NATIONAL INSTITUTE FOR

OCCUPATIONAL SAFETY AND HEALTH

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INFORMAL PUBLIC HEARING

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THURSDAY, JUNE 23, 1994

The hearing was held in the Ballroom of the Vista Hotel, 1400 M Street, Northwest, Washington D.C., at 10:00 a.m., Gene Matthews, Moderator, presiding.

NIOSH Panel Members Present:

GENE MATTHEWS, MODERATOR

ROLAND BERRY ANN

DON CAMPBELL, Ph.D.

CHRIS COFFEY

RICHARD W. METZLER

ERNEST S. MOYER, Ph.D.

ROBERT J. MULLAN, M.D.

JEFFREY A. PETERSON

Also Present:

MICHAEL BENNETT,
Racal Health and Safety

BERNARD MISHKIN,
Moldex Metric, Inc.

WALTER J. HIERHOLZER, JR., M.D.
Hospital Infection Control
Practices Advisory Committee

BRUCE MAHAN,
International Chemical Workers Union

JOHN MARTONIK,
Occupational Safety and Health Administration

THOMAS J. NELSON,
American Industrial Hygiene Association

Also Present:

BILL NEWCOMB,
North Safety

BARRY PHILLIPS,
Scott Aviation

GINA PUGLIESE,
American Hospital Association

LINDA ROSENSTOCK, M.D., M.P.H.,
Director, NIOSH

ROBERT A. SALATA,
Infectious Disease Society of America

DAN SHIPP,
Industrial Safety Equipment Association

DON WILMES,
3M

I-N-D-E-X

I-N-D-E-X (Continued)

P-R-O-C-E-E-D-I-N-G-S

10:01 A.M.

MR. MATTHEWS: Could we take our seats, please, and we'll try to go ahead and get started. In case you wandered into the wrong meeting, this is the informal public meeting on the notice of proposed rulemaking on respiratory protective devices. If you're here for something else, this is your best chance to go. Okay, we're ready to start.

Good morning. My name is Gene Matthews. I'm with the Office of General Counsel of the Department of Health and Human Services. I serve as the Legal Advisor to CDC. I will be moderating the two-day public meeting we have scheduled here. If you -- I assume when you came in you got a copy of this tan-colored tentative schedule of appearances, the agenda. Before we go any further, let me introduce Dr. Linda Rosenstock who is the NIOSH Director and she has some opening remarks.

DR. ROSENSTOCK: Thanks, Gene. I really just have a few brief comments I wanted to make and then I'll turn the proceedings back to Gene who will

review some technical comments before we get into what we hope will be a very productive and open and truly informal but meaningful day and a half exchange.

As I think many of you know, I have been recently appointed as the Director of NIOSH and feel fortunate and pleased to have joined NIOSH at this critical and, in many ways very exciting, time. The jargon of the day is, in fact, the reality in the sense that Government programs are being transformed across the entire federal system. We feel that sometimes in positive ways as well as in negative ways, but in the positive ways we are undergoing substantial reform, I think, to improve NIOSH's products and services.

We've undertaken some dynamic changes in the Institute in the last few months that build upon some that were started earlier and I believe the way we work will change in a way that I hope will be palpable to many of you in terms of improving our commitment to quality, to revitalizing existing, and starting new and nurturing new partnerships, developing state of the art laboratories and research

programs, and Morgantown is one example, creating and staffing as we have been doing over the last few months the Institute's Headquarters and Director's Offices back in Washington D.C.

As I mentioned, I think there are some difficult things that come with change, but I think that these changes are not merely to say that we need change. There is a need for reform and we want NIOSH for our consumers and partners to be less, I think, of the autonomous bureaucracy that sometimes is unnecessarily at odds with key sectors of society on issues of science and policy, and we would like NIOSH to become more of what I think it can be, which is a catalyst for effective social action that ultimately leads to our shared goal of improved worker safety and health.

And the need for improvements in our respirator certification standards I think is evident. I think that will be something that we all share at the end of this day and a half meeting. There have been no substantial regulatory changes for years, and this has impaired our ability to incorporate

technological advances into our standards.

The proposal today is significant for a number of reasons. It introduces a modular approach to regulatory improvement. The first modules, you know of course, incorporates currently available technology that improves the very important component of respirator safety and effectiveness which is filter efficiency. And improved efficiency, of course, is important for many workers in many different settings in a variety of different kinds of work places, and in addition, of course, the provisions of this rule have an important public health and timely public health implication in terms of regarding the control of tuberculosis and health care settings.

Currently air purifying respirators with the HEPA filters are the only respirators that meet all of the proposed CDC respirator performance guidelines, but we anticipate the new classes of air purifying particulate respirators certified under our proposed Part 84 would meet or exceed the draft, and soon to be final, CDC guidelines. Therefore, these new regulations should provide a larger variety of

respirators. We think they'll be more practical in these settings and hope that indeed they'll be less expensive than the respirators with the HEPA filters.

And for all of these reasons and more, NIOSH is planning then to publish a final rule pertaining to particulate filters within the year. Just to mention a brief word about future modules, they'll not only incorporate technological improvements and other respirator types, they'll be developed with a greater interaction, I hope, with and sensitivity to the needs of our partners.

Greater private sector participation is something that I strongly support and came to my job committed to, and this will be encouraged by increasing the number of public meetings and other fora for public involvement in the process. The Institute has published a suggested schedule for additional modules as the first step in this process, and we're open to hearing your priorities about this, your suggestions, and your comments.

So I think we have the opportunity to work together to replace the obsolete process with a

process that produces timely improvements and ultimately improved respirators and reduced workplace exposures. I look forward to working with all of you in achieving the goal of enhanced worker safety and health through these quality partnerships. Thank you.

MR. MATTHEWS: Thank you. Just a couple of housekeeping functions: I need to say this meeting is being held in accordance with Federal Register notice of May 26, '94, and the notice of proposed rulemaking that was published on May 24th. As indicated in that notice, the administrative record for this rulemaking will consist of the notice itself and other Federal Register documents, the Agency records on this subject, and all written responses that are given to the Agency with respect to these notices.

In addition, the administrative record will include the record of this informal public meeting. Please note that no written submissions to NIOSH with respect to this rulemaking will be held in confidence, and it will all be open and above-board. The proceedings themselves, as you will note, are both

being transcribed and videotaped. Any person may record or make a transcript so long as it is not disruptive to the meeting.

We expect the participants to present any relevant written information, data, or views for their inclusion into the record of this meeting. The participants were requested to notify NIOSH by June 16th of their intent to appear today to give a presentation. This meeting is scheduled for two days. You will note on the agenda that it would appear that we have ample time to cover this and we perhaps may get done around lunchtime tomorrow. It's hard to predict how this goes, but that's how it looks now if you're trying to make your plane reservations or whatever.

I am informed that we have approximately 20 participants that have requested to appear, as indicated on the schedule. We will proceed in the order that is listed in the agenda. If a participant is not present, we will continue on in order and at the end of the proceedings, we will give any participant who had previously requested time to make

a presentation -- an opportunity if time is available.

In addition, any interested persons who are attending here today who did not request to participate or give an oral presentation may be given an opportunity at the conclusion of the meeting, again if time is available. If you are so interested, there is a sign-up sheet out on the table outside the doors.

The purpose today is to provide interested persons, as I said, with an opportunity to make oral presentations for the record, to hear the other presentations that are being made -- I'm getting feedback -- and to submit to NIOSH by July 22, 1994, any comments or statements regarding what is in the proposal and what was presented here today.

As indicated in the Federal Register document, those comments and statements should be submitted to the NIOSH Docket Office in Cincinnati. Let me also pause for a minute to introduce Nancy Bollinger, if you will stand. She will be the alternate moderator, and may from time to time be helping conduct the proceedings.

What we intend to do next is Rich Metzler will give us just a quick overview. I realize we have a number of disciplines and interests here today. So Rich is going to give sort of a quick, ten-minute overview of what is in this rather scintillating document in the Federal Register that has everyone rivetted to their chairs here.

After that, we will then, as indicated on the agenda at 10:30 a.m., have overviews of the proposal from sort of the representative segments of the respirator community: John Martonik of OSHA, Bruce Mahan of International Chemical Workers Union, Dan Shipp from ISEA, the Manufacturers Association, Tom Nelson from American Industrial Hygiene Association and Gina Pugliese from American Hospital.

So why don't I turn it over now to Rich Metzler who will give you a quick overview and then we'll proceed.

MR. METZLER: Good morning. I'm pleased to welcome you here today to discuss improved respirator certification standards and the Institute's new process for proposing them. This will be the

first of many meetings to welcome and solicit public involvement in updating certification programs and standards.

The regulations that implement the Occupational Safety and Health Act and the Mine Safety and Health Act require the use of NIOSH-certified respirators. Respirators are currently certified by NIOSH and MSHA in accordance with the Code of Federal Regulations, Title 30. These regulations are largely based upon criteria developed by the U.S. Bureau of Mines between 1919 and 1969. They were last promulgated in 1972.

They need to be updated to include contemporary performance, reliability, quality assurance standards, as well as the state of the art and testing methodology to address emerging hazards and to incorporate new technologies. This need was recognized in two concurrently published proposals in the Federal Register by the MSHA and NIOSH in 1987.

Consummation of this regulatory reform has been difficult because of the extensive scope and complexity of the reforms that were proposed.

Revising all the respirator standards for all types of respirators simultaneously proved to be a formidable task. Many difficulties were encountered that delayed the process.

The process itself was found not to be equipped to meet the needs of the Institute: timely implementation or addressing of emerging hazards and timely revision of technically obsolete standards. I think this is evidenced by the age of the present filter penetration test, often referred to as a silicate dust test, which will be 60 years old this August.

NIOSH developed a new process, one that will propose revisions in a series of smaller steps or incremental improvements, thus adopting a strategy that will permit continuous improvement. By re-codifying 30 C.F.R. 11 requirements into 42 C.F.R. Part 84, this proposal will signal the closure of earlier regulatory reform efforts and the beginning of a new process.

The new process has been referred to as a modular approach to rulemaking. It introduces

standards incrementally rather than simultaneously revising the entire 30 C.F.R. 11 certification standards. We're very excited about the possibilities for improving worker protection by accelerating the incorporation of new technologies into those standards and improving our abilities to address emerging or reoccurring hazards.

I would like to describe some of the advantages of the modular approach. The Institute's scientific talents and resources can be focused at developing improved standards needed to address the most pressing worker safety and health issues. This will enhance the Institute's ability to address emerging hazards, such as that faced by health care workers with the threat of multi-drug resistant tuberculosis and allowing the incorporation of contemporary technologies offering important health benefits to workers.

