disqualify that laboratory, but we do, in fact, take that into account in the evaluation or in the decision of whether we should proceed with continuing accreditation of the laboratory.

MR. CAMPBELL: Would it be fair to say then that a properly validated test method would be a primary concern of the program in that without such reproducible test methods the program could not function properly or with any meaning.

MR. LOCKE: Well, I think we operate under that basis, but when you say properly, that's a very big subjective area.

We have such things as the E84 tunnel test which is a test required by, let's say, testing of flammability of insulation using a 25-foot-long flame tunnel.

That test has been under some serious comment for a number of years; however, it is adopted and used and required in many states and for many different programs, so it is -- as we see it, it

is a valid test, and we have included it in the program although there is some question about its accuracy and precision.

MR. CAMPBELL: The specific problem that we at NIOSH would have in using such a program is that the test methods that are now in the program have never been validated to demonstrate that they are reproducible, and, in fact, in many cases we suspect the reproducibility of the tests, so in view of that situation, could you comment to the extent that this program could be useful in this situation?

MR. LOCKE: Well, we certainly believe that part of our responsibilities is to provide feedback to the standard developers and so if we establish a proficiency test, and we usually do that with the requester determining what is reasonable with the concerned community basically, because we believe that it's important to have proficiency tests.

On the other hand, if you had a proficiency test for every test method, all the laboratories would be doing would be proficiency tests, so we have to have some reasonable judgment.

We do think proficiency tests are really significant and should be incorporated in each

program to some extent, particularly the most complicated test.

Now, we believe also that as these proficiency tests produce data, we will then feed that back to the standards community almost as if it was part of a round robin test in the development of the standard in the first place, but they will get feedback from our program which would help them to determine where the standard possibly should be changed or at least to be more specific about what the precision and accuracy is.

So we also believe that in implementation process, if we have difficulty implementing some aspect of the standard, it's our responsibility to report that fact to whoever developed the standard to ask for or to suggest that some change in the standard would be appropriate for the following reasons.

So we expect a considerable feedback as we gain experience in the program. Yes, sir?

MR. BRENNAN: Bob Brennan, Scott Aviation. Being relatively unfamiliar with your program, I would like to ask you what, if any, classes of laboratories or technical institutes or technical establishments might be excluded from your program and specifically,

going back to a comment raised by the people making the presentation from Racal, what is to prevent a laboratory which is affiliated in some way with a competitor from being accredited to test the competitor's project.

MR. LOCKE: Well, the program by incorporation and procedures does not allow us to discriminate between an in-house laboratory and a third-party laboratory and so on.

There was one reason for that and that is that definition of a third-party laboratory is pretty much subject to the perspective of the person making that decision.

It's very difficult. If you end up with a decision that says, you know, if 20 percent of your business is with more than one firm, you're really not a third-party laboratory, and then you have to get into business records and all kinds of logic like that.

It may or it may not be appropriate in specific programs to use third-party laboratories. That's not our decision to make.

For instance, if NIOSH would decide that third-party laboratories were necessary, then they could certainly indicate whatever criteria they

needed for third-party laboratories. The third party NVLAP accredited laboratory.

Now there is a use for industry, I think there is a need that industry has perceived anyway. They'd like in many instances to have their laboratory really evaluated in the same way that a third party laboratory is, so they can have confidence in the testing that's done privately irrespective of how it relates to a certification program.

So we felt that that was serving a useful need also.

MR. BRENNAN: One more further question. There is nothing then in your by-laws, there's nothing in your organization that would prevent any laboratory from responding to a call for interested laboratories in a -- I keep wanting to use certification -- an accreditation call.

MR. LOCKE: That's correct.

MR. BRENNAN: And, in fact, which laboratory gets what assignment would be a function of the way the program would be set up by NIOSH and not anything to do with your particular organization.

MR. LOCKE: That's correct.

MR. BRENNAN: Thank you, sir.

DR. MAY: Any further questions or comments

for John? Thank you.