Public participation in the rulemaking process would be encouraged. By proposing important regulatory changes in small segments of limited scope rather than a comprehensive change, public attention

can be focused on a single topic rather than being divided among many technically diverse and complex standards.

A greater number of public meetings are anticipated in preparing proposals as we strengthen our partnerships. Other forums for public involvement will be explored. With modular approach, the Institute has an opportunity to integrate national and international standards which were not part of the '87 comprehensive proposal. This affords the Institute an opportunity to upgrade those standards to the most contemporary available standards anywhere; that's offering the best protection for workers while stimulating innovation and competition among manufacturers.

This modular approach should facilitate the transition to new requirements by the respirator manufacturer and user communities. We hope that it will also minimize the potential for any disruption in the supply of certified respirators to the field.

Finally, the modular approach allows the Institute to implement new standards and to develop

new programs most efficiently because it allows us to focus our scientific staff and our resources in limited improvement areas.

This proposal introduces another important administrative revision. The Institute's approval responsibility is modified so that it will be the sole certifying agency for the majority of respirators. MSHA will retain its role in the approval of respirators designed for mine rescue or mine emergency use. This is a modification from the '87 proposal. This provision recognizes MSHA's unique expertise in identifying special needs and applications in the mining environment.

This joint review and certification that will be conducted by the agencies will include examination of associated approval documentation such as reliability assurance service life plans, user manuals, other use restrictions, which might be specified as a condition of the certification.

NIOSH and MSHA would also jointly conduct product and manufacturing site quality assurance audits and jointly investigate recall and retrofit

matters which arise from field complaints or from nonconformances which have been identified. These joint certification activities are consistent with current practice.

NIOSH is also proposing a revision to the existing technical standards of 30 C.F.R. 11. In this first module, improved filter standards that were initially proposed and introduced in Subpart U in 1987 will be proposed. These new standards replace those of Part 11 that were developed in 1934. These proposed changes significantly improve filtration efficiency.

New testing methodology will demonstrate a filter's efficiency against particulate in the most penetrating particle size range throughout the test period. These new filter standards will improve particulate efficiency classification system consistent with advances in respiratory protection technology. Users will be able to easily discern the level of protection that can be expected when using a particular respirator.

These filter performance standards address

the Institute's concern over the health risk to workers due to excessively high filter penetration of current certified dust/mist and dust/fume/mist respirators. Excessively high filter penetration can occur when these respirators are used against aerosols containing submicron particles, and the new process that we are proposing is consistent with strategies to reinvent the Government. They will posture us to meet global challenges and to make the most of the opportunities that they present.

MR. MATTHEWS: Thank you, Rich. Perhaps I might take this opportunity to just have the panel introduce themselves, and also we can check our sound system as well. What we intend to do is a little departure from the last time we did this at the '87 proposal. We have a panel that sort of represents the various disciplines and expertise with the Institute that have helped prepare the proposal.

What we intend to do following the overviews is have the presenters make their ten-minute presentations. Then if any of the panel members have questions for clarification or information, they can

engage -- and similarly if during the presentations, if any of the commentors have questions for the Institute, we will take that opportunity to respond if we can.

During the next -- we're running a little bit ahead, but during the next hour, we will have the five overviews here. We don't intend to go into engagement with the panel at this time, but I think you sort of need to get some sense of where we're going. Let's have -- just take yourself down and introduce yourselves.

DR. MULLAN: Good morning. I'm Bob Mullan. I'm a physician with the NIOSH HIV activity.

MR. METZLER: Hello again. I'm Rich Metzler with the Certification and Quality Assurance Branch.

MR. BERRY ANN: Good morning. I'm Roland Berry Ann. I'm with the Certification and Quality Assurance Branch.

DR. CAMPBELL: Good morning. I'm Don Campbell. I'm with the Certification Program also.

MR. COFFEY: Good morning. I'm Chris

Coffey. I'm a Researcher in the Certification and Quality Assurance Branch.

DR. MOYER: I'm Ernest Moyer. I'm with the Protective Technology Branch, NIOSH. I'm a Chemist.

MR. PETERSON: Jeff Peterson, I'm with Certification and Quality Assurance Branch.

MR. MATTHEWS: Okay. All right, if Mr. Martonik is here, step right up and lead off.

MR. MARTONIK: Thank you. Good morning. I am John Martonik. I'm acting Director of Health Standards Programs of the Occupational Safety and Health Administration. I'm here to present OSHA's comments on the 42 C.F.R. Part 84 particulate filter testing proposal that NIOSH has proposed as the first module of a comprehensive revision of existing respiratory certification standards in 30 C.F.R. Part 11.

First, OSHA would like to congratulate NIOSH on the publication of this first module of the 42 C.F.R. Part 84 revision. However, this very important first step in updating the respiratory

certification standards is only the beginning of a process of revising respirator certification.

OSHA supports your efforts in this area and hopes that NIOSH will be able to expedite the rulemaking process to quickly produce a much needed final standard to bring respirator certification out of the past and into the present decade while containing flexibility to address future needs.

OSHA understands why NIOSH chose to utilize a modular format for revising the respirator certification standards in the interest of making these revisions as expeditiously as possible. However, the overall respirator certification standards that NIOSH finally adopts are of vital importance to OSHA.

It is important for OSHA to know what NIOSH will be using for approval criteria for each of the various types of respirators under the new 42 C.F.R. Part 84 provisions, particularly for gas and vapor respirators and self-contained breathing apparatus, modules that NIOSH will be addressing much later in this modular rulemaking process.

It is important that OSHA understands what NIOSH will be requiring for certification as it will impact what OSHA requires in the selection of certified respirators for hazardous chemicals. As NIOSH knows, OSHA is also in the process of revising its own respiratory standard, 29 C.F.R. Part 1910.134. It's a standard which relies on respirator certification standards established by NIOSH.

OSHA and NIOSH are coordinating regulatory efforts to attain consistency between the agencies and to utilize our resources efficiently. OSHA has a particular interest in the issue of assigned protection factors, an area that NIOSH will be addressing in the second module of this respirator certification revision.

The NIOSH protection factor review will have an important impact on a critical part of our proposal and OSHA encourages NIOSH to expedite its work in this area. The issue of protection factors is one of great practical importance to the respirator user community and OSHA is anxious that NIOSH proceed with this next phase of its rulemaking agenda.

OSHA has been asked to comment on whether a respirator that meets requirements for filter penetration contained in the NIOSH proposal would be acceptable for use against M. tuberculosis exposures. At this time, OSHA believes that a respirator that meets the new NIOSH test criteria for Class A, B or C respirators would be acceptable for use against TB.

However, there are other issues other than filter efficiency that must be addressed before respirators can safely be used for TB. The respirator must be able to fit, tested, and the wear to demonstrate that the faceseal leakage is more than ten percent. Second, the respirator must be able to fit different face sizes and characteristics which can usually be met by the respirator being available in three respirator sizes.

Lastly and importantly, the respirator must be able to be fit checked by the wearer each time it is put on to ensure proper face-piece fit before entry into TB exposure areas. The NIOSH proposed filter testing criteria meet only one of the CDC criteria for respirator use with TB, that the filter

exhibit filter leakage of five percent or less, a filter efficiency of 95 percent or greater.

OSHA plans to promulgate a standard regulating occupational exposure to TB. In the process of that rulemaking, OSHA will publish a proposed standard and obtain public review and comment. OSHA expects all aspects of respirator use will be evaluated in this process.

In order to optimize the possibility that a respirator will achieve its assigned protection factor, that respirator must be chosen by the use of fit testing. NIOSH has, so far, left out of its certification proposal the evaluation of fit testing procedures and programs. As a part of the respirator certification, the manufacturer of the respirator submits its respirator use instructions for the respirator wearer, including any fit check procedure the manufacturer recommends for its respirators.

NIOSH currently does not review this material for the adequacy or appropriateness of any fit check the manufacturer recommends. Some manufacturers believe that since NIOSH received their

use instructions as part of the certification process, therefore NIOSH has reviewed them for adequacy and approves of them as a fit check method.

A respirator which cannot adequately be fit checked by the wearer prior to entry into a hazardous atmosphere has a reduced chance of obtaining its assigned protection factor. NIOSH needs to evaluate all of the manufacturer use instructions, including any fit check or fit testing recommendations before issuing a certification for that respirator.

At this time, OSHA has no other specific comments on the provisions of the particulate filter testing revision. OSHA supports NIOSH in the need for updating the filter testing provisions to reflect current state of the art testing procedures and equipment. The NIOSH proposal has made extensive changes in the filter testing requirements and the test equipment from those in the original 30 C.F.R. Part 11 standards and NIOSH has presented supporting data and explanations for those changes as part of the rulemaking record.

OSHA supports NIOSH in its revision of the

respirator certification standards and encourages NIOSH to proceed with all the modules in its rulemaking agenda in an expeditious manner to produce a new 42 C.F.R. Part 84 standard that will address the needs of the respirator community for many years in the future. That ends my statement.

MR. MATTHEWS: Thank you very much.

MR. MARTONIK: Okay. Would you like copies of the statement?

MR. MATTHEWS: Please, if you would. If you would leave them out at the door, and we will try to get some copies made if anybody's interested. Thank you. Next, Bruce Mahan, International Chemical Workers.

MR. MAHAN: Good morning. I'm Bruce Mahan and I'm the Field Training Director at the International Chemical Workers Training Center in Cincinnati, Ohio. We are one of the NIHS grantees and in 1987, we were awarded grant money to train union members in chemical emergency response.

The Center is a cooperative effort involving the International Association of Machinists,

the Aluminum, Brick and Glass International Union, the Aluminum Plate Glass Workers, the United Rubber Workers, the University of Cincinnati and Environmental Department and the Greater Cincinnati Occupational Health Center.

Our participatory approach to training has been well received by both our members and management and as a result, we've been invited to conduct a great deal of on-site facility-specific training. We've had over 60 corporations pay tuition for us to train both salary and hourly employees. As a result, we've had the opportunity to observe up close and personal a wide variety of monitoring programs. We've developed a good working relationships with a number of industrial hygiene and health and safety departments.

I'd like to thank NIOSH for the opportunity to present the views of the Union relative to proposed revisions. We feel that input at this stage of proposed rulemaking is vital and we welcome the opportunity to comment. Mine shall not be later today a scientific approach for presentation, but more an attempt to link what happens in Morgantown to what

takes place out on the shop floor.

MR. MATTHEWS: Thank you very much. Dan Shipp, ISEA.

MR. SHIPP: Thank you. Good morning. I'm Dan Shipp, President of the Industrial Safety Equipment Association, which is the trade association representing manufacturers of approximately 95 percent of the respirators made in the U.S. For our presentation this afternoon, I will be joined by representatives of four of our member companies to provide technical expertise.

The ISEA supports improvements in proposed filter performance requirements, recognizing that respirators are a critical asset in protecting workers: workers in factories, construction sites, mines, farms, transportation, as well as health care facilities. In our comments, we will address the modular approach taken by NIOSH which we believe is an effective tool to advance respirator certification rulemaking.

We will advocate inter-agency coordination and harmonization of NIOSH requirements with

international standards and norms and we will support the industry empowerment to expand the resources available to the Agency. The Association will recommend certain specific alterations to the proposed rule that we believe will make the standard more effective and make its requirements more realistic and reproducible in the laboratory and in the workplace.

We will address the grandfathering provisions of the proposal, setting time limitations for certain products under existing regulations, and we will make specific recommendations, either endorsing the proposal by NIOSH or recommending changes. We will address the proposed testing parameters, recommending improvements and further cooperative research where necessary. This will include comments on the aerosol generation, test equipment specifications, pre-conditioning, air flow tolerance, inhalation and exhalation resistance, filter loading and particle size distribution.

We will make specific recommendations on filter efficiency supported by tests conducted by member companies and our understanding of market

needs. We will also recommend a change in the nomenclature of filter classes to harmonize with international standards.

We will recommend a separate module for powered air purifying respirators, rather than the incomplete requirements proposed in 42 C.F.R. 84. We will critique the statistical methodology proposed by NIOSH and make specific recommendations for an alternative.

We will propose elimination of fit testing as part of the certification program, and we will address the issue of assigned protection factors, recommending that NIOSH call a technical meeting to discuss the issue of appropriate uses for respirators under the new classification scheme.

The ISEA looks forward to working with NIOSH to complete this rulemaking and offers its technical resources and expertise to help advance this and subsequent modules. I look forward to our opportunity to appear before you this afternoon.

MR. MATTHEWS: Thank you very much. Next is Tom Nelson, American Industrial Hygiene

Association.

MR. NELSON: Thank you. I'd like to do just a few comments on the role of certification in general, rather than the specific comments on this proposed rulemaking. As industrial hygienists, certification or some recognized national guideline of performance characteristics of respirator products is very important to us. Equipment built to these test specifications will have some minimum level of performance.

This allows me, as a hygienist, to be able to make recommendations on specific respirators to be used in the workplace. It is important in the process of respirator selection to be able to have an understanding of the expected performance of limitations of a piece of equipment.

The current situation is that the NIOSH certification rules are based on very old technology, as will be discussed at this hearing. The OSHA respirator standard is about 25 years old. ANSI Z88 and NFPA representing other groups that write standards and give guidance have maintained their

standards with regular updates and revisions.

Since each group's advice is based on differing technologies and time frames, what each group lists as a requirement varies. This leads to confusion in the industrial hygiene field when respirator selection and use is involved. Which group's advice do I follow? What happens when I select one group's advice? Have I made a bad decision?

As an example, let me just put up an overhead that lists the assigned protection factors for PAPR. The ANSI standard that was revised in 1992 basically --

MR. MATTHEWS: Could you speak into the microphone?

MR. NELSON: Yes. The ANSI standard, which was revised in 1992, basically lists four different types PAPRs. ANSI also has different requirements when dust/mist filters are used versus HEPA filters. NIOSH basically has two types of PAPRs, loose-fitting and tight-fitting.

OSHA, the assigned protection factors vary

by standard. And I guess I looked at this this morning, I think OSHA -- most of the time they say HEPA filters for PAPRs. They don't have a classification for dust/mist. So you can see that there is quite a bit of confusion in just this one small area.

The values that each group lists should be rather close since they should be based on a common set of science. You know, it does not appear that this is the case. And what does this point to? What it points to is we need an understanding of a science that supports the certification process and how these tests relate to the workplace. We need an understanding of the performance of respirators in the workplace, and we need professionals in place to manage the development of programs to the selection and use of respirators.

As far as the understanding of the science of certification, NIOSH in this area has conducted a large amount of highly respected work; for example, the study by Ernie Moyer sitting up here on the panel on filter efficiencies led to the development of

proposed filter testing.

The certification tests, however, are performed in the laboratory. We need to understand how the test results and the test criteria relate to the performance of a respirator in the workplace. It is tempting to design tests and set performance specifications in the worst conditions and then any equipment which passes this test will perform well above the needs of the workplace. But does this serve the user? Is it necessary to have equipment that performs at such high levels?

For example, this will probably be discussed here at the hearings, the filter test for the lower performing filter is set at a minimum of 95 percent efficient for the most penetrating particle under the worst penetrating conditions. It is highly unlikely that such an aerosol exists in the real world. Are the costs involved in developing and using such a filter -- to meet such a test requirement, worth the effort?

One driving force for this change has been the health care use of respirators. Would it be more

efficient to provide better equipment if a certification test was designed specifically for that environment?

Another example considered is the use of filters for paint spraying. I agree that the current certification for paint spray respirators leaves a lot to be desired. However as an aerosol, paint spray is a very large particle. Do we need equipment that is designed for small particles like that for that use as a proposed regulation?

As far as understanding how respirators perform in the workplace, more research is needed to better understand the performance of respirators as they are used in the workplace. There is a lack of workplace protection factors study on most types of respirators. The ANSI standard used would replace protection factor studies as the primary supporting science for their assigned protection factors, so they play an important role in how a hygienist selects respirators.

A search of the published and unpublished literature shows that there are about 15 workplace

protection factor studies that have been reported on half-mask respirators in about the last ten years. For powered air purifying respirators, there are several studies on loose-fitting face piece types, only two studies with half-mask PAPRs, and one study each with full face piece and for helmets and hoods.

For airline respirators, only one WPF study was used by the ANSI Committee to set their limits. The quality of these studies varies since no set protocol for conducting WPF studies exists. We are still in the process of understanding what affects the results of such studies. We have several clues, such as Warren Myer's work on the face piece sampling errors, but there are other areas that need to be better understood. For example, in an unpublished study by Johnston, they found relationship between the mask and the analite at the workplace with the WPFM. How is the effect taken into account in designing such studies?

As a start, members of the AIHA Respirator Committee did publish an article with some of their thoughts on what should be in a workplace protection

factor study. This is a starting point, but much more work needs to be done.

Finally commenting on the professionals in the workplace that manage and develop the programs, once the process of certification is set and OSHA has revised their standard on respirator use, it will be up to these competent individuals to manage these respirator programs. This calls for a cadre of professionals such as certified hygienists and other trained individuals.

Within this community, there will need to be provided a course of continuing education. The IHA provides some of this education through professional development courses and publications.

I think these three points really point to a need for an interactive process within the hygiene community. We have issues that are very complex. The amount of work that needs to be done is very large, and I know that the IAHA Respirator Committee would be willing to work with NIOSH in developing answers to some of these issues.

I appreciate being given the opportunity

to present these opening remarks. Thank you.

MR. MATTHEWS: Thank you very much. Finally we have Gina Pugliese, American Hospital Association. Gina?

MS. PUGLIESE: Good morning. My name is Gina Pugliese and I'm the Director of Infection Control and Environmental Safety at the American Hospital Association, and I'm here today on behalf of the AHA and its more than 4500-member institutions to comment on the proposed rule that addresses NIOSH and the Department of Labor, Mine Safety and Health Administration's certification requirements for respirator protection devices.

Our understanding is that these proposed rules would replace existing MSHA's regulations with new public health regs and also upgrade the current testing requirements for particulate filters. These comments represent those of the AHA's Technical Panel on Infections within Hospitals in collaboration with AHA's staff experts on infection control and occupational safety and health.

The AHA is very concerned about the

dramatic rise in TB in the United States and the recognized risk of TB transmission in health care facilities, including the recent outbreaks of drug-resistant TB that have involved both health care workers and patients. And we continue to supports efforts to protect health care workers and patients against transmission of TB. This includes the support of NIOSH's improved procedures for certifying and testing respirators that represent current state of the art to assure that appropriate respiratory protection is available for workers.

We believe that all TB control programs should be based on a hierarchy of controls to reduce the risk of exposure to persons with infectious TB as outlined in the CDC's 1993 draft guidelines for health care facilities. We have been concerned about the current requirements for the use of HEPA filtered respirators because these are the only currently available respirators that meet or exceed the CDC's recommended performance criteria.

We also recognize that the current NIOSH certification procedures for dust/mist and

dust/fume/mist respirators are not designed to evaluate these respirators' ability to meet the performance criteria. We applaud NIOSH for developing these proposed rules because implementation of these rules will provide a new category of particulate respirators, that is the Class C respirators, which would meet the CDC's performance criteria for protection against TB. And this will ultimately lead to the availability of a broader range of certified respirators for use in health care settings that will be less costly and more practical than the HEPA-certified respirators under the old regs.

In addition, the AHA fully supports NIOSH's replacement of their 1992 recommendations for workers' protection against TB with the recommendation for the use of respirators against TB that meets the CDC performance criteria. We recognize that data are not available to determine the precise level of effectiveness of respiratory protection needed to protect workers in the health care setting.

We also recognize that the studies about the effectiveness of respiratory protection against

hazardous airborne materials are based primarily on experience with respiratory protection in the industrial setting, not from microbacterium tuberculosis.

So we urge NIOSH to support research that will enable us to fully understand the factors that influence the transmission of TB and the level of effectiveness of respiratory protection to protect health care workers from transmission of tuberculosis.

We applaud NIOSH for taking the necessary steps to overcome the regulatory obstacles for developing these new procedures for testing and certifying respirators and we agree that the modular approach to this rulemaking process will expedite the changes in testing procedures and provide the opportunity to incorporate the best available scientific information and expertise into each regulatory module.

We're pleased to see that the first module will improve the current approach to testing and certifying air purifying respirators with particulate filters, the category that will be used for protecting

against TB. In this era of health care reform and fixed resources, this new generation of respirators is urgently needed to protect workers against TB as well as hold down the costs of providing quality health care.

We urge NIOSH to place these regulations on an accelerated implementation schedule so that the market can be expanded swiftly and users will have a broader selection of certified respirators for TB control. We also ask that NIOSH assist health care facilities with training and fit testing protocols for these respirators.

The AHA is committed to supporting measures to control the transmission of tuberculosis. We recently conducted a survey of hospitals in collaboration with the CDC to assess the status of infection control programs in U.S. hospitals, and we will use the results of this survey to identify those areas that will need further emphasis and additional resources.