PARTICIPANT: I think I'm going to turn to a specific, John. We certainly have known about the NVLAP, and that's why we encouraged the comment to be made to the panel, and I guess you had a little experience. The last time I talked with some of you people, you were just starting out, and I guess it comes down to some actual experience data, and really in the carpet, let's take that as an example with HUD, how much of a fee did you charge?

I'm not expecting an exact number but in a range of cost that these laboratories are paying you or have paid you or whatever, and also, what did it cost HUD?

MR. LOCKE: The average fee on the carpet program is about $1050 per laboratory.

PARTICIPANT: Per laboratory?

MR. LOCKE: Per laboratory. The fees on the insulation program were somewhat higher because there were more tests. The fees vary on the number of tests.

The fees for concrete are somewhat less.

PARTICIPANT: Is that the fee that the laboratory is charging whoever, or is that your fee? I'm interested in what you charge to get accredited.

MR. LOCKE: That's the fee that we charge

the laboratory. That's the fee that the laboratory pays to us.

The program is designed to be self-supporting eventually. At the moment, it has some commerce money in terms of developing the program.

There is considerable work that we have to go through, for instance, if there was a program with NIOSH, our evaluation staff would have to go through a rather rigorous assessment of the test methods.

We would have to train the people going into the field to do the evaluation so there is some overhead associated with getting a program underway.

We have -- that overhead money has been coming from appropriations, but the actual cost of going out and evaluating the labs and evaluating the proficiency testing is paid for by the laboratories.

Now, is there a fee to HUD? There was not a fee to HUD.

There are limited resources. If we ended up with 30 requests, we would not be able to handle 30 requests, so if the request for laboratory accreditation programs are reasonable within bounds of our available resources, there is no charge; however, if an agency felt that it wanted the program to begin

and we had not the resources, there is a provision for some transfer of funds to assist in the rapid development of that program.

MR. BRYSON: I'm Jim Bryson. I'm with the National Bureau of Standards. I'm with the organization the provides the technical support to the NVLAP program, and I just wanted to add to John's comment about the fees, as further explanation, those fees range over -- in the case of carpeting, a value of about -- from about $350 up to maybe 12, 13, $1400 depending on the test methods that the laboratory chooses to be accredited for.

So John's explanation of about $1000 is an average, and that's the same in the other cases of the thermal insulation material lab too.

PARTICIPANT: I had another question, and it had to do with a comment that you were making on the bottom of page two, and it had to do with number two says, what is the national need for laboratory accreditation that is not now served by existing programs.

Who and how is this determined? Maybe you explained it, and I didn't catch it.

MR. LOCKE: No, I didn't explain it. Basically, we ask the requester to identify any

other laboratory accreditation programs or certification programs or any other programs dealing with evaluation of laboratories in the particular area in question.

We ask him to make a statement about that, whether it's adequate, not adequate, if it's not adequate for what reasons. If it's adequate, we presume he wouldn't ask for it, so we must presume it's probably not adequate for some reason or another.

We publish that in the Federal Register for comment, and we respond to those comments that come in on that, whether there's agreement or disagreement that that is a need.

Now, I think that, for instance, in the concrete area there's this cement and concrete reference laboratory program now in existence.

That program does evaluation of laboratories, but does not provide accreditation of those laboratories, so this was explained and described and basically the public was asked to comment on that situation.

Yes, sir?

MR. POWERS: I have a question. My name is Jim Powers. As one of the options that's listed

by NIOSH as using accredited laboratories, and I was noticing in your talk here that the 7A procedure takes two years, and you revised it now and you come up with the 7B procedure, and you believe you can get that done in one year, and now we're looking for some kind of instantaneous response from this three-day conference, and it's going to take anywhere from one to two years to accreditate a laboratory.

I don't see where there would be very much immediate assistance to NIOSH with this kind of a time frame.

MR. LOCKE: Well, let me summarize what the timeframe is.

It took us a little longer in the HUD program because we were combining that program with insulation program, and there was a revision of the criteria and so on, but we believe the program is stable now.

So if we get a second request from HUD which we're expecting shortly, we think that we can announce to the laboratories availability of programs in about six months.