We believe that prevention and control of TB is vital to public health and we continue to

provide our members with state of the art information in preventing and controlling TB. We've shared this proposed rule with our members and encourage them to send written comments to NIOSH in support of the standard as an important first step in improving the certification process for respiratory protection against TB and other biologic hazards in the health care setting.

And we appreciate the opportunity to share our views. Thank you.

MR. MATTHEWS: Thank you very much. We're running a little ahead. Let me just pause for a moment. I think Gina is the only one that doesn't have further time and I think John -- Mr. Martonik -- has gone. But do the panelists have any questions in particular for AHA or any other comments you want to make in response to the opening overviews?

DR. MOYER: I have one comment and that is in Tom Nelson's remarks, he indicated that there are other standards organizations that are working in the area of respiratory protection and devising new standards. I am aware that ANSI has a committee Z88.8

to look at air purifying respirators and would like to recommend that a part of that draft document, if available, be made and submitted to the docket at this time.

MR. MATTHEWS: Rich?

MR. METZLER: Yes, I'd also like to make a comment on Tom Nelson's remarks, and I do agree that the understandings of how a respirator certification works from a worker perception, the standards that the certification is based on, selection standards, environmental situations in the actual workplace, are all very complex for a worker to understand all those issues. And as Tom indicated, there is a range of different standards among the different standards organizations, which makes it further complicated for a worker.

The interest of the Institute is for all workers, those who work in large operations who have the benefit of an industrial hygienist and those workers who work in small operations, such as auto body repair shops where there may be one or two workers without the benefit of an industrial

hygienist, therefore certification standards to make selection and certification understanding easy, we choose to use the worst penetrating aerosols so that an understanding of the filtrating mechanisms and certification standards does not have to be well understood by all workers.

MR. MATTHEWS: I'd just like to make one comment particularly to Gina of AHA and also I suppose it also applies to Laura Kenney and the Service Employees International Union, that this -- coming to this from the sort of hospital infection, hospital worker community, this is probably a little bit of a bizarre proceeding with all of the respiratorese that some of us who have been steeped in this for some time have been dealing with.

We understand the responsibility for us to try to focus these issues down where they are presentable in your particular context. But you have to understand there's also a vast base of technical information on this pyramid that we've got to work our way through. So I appreciate your patience. I also appreciate your comments.

Any other comments from the panel, questions? If we could gain a little time then, we were supposed to have a break now, but we've just been at it about 50 minutes. So if Jeffrey Birkner of Moldex is prepared to go forward, if you'd like to step up and do so. You get tread water time for having a pop quiz called on you here.

And perhaps Bruce, if you want to do your comments too, we might could get those two in before the break and gain a little bit of time. This is sort of like David Letterman. We'll edit all this out when we broadcast this to the networks, so don't worry about it.

MR. MISHKIN: Good morning. My name is Bernard Mishkin. I'm not Jeffrey Birkner. He's not available. I'm Vice President of Marketing with Moldex. Please bear with me.

MR. MATTHEWS: Sure. I don't mean to hotbox you at any time.

MR. MISHKIN: Moldex Metric is a major manufacturer of disposable dust/mist/fume particulate respirators and twin cartridge half masks. We've been

in this business for more than 15 years. We've been actively involved in the development of ANSI standards, commented on previous NIOSH and OSHA proposals, participated in the American Industrial Hygiene Association Respiratory Committee and serve on the Board of the International Society of Respiratory Protection. We are also members of the Industrial Safety Equipment Association, ISEA.

We have accumulated a lot of expertise and knowledge in the field of respiratory protection, and we support any reasonable Government standards that improve worker health and safety. In this regard, we have diverse research and development staff in addition to well-equipped laboratories, both in the U.S. and Europe where Moldex has a manufacturing and marketing subsidiary.

We have requested time today to comment on the proposed 42 C.F.R. Part 84 supplementary information Section 5.26.859 to illustrate to those present and for the record the potential economic impact that this proposed standard will have on U.S. industry and workers currently using NIOSH-certified,

disposable, particulate respirators.

These are by far the most popular and widely used particulate respirators. NIOSH has estimated that employers annually purchase over 110 million, and this proposal will have by far the most impact on these products and the workers who use them. Generally speaking, we are in agreement with NIOSH's goal of an improved regulation that ultimately improves respiratory protection for American workers.

To this end, we commented in 1987 that we would like to see a new NIOSH respirator standard that is in alignment with the European CEN standards. We take this opportunity to reiterate this concept for the following reasons.

Why reinvent the wheel? Many of the same U.S. respirator manufacturers and industries have already been living with CEN regulations in Europe that go well beyond the performance and protection levels that are currently regulated here by NIOSH and OSHA.

Let's rise beyond the not-invented here cliche and look to the OMB circular A-119 7a(2),

October 20, 1993, which states that "International standards should be considered in regulatory applications", etc.

Costs to both users and manufacturers of the current proposal would be reduced while users would have available products of greatly enhanced performance. These products are available now for most major U.S. respirator manufacturers and at a reasonable cost increase over current NIOSH-certified products.

The global economy may soon extend to respiratory protection. We see the testing and performance requirements of the proposed 42 C.F.R. 84 as a step away from globalizing these types of standards and they would actually make harmonization of international respiratory standards more difficult.

We ask NIOSH to examine this proposal to see if it is in line with the spirit of OMB Circular A-119 and take the comments of NIOSH staff who are currently assigned to work on international harmonization.

Beyond this, we feel that with this

proposal, NIOSH is attempting to make up for lost time and so the pendulum has swung too far the other way. No one would disagree that 30 C.F.R. 11, now more than 20 years old, needs revision. And yet, it resulted in respiratory products which, if used properly and for the appropriate use conditions, perform quite well, as evidenced by many workplace protection factor studies.

42 C.F.R. 84, as proposed, has swung past the CEN standards in terms of stringency and will result in a cost to industry of many times what is now spent on respirators that are currently certified under 30 C.F.R. 11.

Firstly, we have examined and tested every commercially available filter media and we have not found any available that would meet the requirements of all three types, A, B, C, in both the solid and liquid/solid categories at a reasonable cost. The only media that would meet certification requirements of a limited number of the new types is currently made in the United Kingdom at a cost to U.S. respirator manufacturers that is at least 20 times the media used to meet current standards for disposables.

MR. MATTHEWS: Could you hold that for just a moment?

MR. MISHKIN: That's all right. I'm going to leave it there.

MR. MATTHEWS: Okay.

MR. MISHKIN: For example, the cost of commercially available filter media to meet 30 C.F.R. 11 disposable dust/mist requirements is between 60 cents and one dollar per square yard. The cost of European commercially available filter media to meet proposed 42 C.F.R. 84 requirements is between 12 dollars and 17 dollars per square yard, depending on the type, A, B, and C, and whether it is for solids or liquid/solids.

Secondly, the fit test requirements of Section 84.181 would necessitate elastomeric inner flanges to be added to all certified disposable respirators in all categories. We have attempted to project the average user cost of disposables designed to meet 42 C.F.R. 84 and make a cost comparison with current 30 C.F.R. 11 approved products. Our best efforts follow.

30 C.F.R. 11 NIOSH estimates 110 million disposable respirators, average current user cost, one dollar each. NIOSH estimates between one dollar and eight dollars each. 42 C.F.R. 84 Moldex projected average user cost with enhanced European media and inner flange, five to ten dollars. The projected increased user cost for disposables of 42 C.F.R. 84 would be between $440 and $990 million.

Moldex strongly believes that the total cost impact to U.S. industry of the currently proposed 42 C.F.R. 84 will be well beyond $100 million. We suggest OMB and NIOSH need to investigate and take into account the following factors for all types of respirators in addition to the figures above:

(1) The cost of upgraded filters including the substitution of stacked chemical/pleated fiberglass HEPA-type cartridges in place of currently used single-ply pre-filters for all applications such as spray paint/pesticide. This is applicable to twin cartridge elastomeric half mask respirators.

(2) The possibility that inexpensive, widely used, and worker-accepted disposable

particulate respirators would be replaced by costly reusable elastomeric cartridge masks.

(3) The increased costs of respirator maintenance and training programs that are associated with reusable respirators.

(4) The training and education programs needed to explain the new regulations to the user public. This will have to be extensive in order to minimize confusion misuse and therefore limit liability.

(5) The statistical standard deviation requirements of the current proposal might necessitate much higher waste costs to the respirator manufactures. And for more detail of this, I suggest you see the ISEA comments later. And these will have to be passed on to users via higher prices.

(6) The cost of liquid/solid filters are considerably higher than solid filters due to the extreme degrading effects on filter efficiency of the loaded DOP challenge. If users upgrade to liquid/solid filters by a high percentage because of liability or worker compensation considerations or

NIOSH user guidelines or market pressures, then cost to industry would be significantly higher.

The question that comes obviously to mind is will the magnitude of the potential cost increase have a commensurate increase in improved worker safety and health? We do not believe so. We want to see an upgrade in the regulations, but not to the extent that the cost might result in decreased health because employers might decide that they cannot afford to provide adequate and appropriate protection.

NIOSH has an opportunity now to increase worker protection for a modest cost increase to U.S. industry by taking a more reasonable and international view of testing equipment and performance requirements. Thank you.

MR. MATTHEWS: Thank you very much. Again, I apologize for you getting hot-boxed as the lead-off presenter here.

MR. MISHKIN: Well, I have an apology for you and that Jeff Birkner isn't here to answer your questions.

(Laughter)

MR. MATTHEWS: But not --

MR. MISHKIN: It's a fair trade-off.

MR. MATTHEWS: But could you stay at the mike just for a minute. Let's see if we have any comments or responses. I understand if you want to demur, that's fine.

MR. MISHKIN: Okay.

MR. MATTHEWS: Any comments or questions?

DR. CAMPBELL: One question I had is sort of -- I guess it might be for protocol. Is this mike on? Oh, it's now working, okay. I couldn't hear it. Sorry.

Just one question. You indicated that the respirators, in order to pass the fit test here, would have to be redesigned and I'm curious about that because our intention with this rule was to change only the requirements for the filter penetration test. So our intention was to leave the fit tests as they were.

We in fact have a lot of problems with what's there, but our intention in this rulemaking activity was not to change that. So I'm curious about

why respirators would need to be redesigned, and that would be a large part of the cost, I assume.

MR. MISHKIN: As part of your proposal, you have a banana oil fit test which is a vapor, and you're requiring that to test a particulate respirator. Now the respirator would have to be redesigned to pass the certification tests with a banana oil challenge.

DR. CAMPBELL: The banana oil test that's in these regulations is the same banana oil test that's in the current Part 11.

MR. MISHKIN: But they're not applicable to disposable dust/mist respirators.