This means that we have to publish in the Federal Register the criteria which will be used to evaluate laboratories and whatever new product area it is so that those laboratories doing that

but never applied to a respirator.

How would you react to that laboratory for accreditation?

MR. LOCKE: We would not have anything to do with that program. There are some questions that have arisen with respect to will you accredit a laboratory for getting the right answers, and we would say no.

We will accredit a laboratory for performing the tests competently and properly. The tests have to be recognized tests and they have to be specified.

Now, in the area of corrosion, we have two ASTM tests in corrosion which are used, for instance, with insulation.

We do accredit laboratories a test for corrosion caused by insulation, according to the requirements of those tests, but to ask an accreditation system to accredit a laboratory on the fact of whether it gets a right answer or not is beyond an accreditation system, as far as I can see, because how do you determine whether he's got the right answer or not. You've got to go to the test method.

That's the very thing that's missing, and if it's missing, how can you accredit somebody to get the right results.

DR. OPOLD: So you wouldn't try to extrapolate from the ASTM insulation corrosive tests to respirators in any way? You would definitely stay out of that?

MR. LOCKE: We would not extrapolate, but you might want to extrapolate. If you want to put the requirement on, then that's you prerogative.

DR. OPOLD: Okay, thank you.

DR. MAY: Any other comments or questions for Mr. Locke?

Thank you, John, very much. Okay. At this time, there are a few comments to be made and announcements, and I'll proceed in this fashion.

First, I'd like to take this opportunity to thank all of those people who made presentations during this three-day meeting.

We realize that it required some considerable effort, and expenditure of time, and we appreciate it, because these comments are intended to help us in reorienting our thinking about this program.

The second item is that it is our intention to obtain copies, and there are still a few that I have to get, copies of all presentations made.

NIOSH will photoreproduce those papers, and we will send a copy to all registrants of the

meeting, so sometime within the next, I'm hoping for three weeks at the outside, you will receive a copy of all the papers received at this meeting.

Now, again the verbatim transcript is not something that NIOSH will provide to registrants. If you want a copy of the verbatim transcript, you will have to make your arrangements with ABL Associates Incorporated, and I gave you a phone number the other day to make contact.

The third item is largely in response to a request made by Bill Revoir, I can see no other course of action than that NIOSH will hold the public record open until October 29 which will be a period of 90 days instead of 30 during which time we will be happy to receive any additional comments, suggestions, advice, from anyone attending the meeting or anyone interested in the program.

To repeat, and I'm not singling this group out, but because they have formed the ANSI Ad Hoc Committee, I, for one, I think speaking on behalf of Dr. Robbins, will welcome their input to this effort to improve the program, and that is not saying in any way which final form we care to -- which final form a program will take.

We feel this group includes some of the

country's acknowledged experts in the field, and we welcome their comments.

The institute obviously plans to take the record of these proceedings and evaluate them over the next months and try to come up with a suggested course of action for our involvement in this testing and certification program.

We obviously announced on June 18 that we preferred alternative two. We've heard a lot of comments, both pro and con, regarding alternative two and other suggested courses of action.

Our role will be to evaluate that record and try to determine which way we should go.

I can guarantee you, and I can't say this too often enough, that the institute does not intend to continue to operate the program the way it was operated, say, in the past or from '77 when the last meeting was held, your perception is that not much happened with the program, and that may, in essence, be pretty accurate.

We intend to do something with this program to try to improve it.

At this time, a gentleman did inform me earlier that he did want to make a comment, and also I'm not closing out any additional comments to the

meeting. Dr. Opold has some closing comments, but at this time, I will acknowledge the gentleman at the microphone.

MR. PACKARD: I'm Larry Packard of the Dow Chemical Company, USA, and also a member of the chlorine institute respirator task force.

In the 1977 hearings our company and the chlorine institute made sincere and extensive presentations on the use of respirators, and I think it would just be appropriate that I use this forum to ask that those be, in effect, resurrected and included.

I'll have to say that we have from time to time expressed or felt the same feelings that have been expressed here, what happened to our comments, and so I would like to make that request, Mr. Chairman.