MR. METZLER: I think there may be one point of confusion here. The banana oil test as part of the certification process will have a modified respirator that's used for that testing. But respirators which will be delivered to the field will continue to be fit tested in the field under any fit test methodology that is acceptable to OSHA. There will be no change in those respirators.

So the impact of making a modification to

the respirator for the isoamyl acetate test is only on those prototypes submitted for certification, not for all respirators delivered to the field.

MR. MISHKIN: But that means the prototypes submitted for certification would be significantly different from those that go out into the field.

DR. CAMPBELL: That's correct, and that's a deficiency in our fit testing requirements. But I fail to see how that causes an increase in the cost or causes the respirator that's sold to the customer to be redesigned.

MR. MISHKIN: Well in order to pass the certification tests, there would have to be an elastomeric face piece. Now would you accept a respirator with an elastomeric face piece for certification purposes, but that same respirator would not have a elastomeric face piece when it goes out to sell to users?

DR. CAMPBELL: I don't understand why it would it have to have an elastomeric face piece because as we now certify respirators in that face fit

test, the respirator is modified to include a different filter media, but the inherent design of the respirator is the same.

MR. MISHKIN: The elastomeric -- Rich, do you want to comment?

MR. METZLER: No, I was going to say that is very misleading in that the qualitative fit tests done in the current process with dust/mist/fume respirators does not require respirators to be modified with an elastomeric fit. In fact, the disposable respirators will often just have a carbon lining in it as a surrogate respirator to conduct that test. It does not require an elastomeric fit to conduct that test.

MR. MISHKIN: But my understanding is that disposable dust/mist respirators at present are not challenged with banana oil for certification purposes.

DR. CAMPBELL: Okay now I understand.

MR. MISHKIN: Okay.

DR. CAMPBELL: So the fit test that is presently in Part 11 does not apply to all types of respirators.

MR. MISHKIN: Correct.

DR. CAMPBELL: Okay, I understand.

MR. MATTHEWS: Let me just make one comment about your point of trying to merge with the CEN standards. Clearly that's an evolving process, as well as what we're trying to do to move these regulations out of 1972 and 1934, however you want to characterize it.

It certainly is the intent of the Agency to provide a strategy that will merge where we're going with the international standards. So we're very much sensitive to that point.

MR. MISHKIN: We are very happy to hear that.

MR. MATTHEWS: It's got to worked out carefully.

DR. MOYER: I have one follow-up question in regard to that. I would assume that since you're basically promoting the CEN-type of standards that you also believe that there should be different classes of respirators according to the challenge aerosol, which means there should be a solid class and a solid and

liquid class. Is that correct.

MR. MISHKIN: You're talking to a marketing person.

DR. MOYER: Well, I thought the European standard --

MR. MISHKIN: Right.

DR. MOYER: -- basically puts forth.

MR. MISHKIN: Yes.

DR. MOYER: So your argument here of endorsing that, I would assume that you therefore endorse the use of two classes, a solid and a liquid aerosol.

MR. MISHKIN: Yes.

MR. METZLER: I'd like to follow-up with a comment to on the CEN standards, primarily from a process point of view. It's not NIOSH's interest to achieve international integration. In papers that I have given, I have been very careful to use the word "integration" rather than "harmonization".

The European community has been working for 20 years or more to harmonize its standards. And even with the common economic interests that they

have, that process has been evolving over almost a quarter of a decade to reach the point where they're currently at.

Seeing the obstacles that harmonization creates, we are embarking on a process of integration, integration meaning selecting those standards which we think appropriately fit in the American workplace and then incorporating those into our certification standards.

Harmonization also implies harmonizing not only the certification standard, but the entire enforcement strategies in the industries in Europe. That's a much bigger topic to address than just certification.

MR. MISHKIN: Thank you.

MR. BERRY ANN: I have -- could I ask a question please? Since you're in marketing, hopefully you can answer this. In the 1987 proposal, which you said you commented on, the Subpart U tests were more stringent in that there were the -- all the classifications had to pass the liquid test.

The cost estimates that we received to

that proposal were in the neighborhood of $500,000, not $500,000,000 to $900,000,000.

MR. MISHKIN: In 1987 --

MR. BERRY ANN: Could you explain the difference, please?

MR. MISHKIN: In 1987, did you have a 200 milligram loading test?

MR. BERRY ANN: No, it was go until failure.

MR. MISHKIN: Okay.

DR. MOYER: It was 100 milligrams in 1987, but that test continued until the filter no longer showed any degradation at all, which in fact could be more critical than the tests that are proposed at this particular time depending on the filter media that is used. So that isn't necessarily true.

DR. CAMPBELL: I also have one. Are you finished? On your original cost estimates, were you assuming that all currently available respirators would need to be redesigned and that none of the available products --

MR. MISHKIN: No, we were talking about

disposables.

DR. CAMPBELL: Okay, then does that apply to all disposables? All disposables would need to be modified in order to meet --

MR. MISHKIN: The most popular types, yes.

DR. CAMPBELL: And what would that be?

MR. MISHKIN: The dust/mist/fume types.

DR. CAMPBELL: Okay, thank you.

MR. MATTHEWS: Okay? You've got a --

MR. METZLER: Yes, I'd like to make another comment for the record, and that is in the submittal of comments to CDC's proposal on respiratory protection for health care workers, one manufacturer of respirators of this type stated that the Subclass C respirator would be comparable to the dust/mist in breathing resistant and comfort for wearer and several times less expensive than HEPA filter products.

MR. MATTHEWS: Okay. Let me ask Bruce, do you have a feel how long you're going to take?

MR. MAHAN: About two minutes.

MR. MATTHEWS: About two minutes?

(Laughter)

MR. MATTHEWS: My kind of guy. While you're coming up to the microphone, let me just make an announcement. I have a message here for Richard Stein, phone message, if you want to come up and get it. It's on the phone table.

MR. MAHAN: I'd like first to make a comment on the modular approach that's being utilized. Given the history of attempted changes to 30 C.F.R. Part 11, this approach is both welcome and refreshing. I'm quite sure that you'd be hard-pressed to find anyone specializing in respiratory protection who would not agree that revision is long overdue.

At the same time, I'm also quite sure that you would equally be hard-pressed to find many within the same community who would be in agreement on specific changes. The modular approach just makes good common sense.

I'm not sure it's permissible to use the term "common sense" when referencing a regulator document --

(Laughter)

MR. MAHAN: -- but I'm hopeful that this

approach will be a step in the direction of getting necessary changes implemented. We wish NIOSH all the luck in the world in using this approach.

Okay using just a few examples, such as metallurgical dust and fumes, carbon black, zinc oxide, sulfuric acid mist, it becomes obvious that potential occupational exposures may be very small sized particulates. While particulate size may be as small as one-one thousandth of a micron, there is just a need to challenge respirators accordingly prior to certification. We support NIOSH's effort to reduce the particle size which would most easily penetrate the filter.

In addition to filter efficiency classification, we feel that there is further need to identify respirators according to breathing resistance. Perhaps NIOSH could consider this for future modules.

We've trained over 17,000 workers from all over the country since '87. We've conducted 168 sessions in Cincinnati, 400 sessions in the field and active plants where we represent the workers. We

consistently hear from the workers that we train that they are not aware of any monitoring being done in their work area.

I am personally convinced that a large percentage of respirator selection is done based on knowledge of what the contaminant is without knowledge of levels or particulate size. It is our opinion that even when attempted, that it is very difficult to get precise particulate classification according to particle size while taking samples in the workplace.

And another area I'd like to comment on is fit testing. I'm aware that this is outside the subject matter of today's informal meeting. I heard -- - John's gone -- but I was pleased to hear John address respirator testing. I'm also pleased to hear to Moldex reference it.

In order to obtain an adequate fit, they may have to use elastomeric face piece. It doesn't really matter how well a filter performs if you don't get a good face to face piece seal. While I don't pretend to have answers on how to address this concern within the certification stage, I would like to take

this opportunity to plant seeds for future consideration.

While we have fit test protocol spelled out in specific standards: asbestos, benzene, formaldihyde, various specific standards, they apply to a very small percentage of respirator users. Before being approved for use, it should be demonstrated that a respirator can attain adequate fit factors on human faces.

It is the opinion of many that this is difficult to demonstrate using any non-elastomeric face piece material. The current qualitative test using isomyl acetate (banana oil) requires that certain face pieces be modified by impregnating charcoal into the filter media.

The end result is that the respirator that is approved is not the same respirator that's used in the field. We would like to see a module added that perhaps addresses fit testing specifically.

Back to the monitoring that goes on in the workplace, I understand there is an argument to be made for a select few large corporations that have

both resources and expertise to do a good job of monitoring. Regrettably, I've found that to be more the exception than the rule.

Smaller employers, and especially those with less than 50 employees, are not likely to have the resources or the expertise to do adequate monitoring. What I also find to be consistently true as we travel around the country doing training is that a lot of people responsible for this area of doing monitoring are also responsible for security, fire, and ten other areas.

There's a lot of downsizing going on and it's very difficult to make a selection based on what results you can get in the workplaces that I have visited, and they're not all mom-and-pop's. That scares me even more.

The places we do go train are the Monsantos, the Union Carbides, the corporations that are not the Earl Scheib's paint shops. If you take that a step further, what I have not been exposed to, I really don't think that you can safely say that we have monitoring in place to make an intelligent

selection when it comes to respirators.

MR. MATTHEWS: Okay.

MR. MAHAN: Any questions?

MR. MATTHEWS: Questions, comments?

DR. CAMPBELL: Based on your experience, could you characterize the ability of typical respirator users to characterize the size of the aerosol that they're concerned with?

MR. MAHAN: The typical respirator user doesn't know what the word "aerosol" means, let alone characterize anything as a result. What I find in workplaces, is that you have to dig and touch several bases before you can even get the results available for the worker to see. When a worker does see the results, they're in a format that's not understandable and that's part of what our job is, to translate some of these results into language that a worker can understand.

MR. BERRY ANN: Based on your experience, do you have any feel for what the particle sizes are in the environments?

MR. MATTHEWS: Anything that I have a feel

for in the way of particle size comes out of textbooks, typically written by those that haven't visited the workplace. But I know these results are from labs, but the National Safety Council, the one chart that I used just to try to get myself a little more knowledgeable, has seen particle sizes down to one-one thousandth of a micron.

And probably half of those on that chart, the chart that I was referencing out of their Fundamentals of Industrial Hygiene text, Third Edition -- probably half of those on that chart were less than one micron. So --

DR. CAMPBELL: The fundamental basis of this proposal is that it uses a worst-case aerosol. And the effect that that has on users is that that removes the burden of the user of having to know anything about the particle size. So I'm taking your comments to mean that you basically would endorse that approach.