DR. MAY: Thank you. I guarantee you that those records are not lost and will be evaluated along with the record of this meeting.

Another comment?

MR. STINGLE: Jerry Stingle from the Bureau of Mines and a member of the ANSI Ad Hoc Committee.

If it's not already been submitted, I'd like to request that some additional information be provided to this public record of all the papers that have been submitted.

The first bit of information, I think it would be appropriate to have the Industrial Safety Equipment Association, ISEA, provide some additional details similar to the detail that was asked of Mr. Revoir for the ANSI position that that committee has taken, namely in this case a list of the manufacturers represented by ISEA in their position and what the voting record was on those positions.

Secondly, as evidence of NIOSH's commitment to this major organization change, it seems appropriate and it would be helpful if we could see as part of the record whatever program plans were developed to support and initiate the changes proposed in the Federal Register notice, and some of the details that would be of interest to people, I believe, have to do with what planned increased funding is in the works for the program and what increased staff at Morgantown is contemplated, what specific funds for respirator research to improve performance standards and test procedures, and estimates of the timeframe for the immediate and long-term plan changes that you have in mind as a result of this open meeting.

DR. MAY: Thank you, I guess, for your comments. We will certainly do our part to provide that information. Considerable effort has gone

into coming up with what we propose in the 18th Register, and I can guarantee the institute has made plans for considerable increase in resources for Morgantown, and I can make no further comment as to whether they will be blessed at higher levels, but we are proceeding to get those resources, and I think your comment regarding ISEA's position is well taken in light of similar comment made regarding ANSI.

If Frank can provide that information, we'd be very happy to receive it.

The next thing I have, Jim, is if you have some closing comments that you'd like to make as Director of the Division of Safety Research.

DR. OPOLD: I just wanted to say in closing that we initiated the panel. I think they did a very thorough, professional job in coming up with their report.

The next thing was to have this public hearing. We expected to hear some criticism. Obviously we weren't let down in our expectations of that. However, I'd like to add that I think more than some of the things that we knew we were going to be criticized for, we received a number of positive comments from this.

for what he's doing.

I would appreciate that; we will do that. So with that type of thing and witnessing of tests being brought back, we can make some of these changes, as I say, from this meeting.

We would ask that we not necessarily shut off any criticism or comments coming in to us subsequent to this meeting, and I'm sure they won't.

I would like to ask the chairman one additional thing, and I've asked several of the manufacturers this question, and I did not ask them all.

I would like for our planning purposes and for us to get a feel for the magnitude of the respirators in the work place, I would like to have Dr. May request of all manufacturers the number of sales in respirators during the past year. I would like to also have him request an estimate, if nothing more, actual figures if they're available, of their respirators in the work place in the United States.

I would hope that we could get some handle on, as I say, the magnitude of the respirator in the work place, so I've finished with that request.

I thank the participants here, and hopefully we'll be in touch. Do not forget the international respirator workshop that is going to be held in

Morgantown September 9, 10 and 11. I said to several of you people privately and individually that some of your comments ought to be brought to that workshop and I sincerely mean that, and we will have -- hopefully we will certainly have an agenda and speakers specified, but we're going to have time for everyone to put in their two cents worth, and I think some of the comments that were made here should be brought to that workshop.

Thank you, John.

DR. MAY: Thank you, Jim. I guess the only thing I can say is Dr. Opold introduced into the record of the meeting his request for that information.

All I can say to the manufacturers at the meeting and those who obtain a copy of the record and the Industrial Safety Equipment Association which represents a large group of them that if you care to provide that information, we would be happy to receive it.

Please send it to me or your position on that matter to me at the address listed in the Federal Register of June 18.

We all realize there are legal implications and proprietary indications to the comment, but I would appreciate your response to that, if it's in the form of information or if it's in the form that

your legal department tell you that you do not care to do so. That simply will be a response that is totally satisfactory.

At this time, I would just simply ask would anyone else care to make any comments, supplemental statements or ask any questions at this public meeting.

Hearing none, I declare that this public meeting to discuss NIOSH's role in the testing and certification of respiratory protective devices is over.

(Whereupon, the meeting adjourned.)