MR. MAHAN: Absolutely.

MR. METZLER: I'd like to make a comment concerning the fit testing. The fact that it has not

been addressed in this module is not an indication that we don't see that it's extremely important. In fact, the Institute recognizes that protection provided by a respirator is important in both filter penetration and also in face fit.

So we recognize your concern and hope to address that in a future module.

MR. MAHAN: It wasn't meant as a negative comment. It was just meant as something that I noticed -- I led off by supporting the modular approach because I know when you try to take this whole thing on at once, you might as well not even attempt it.

So I endorse that. I just know that regardless of what we come up with in the way of filter presentation, we can have the best filter available, but if this respirator doesn't fit, which we don't believe that you can get with anything short of elastomeric on a consistent basis, then it doesn't really matter.

MR. METZLER: In fact, I believe that that is an area where we need to focus our attention on

building stronger partnerships to work together to identify proper fit testing, the requirements in the future, as well as assigned protection factor modules with additional public meetings and discussions to hear every perspective on the issue in advance of a proposal.

MR. MAHAN: I don't know that this is the format, Rich, but just one other quick comment. I said two minutes, and I think I've probably exceeded that. But even the fit testing that's done properly -- and I don't want to be over cynical, but it's done in an air conditioned tailer somewhere or it's done up in the hygiene office and it's not done out where the worker is bending down, getting up under parts, sweating, his nose itches, he's got to sneeze.

I mean, we'd like to somehow move toward workplace protection factors, and I know that's in the works. I don't pretend to have the answer to that, but somehow get some sort of a quantitative number on what occurs when that respirator is actually used out there in the real world. And I think those numbers will be dramatically different.

MR. MATTHEWS: Thank you very much. One housekeeping comment. Again, I appreciate Moldex's good humor and flexibility for leading off a little ahead. Would all presenters, if you have slides, leave a copy of the slides at the front desk so we can also make the slides a part of the public record on this meeting?

Why don't we then take a break with the caveat we will come back and ask Bob Salata of the Infectious Disease Society, and then if Walter Hierholzer is here, and could be prepared to also go, we will do those two presentations, and then probably break for lunch and pick up with ISEA after lunch. So I have now 11:28 and we will start back promptly at 11:45.

(Whereupon, the proceedings went off the record at 11:28 a.m. and resumed at 11:46 a.m.)

MR. MATTHEWS: Could I have your attention? What we will plan to do then is, we're at Infectious Disease Society of America, then Walter Hierholzer from Hospital Infection Control Practices Advisory Committee will go also. Then we will break

for lunch after that.

There has been at least one sign-up of a person that wants to have some air-time. So we may fit that person in, depending on how this goes, either before lunch if they're prepared or sometime this afternoon after the ISEA presentations. We'll try to be flexible. Nobody has missed their slots yet in the proceeding and we understand that we're running a little ahead, so we're not trying to blind-side anybody on this.

But as of now, we don't have any intentions of flipping over into tomorrow's 9:00 a.m. order unless there's somebody here, if you want to come up at lunchtime and say you'd be interested in going early if time permits. Please let me know, okay?

So we are now at Robert Salata, Infectious Disease Society of America.

DR. SALATA: Thank you and good morning. I'm Dr. Robert Salata. I'm Associate Professor of Medicine, Associate Chief of Infectious Disease and Clinical Program Director, and Hospital Epidemiologist

at Case Western Reserve University and University Hospitals of Cleveland in Cleveland, Ohio. Today, I am representing the Infectious Diseases Society of America, and we appreciate the opportunity to comment on the NIOSH-proposed rule revisions in the Federal Register of May 24, 1994 and the OSHA mandate for the use of HEPA filtered masks for personal respiratory protection against tuberculosis in health care centers.

The Infectious Disease Society of America offers a unique perspective on the difficult problem of tuberculosis control. With over 4,300 members, this Society is the largest organization of infectious diseases physicians in the world. We provide primary care for patients whose principal problems are infectious in nature, and we are frequently called upon as consultants for patients with difficult and complex infections, including tuberculosis.

Epidemiologists at many hospitals in the United States are also infectious disease physicians. Since the care of tuberculosis has moved from the sanitarium to the general hospital environment, the

prevention of nosocomial or hospital-spread of TB has become a major concern for our membership.

Infectious diseases physicians are at the forefront of TB clinical cases with the ID physicians frequently being the primary sub-specialists dealing with TB patients in many communities. As a group, we have as much face-to-face contact with TB as any other group of health care workers. As such, we have much to gain from carefully designed TB control measures.

Since 1985, the number of reported TB cases in the United States has been rising. An additional complication has been the emergence of multi-drug resistant TB. With the risk for a hospital-associated spread and transmission and increased mortality rates, the IDSA recognizes the legitimate fears and concerns of health care workers regarding acquisition of TB.

However, as the CDC noted in the summary of the draft guidelines for preventing the transmission of TB in health care facilities published in the Federal Register on October 12, 1993, it is not reasonable to expect that TB transmission will be

completely eliminated in the hospital setting.

We would also argue that the major problems with TB currently, particularly regarding hospital transmission, are largely limited to a small number of urban areas. All experts in TB infection believe that the primary efforts and effect of TB control activities must be in the early detection, isolation and treatment of active cases, as well as engineering control such as ventilation changes in isolation areas of the hospital.

The Occupational Safety and Health Act of 1973, which created both OSHA and NIOSH, charges them with ensuring that no worker shall suffer an injury in the workplace. Where no maximal tolerable levels of exposure to toxins, pollutants or microbial pathogens has been defined, the law mandates zero tolerance.

As already pointed out, the CDC has acknowledged that transmission of TB in hospital settings cannot be totally eliminated. Nonetheless, the CDC opened the door for OSHA and NIOSH in the area of respiratory protection for health care workers by making reference in the December 1990 guidelines to

particulate respirators to protect health care workers and not the patients.

Specifically, the law requires that NIOSH certify the use of all particulate respirators regardless of the setting and that NIOSH and OSHA require that where particulate respirators are in use, a planned program of fit tests and fit checks must be established.

NIOSH is charged by law with establishing optimal means of respiratory protection without consideration necessarily of price or feasibility. OSHA, on the other hand, is empowered to consider issues in the context of feasibility and economic ramifications.

The requirement for HEPA filters will be extraordinarily expensive for institutions to implement as the acquisition cost for these masks may be up to ten times that of currently recommended dust/mist respirators. Additionally, fit testing and fit checking programs substantially add to the cost.

The HEPA filter mask requirement goes well beyond any objective documentation of benefit as

acknowledged at the NIOSH workshop in Cincinnati in July 1993. In short, the recommendation for HEPA filters is based upon theoretical benefit. No scientific data exists to support the mandate.

No other change as drastic as that of HEPA filter respirators has ever been brought into the health care environment without some period of site testing. To the best of our knowledge, HEPA filter respirators have never been site-tested at any health care facility.

The current CDC guidelines state, "Respirators with HEPA filters are the only currently available respirators." This is true but only because NIOSH and CDC have not provided certification procedures for evaluating other less costly alternatives that could potentially meet the standards.

Until these agencies have evaluated such alternatives, it is a needless waste of health care dollars to mandate HEPA masks as the only acceptable personal protection control. The draft CDC guidelines of October '93 contain the important acknowledgement

that certain dust/mist and dust/mist/fume respirators may have the filtration capacities as required by NIOSH to exclude respiratory droplet nuclei of a size that carry the tuberculosis bacteria.

Under considerable pressure, NIOSH is now in the process of changing the ideas about certification. This really will provide a window of opportunity for manufacturers to submit alternative respirators for NIOSH approval. We fully support the NIOSH proposal published May 24, 1994, in the Federal Register which would upgrade current testing requirements for particulate respirators.

The new process should provide a fair, reliable way of evaluating particulate respirator use in the future, but is not intended to address design or improved fit of the masks. The proposal and certification process finally addresses the health care setting and the 95 percent filter efficiency should be acceptable to most health care worker needs.

This discussion about filtration capabilities and characteristics of the respirators does not take into account problems related to facial

fit and seal as well as comfort. First of all, it is extremely difficult and unlikely that any particulate respirator can be optimally fitted to a person with facial hair or certain facial types. The expense of these programs needs to be factored in.

There are also issues related to respiratory filter storage and reuse. If HEPA filter particulate respirators are mandated, few health care facilities will be able to afford single, disposable use unlike what is currently the practice for the less expensive dust/mist respirators.

Because of the cost of HEPA filter masks, many institutions have concluded that health care workers caring for tuberculosis patients will have to be cohorted so that as few individuals as possible will need to be fitted for these protective devices.

These masks can be worn for only short periods of time before they become oppressive because of respiratory difficulties. The ramification of this difficulty will undoubtedly be much worse in health care workers with pre-existing respiratory ailments.

The relative increase in prevention of

cases from the use of HEPA filter respirators compared to other respirators has not been assessed in areas where other protective measures, which the Society considers to be of greater importance, have been implemented.

There are settings where the risk of TB transmission to health care workers has been significantly reduced and where the outbreak of hospital transmission has been eliminated without the use of such costly measures as HEPA filtered particulate respirators.

Many TB control experts argue that HEPA respirators afford little benefit beyond administrative measures, engineering controls and personal protective devices already written into the CDC 1990 guidelines. In fact, the current CDC/OSHA recommendation for HEPA filtered respirators have drawn virtually no support from the infectious diseases, infection control or pulmonary medicine communities.

The CDC guidelines that establish new standards for TB control in hospitals will, in

practice, become mandatory standards to which hospitals and health care workers will be held. As a result, the guidelines will have the force and effect of regulations issued by the Agency. Therefore, these guidelines must meet the standard of reasonableness imposed upon all regulations by the Administrative Procedures Act.

Since the CDC has failed to meet this reasonableness standard with regard to provisions in the above-mentioned areas, it must revise the draft guidelines. Agencies are required to issue a concise, general statement of basis and purpose as the final procedural step in the informal rulemaking process. Where agencies have failed to articulate a reasonable basis for their decision to issue a particular regulation, courts have invalidated such regulations and have required agencies to reconsider.

While a court will not substitute its judgement for that of the agency, it will determine whether an agency has considered the relevant factors and articulated a rational correlation between the facts found and the choice made. Recently, a Federal

Court invalidated an existing set of regulations because there was no longer a rational connection between the facts originally supporting the regulation and the regulation as it operates today.

Although agencies are not required to support their proposed guidelines or regulations with scientific certainty, they are required to provide a rational basis for such guidelines which must include some rational connection between the proposed regulation and the desired outcome.

It is the position of the Infectious Disease Society of America, that in some cases the basis for the guidelines do not satisfy the legal requirements. Thus, the IDSA believes that the guidelines must be revised to reflect current medical and scientific data.

On behalf of the IDSA, I have carefully outlined the multiple concerns about and suggestions regarding the proposed guidelines for HEPA filter particulate respirators as personal protection devices against tuberculosis. Prioritizing among the recommended measures in the draft guidelines from the

CDC will result in the most efficient use of TB transmission controls by health care facilities with limited resources.

Impractical or unworkable standards may detract from efforts to protect patients and health care workers. It may interfere with the delivery of care and increase the cost without evidence of reducing risk. The enormous cost implicit in the widespread adoption of the OSHA mandate for HEPA filters would seriously and inevitably decrease funding of a variety of hospital and community-wide tuberculosis control programs.

Such drastic measures, particularly in the areas of low prevalence, will divert resources for more important and necessary strategies for the identification and management of TB cases. Thus, we urge the CDC, NIOSH and OSHA to focus on identifying the requirements that have been demonstrated to improve current TB prevention measures.

Further, we urge these agencies to immediately support the research needed to answer the questions raised by these recommendations. Many of

our members participate actively in TB research and stand ready to assist in this important effort. Thank you.

MR. MATTHEWS: Could I ask you one question?

DR. SALATA: Sure.

MR. MATTHEWS: With respect to your discussion about the legal standard for supporting an Agency position, there really -- I know this is a complicated area, but there are really sort of three pieces hovering in mid-air right now. One is the NIOSH Part 84 module one that we're working on now. Then there is the CDC recommendations of October 12, 1993, for preventing TB transmission in health care settings, which has gone out as a draft document for comments.

And then the third piece of it is the OSHA enforcement standards, which is currently raising the concern which we've already received in both of these other two contexts about the HEPA filter enforcement. Now are the remarks you made about the sub -- I really have two questions.

The first one is, are you addressing with respect to your comments about a legally enforceable standard, are you putting that to what we are doing now on Part 84 or are you doing that with respect to the CDC draft recommendations for TB or are you talking about the OSHA enforcement?

DR. SALATA: This is more related to the CDC draft guidelines. However, I think it's important to understand that the recommendations made through this effort are all interwoven and everything derives from each other, and I think we need to recognize that. But my comments were really based on --

MR. MATTHEWS: Well again, I don't want to lead us too far down --

DR. SALATA: Sure.

MR. MATTHEWS: -- the tuberculosis trails in this meeting, which is really focusing on filter standards --

DR. SALATA: Right.

MR. MATTHEWS: -- but in the October 12th CDC draft guidelines, it recommends a proposal for protection against TB in workplaces. It recommends a

proposed standard of 95 percent filter efficiency at a one micron particle size. Are you supportive of that or --

DR. SALATA: We are supportive of that.

MR. MATTHEWS: Okay.

DR. SALATA: However, currently, to meet that standard or recommendation, the HEPA filter masks are the only ones that apply. In that respect, my comments are really related to the support that we give NIOSH in broadening this certification process, which I think will then have ramifications to the other agencies. And so we are very supportive of this process right now.

MR. MATTHEWS: Okay, and I was just wanting to clarify while the short-hand code, certainly in the hospital infection community, is at -- CDC is recommending HEPA in TB circumstances, that's not quite what was said, is we're recommending a respirator that has this particular property of 95 percent filtration at one micron particle size.

Then we go onto say the only thing currently on the market which we can recommend now is

HEPA due to some other problems that we articulate in that document.

DR. SALATA: The further complexity is that OSHA had made the recommendation as of January of this year that hospitals begin the process of this, with enormous costs already having been undertaken with respect to this.

MR. MATTHEWS: Yes.

DR. SALATA: So we again appreciate the efforts of NIOSH at this level. We think the ramifications will be broader and obviously affect all these other agencies, and we need to be very broad-minded about the ramifications that are decided here as to what areas, such as health care, tuberculosis control will have in the end.

MR. MATTHEWS: Well, just one final comment that I have. I agree with you that this is interwoven and in our discussions we talk about it sort of which comes first, the chicken or the egg, piece of it. We're going to have this -- I mean, we had this in the discussion with fit testing. I'm sure it will come up with respect to protection factors.

You have it with respect to what is OSHA going to do on a TB standard that was alluded to earlier this morning.

It is very difficult -- we've already amply demonstrated the difficulty of trying to change all these regs in one big bolus that's 500 pages high. Okay, so we're trying to break it into digestible modules. Obviously one of the disadvantages of doing that is you can say, well what about this other piece down here and how can you solve that?

I think the Agency's position is that we've got to roll up our sleeves and start, as Rich said in his initial overview, going at what we think is the most important issue to address first, and then take these, as Dr. Rosenstock says, on kind of a continuous basis. We will continue to refine this.

But I agree, these are interrelated and I appreciate your comment on that. Any other comments or questions from the panel? Okay.

DR. SALATA: Thank you.

MR. MATTHEWS: Thank you very much. Probably that's a nice segue for Walter Hierholzer of

Infection Control Advisory Committee.

DR. HIERHOLZER, JR.: Good morning. I'm Dr. Walter Hierholzer. I'm the Hospital Epidemiologist at Yale Haven Hospital in New Haven, Connecticut. I'm here today as the Chairman of the Hospital Infection Control Practices Advisory Committee, called HICPAC --it's not really a hiccup, but close -- to offer support and comment on the proposed rule for certification of respiratory protective devices.

Since HICPAC is not a common word, why I'll take a second to explain that HICPAC is a 12-member Federal advisory committee chartered in 1990 by the Secretary of the Department of Health and Human Services to provide advice and guidance to the Director of CDC and the Director of the National Center of Infectious Diseases regarding the practice of hospital infection control and strategists for the surveillance, prevention and control of nosocomial; this is, hospital related infections in U.S. hospitals.

HICPAC thanks NIOSH for the opportunity to

comment on the Notice of Proposed Rulemaking on respiratory protective devices. HICPAC would note that nosocomial infection control programs have always been concerned not only with the transmission of infectious diseases between patients, but also with the bi-directional spread between patients and health care workers.

At its recent meeting earlier this month, HICPAC began the process of developing the organization for the fifth of its current guideline reviews. This guideline will be devoted to the issues of infection control and the health care worker, and we look forward to NIOSH's assistance with that document.

For the purposes of today's discussion, HICPAC is especially interested and concerned with those portions of the proposal which reflect on the personal respiratory protective devices applicable to the use in the care of patients with infectious pulmonary tuberculosis.

The resurgence of this airborne disease and the increase in its multi-drug resistant forms has

led to several well-described epidemics of nosocomial spread of this disease to other patients and to health care workers resulting in serious disease, and in some cases death.

HICPAC strongly supports the routine use of the 1990 CDC guidelines for the control of tuberculosis and with most portions of the proposed draft of the 1993 division and we have joined in the review and comment on that revision.

HICPAC is of the consensus opinion that the respiratory protection recommendations detailed in Section G of the October 12, 1993 draft guidelines for preventing the transmission of tuberculosis in health care facilities and the performance criteria and other technical specifications in supplement four, respiratory protection of the same document not only meet, but probably exceed the requirements for respiratory protection and personal safety for health care workers caring for patients with infectious tuberculosis.

This is especially so when these features of a personal respiratory protection program are

combined with the appropriate administrative and engineering controls outlined in the same document. HICPAC feels that this opinion is supported by evidence in the historical information of separate institutions and in successful documented control of several epidemic outbreaks of tuberculosis investigated and reported by the CDC wherein transmission to health care workers was controlled by appropriate application of the 1990 guidelines using disposable personal respirators which are less efficient than those recommended in the 1993 draft proposal.

We are especially gratified in the current document that NIOSH is recommending that certification of particulate respirators applicable to TB be given some priority in the hope that the time line to manufacture and certification of a disposable personal protective respirator for the use in the care of TB patients will be as short as possible.

Currently we are caught in a very difficult situation in health care. In order to protect our workers based on the 1993 draft TB

recommendations and to meet the requirements of law under OSHA standards, we are forced to obtain and use a form of protective respirator that is technically excessive, not designed for clinical use, expensive, limited in configuration and in inadequate supply. Obviously this solution is not well suited to our needs.

As you know, this has come about since OSHA, under its General Duty Clause, is now requiring the routine use of HEPA filter respiratory protective devices, since unfortunately they're the only NIOSH-certified devices meeting the content of the 1993 draft proposal.

The difference in cost between the currently available HEPA devices and the projected cost of simpler devices mean the technical specifications of the draft 1993 TB guidelines would appear to be three to five-fold. And the move from the ones that we were using previously to the HEPA filter is ten-fold.

For an institution the size of New Haven Hospital, approximately 900 beds, where we evaluate 70

patients each month for TB, the difference in cost would be between $150,000 and $600,000. Fortunately in our environment only one of these 70 patients is confirmed to have active, potentially infectious TB at the end of our diagnostic evaluations. Unfortunately the trick is to guess which of the 70 it is.

The expense to adequately protect ourselves from infection during the care of that single TB patient is obviously high. Nonetheless, we are willing and feel that we must handle each potential case appropriately including respiratory protection until the diagnosis is excluded.

However, we must do so efficiently and with optimum methods if we are to avoid excessive costs and needless transfers of critical funds from other programs, including the critical administrative and engineering controls that are the most productive features of TB control.

With the production and certification of an appropriate TB respirator mask, such as the Type C that you're proposing, we would ask for assistance in developing highly efficient and easily implemented

training and fit testing protocols. These protocols should not only provide the details for initial training and fit testing of health care workers, but also guidance on easily applied maneuvers to assist the health care worker with appropriate seating or fitting of the mask on each use.

Finally, as with the introduction of all new devices, we would argue for at least a brief period of appropriate field testing in pilot institutions before final introduction. This testing should include both fit testing and proposed in-use protocols and should continue in some form of post-marketing surveillance to identify potential problems and improvements.

We do not suggest a significant delay in introduction as a result of this evaluation, but wish to avoid potential accidents within our user population as a result of unrecognized product disfunction or misuse.

HICPAC will be delighted to continue work with NIOSH and other collaborators, like the CDC, and other professional groups, in this and other projects

in the area of infection control. We again thank NIOSH for the opportunity to comment at this time and we will deliver these written comments in the next two weeks.

MR. MATTHEWS: Thank you. I guess I sort have the same question to you as to the previous speaker. And again without wanting to drag us far down the decision trees on tuberculosis and health care workers, but I think it's pertinent to ask do you feel like the -- do you feel comfortable with the standard that was articulated in the CDC October document with respect to a 95 percent filter penetration, one micron particle size standard for protection of -- general protection of workers in TB settings?

DR. HIERHOLZER, JR.: Our statement was the we feel it not only meets, but probably exceeds.

MR. MATTHEWS: Okay. Yes, okay.

DR. HIERHOLZER, JR.: And so, we're comfortable with the compromise.

MR. MATTHEWS: And certainly your point is well taken that both hospital employers and employees

are a little bit trapped in a situation of equipment that's been on the market, that's been regulated under these rules, for 22 years now doesn't quite fit the situation that you have to deal with. And we appreciate --

DR. HIERHOLZER, JR.: The usual manufacturer and user industry-wise depend on the durability of the mask, which is quite satisfactory. We have to deal with the infection control problems of the mask, which means that if surfaces are contaminated with microorganisms that are a problem to other patients in its use.

So the surface characteristics that aren't cleanable, give us a problem. Then we have to throw away a very expensive mask and so on.

MR. MATTHEWS: Okay, well we understand. Bob, do you have a question?

DR. MULLAN: Yes, I just wanted a little clarification on your cost figures. You said that it would cost you between $150,000 to $600,000. Is that per year?

DR. HIERHOLZER, JR.: Per year.

DR. MULLAN: And that's to go from basically a one dollar dust/mist mask to the HEPA?

DR. HIERHOLZER, JR.: Yes.

DR. MULLAN: So that's like 120,000 masks per year then?

DR. HIERHOLZER, JR.: Yes. We figure that we have a minimum of 20 patients, health care worker patient contacts, in each 24 hour period. And we're suggesting that there's a certain length of time that it takes us to decide which of these 70 patients has infectious tuberculosis and the product of that is increased costs.

That doesn't including fit testing costs, which we would apply on top of these. Now the cost will vary according to whether or not we feel we can use the mask for one day or obviously for eight days or a month. It's very difficult to use the currently available mask for more than a shift without being concerned about its other potential biological properties in terms of contamination of surfaces and so forth.

MR. MATTHEWS: Any other questions or

comments? Okay. I have 12:20. Perhaps we should proceed this way. There was a person that signed up to do a presentation, a walk-on. Is that person here now? Could you identify yourself?

MR. RUTLER: Joe Rutler of Technol.

MR. MATTHEWS: If you would like, we've got -- maybe we ought to break for lunch now. I don't want to hotbox you unnecessarily. Let us break for lunch now. We're running ahead. We were going to ISEA after lunch and if we could work to perhaps fit you in either before or after the ISEA presentations this afternoon if time permits. So why don't you see me at the start of the afternoon session and we will straighten that out?

Okay, I have 12:21. We're a little ahead. Let us start back here promptly then with the time on the agenda at 1:45 and proceed through this. Thank you very much.

(Whereupon, the proceedings went off the record for a lunch break at 12:21 p.m. and resumed at 1:46 p.m.)

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

1:46 P.M.

MR. MATTHEWS: Just one housekeeping comment. If the presenters have written material or overheads, if you could, the transcriber here would appreciate if he could be given a copy. It would help make the -- expedite the translation for the transcript.

Are we ready to start? I have 1:46, so why don't we get underway? What we are tentatively planning on doing is having ISEA, who by the way represents, I guess, 16 manufacturers, so they're combining a lot of comments from a lot of different units that could otherwise ask for single time.

What we plan to do is as Dan Shipp indicated early on, there are about five different segments and they will present a segment on a particular subject. I'm not quite sure what they are, but we will then respond with each particular -- have a break and respond to each particular segment and then go on and again have responses and go that way.

Also, the gentleman who represents -- what

is it, Techmar, Technol? We will try to fit you in after ISEA and get you taken care of today, okay? All right. ISEA, go.

MR. SHIPP: Good afternoon. I'm Dan Shipp, President of the Industrial Safety Equipment Association, also known as the ISEA. The members of the ISEA support the efforts of NIOSH to publish a standard for respirator certification that will provide manufacturers and end users alike with clear, succinct and workable criteria for evaluating the effectiveness of filters for particulate respirators.

ISEA is the leading national association for manufacturers of personal protective equipment and clothing. Since its founding in 1933, the ISEA has been dedicated to protecting the health and safety of workers at factories, construction sites, farms and health care facilities.

Among the ISEA member companies are 18 manufacturers of respiratory protection products including all the product categories that would be affected by the proposed 42 C.F.R. 84. Let me make a comment here to try to keep some perspective on these

issues as we see them. We are sensitive to the need for respiratory protection against tuberculosis and other airborne pathogens. ISEA members manufacture and market these products, and several years ago the Association organized a health care worker protection section to focus on issues affecting this segment of industry.

Still, the vast majority of air purifying respirators are, and will continue to be, used in other industries. Our comments and recommendations therefore will cover this broad range of uses.

The ISEA, whose members produce 95 percent of the respirators manufactured in the United States, has been an ongoing participant in NIOSH's attempts to revise its existing respirator certification criteria, beginning with the proposed standard released by the Agency in 1987.

This rulemaking is vitally important to manufacturers and end users as it will update the criteria currently codified at 30 C.F.R. 11 to mandate that respirators meet stringent technical requirements and provide maximum protection to workers exposed to

harmful airborne contaminants.

The ability of manufacturers to retool their operations to produce new, higher efficiency respirators will be determined in large part by the implementation of NIOSH requirements as they appear in the Agency's final rule. The ISEA supports the Agency's efforts to update and strengthen its certification criteria, but urges NIOSH to do so in a way that will allow the manufacturing industry adequate time to develop products that meet the new standards.

We also ask that NIOSH consider carefully the requirements it incorporates into its final rule so as to not disable manufacturers with overly burdensome and unattainable criteria.

The ISEA supports improvements in proposed filter performance requirements. During the past seven years, NIOSH has introduced a number of proposed respirator certification criteria, many of which went beyond mere filter performance levels. In 1987, NIOSH published a proposed revision to its current respirator certification standard.

This proposal was viewed widely as an inaccurate reflection of the state of modern science and technology and an unworkable and overly burdensome standard for manufacturers that would not provide measurable benefits to the end user. Several unwieldy proposals were prepared subsequently by NIOSH and the ISEA objected to each of them.

Although the ISEA has not always agreed with positions taken by NIOSH, we have tried to work closely with the Agency in order to reach a consensus on the certification requirements that ultimately would appear in the proposed rule. For example, on March 21, 1991, ISEA provided NIOSH with an extensive compilation of workplace protection factor studies measuring the effectiveness of particulate respirators at various levels of airborne contaminants.

There's valuable information in these studies to assist NIOSH in its thinking in the present rulemaking, as well as for other modules.

The proposed filter performance criteria are, in part, a reflection of this continuing dialogue that ISEA has attempted to maintain with NIOSH. The

Agency has modified several elements of the proposed criteria that ISEA objected to in the 1987 version. For example, in earlier proposals, the manufacturer was required to obtain certification for protection against both liquid and solid particulates, whereas NIOSH's current proposal allows for separate certification for either solid or liquid and solid particulates.

In another example, the statistical handling of test data in earlier proposals used a sample size ISEA considered too small, whereas NIOSH's current proposal would require 30 samples rather than three or six.

The ISEA recognizes and appreciates NIOSH's willingness to understand the suggestions and concerns of manufacturers. Likewise, we appreciate the challenges that NIOSH has posed to manufacturers and their attempt to provide worker protection in the context of a feasible certification standard.

Respirators are a critical asset to protecting workers. Respiratory protective devices are an invaluable component of any work place health

and safety program. We recognize the established hierarchy of controls where an employer looks first to engineering controls to eliminate or mitigate occupational hazards.

In certain situations, however, workplace conditions dictate that engineering controls are not feasible and an alternative means of providing protection must be used. This is especially true in many construction, agricultural, mining and maritime workplaces.

Where engineering controls would fail to provide adequate protection or are not otherwise feasible, respirators and other personal protective equipment are recognized as an effective means of protecting employees against the dangers of the workplace. In other instances, equipment failure or routine maintenance operations may necessitate the use of respirators.

The effectiveness of respirators was demonstrated by the workplace studies that ISEA provided to NIOSH in 1991. As an added benefit, respirators present a less costly alternative to

capital intensive of engineering controls. The degree of protection that a particular respirator provides is dependent upon a number of factors, one of which is filter performance.

Because we recognize the value of well engineered performance in respirators, the ISEA considers this rulemaking to be of critical importance to the industry and to the end user. The member companies of the ISEA share NIOSH's goal of protecting workers from respiratory hazards in the workplace, and see this module on filter performance as the first step towards bringing the Agency's certification criteria up to date with modern science and technology.

Now, if I may, I'd like to turn our presentation over to the experts from ISEA member companies who will discuss specific parts of the proposed rule. And I understand that they will have questions after each of them makes his presentation.

MR. MATTHEWS: That's fine.

MR. SHIPP: First of all, we'll have Barry Phillips of Scott Aviation who will cover the ISEA's

view of the modular approach, inter-agency coordination, international harmonization, industry empowerment and the grandfathering provisions.

Next will be Bill Newcomb of North Safety who will discuss the proposed testing parameters and filter efficiency. Next will be Michael Bennett of Racal Health and Safety who will discuss requirements for powered air purifying respirators and test statistics, and Don Wilmes of 3M Company will discuss fit testing and the assigned protection factors.

And I'd like to turn it over to Barry Phillips now if I may.

MR. PHILLIPS: Thank you. Good afternoon. I'll provide a set of the slides as well when we leave here.

MR. MATTHEWS: Thank you.

MR. PHILLIPS: As introduced, I will start off with discussing the modular approach, and would like to again emphasize that ISEA is focusing on the effect that filter performance and respiratory protection has on the broad base of users of respiratory protection, understanding also that there

are benefits that can be provided to specific segments like the health care industry.

ISEA supports the modular approach to rulemaking. Basically, we're looking at it -- we see it as an innovative aspect to rulemaking with some benefits because of being results-oriented and some measurable successes that we look forward to seeing down the road.

The modular approach provides some of the benefits shown in previous attempts towards rulemaking. Because of the attempts to provide one, large comprehensive rule, we've had elements that have potentially caused confusion and who were overly excessive to both users as well as manufacturers and also to the regulating community.

In some cases, there were inaccurate reflections of current science and technology; overall, overly burdensome potentials again for both users and on the manufacturing end, and in some cases limited user benefit that could be caused by overall confusion, outdating due to time frames involved, and the lack of coordination between other agencies.

The incremental approach provides some additional feasibility by going with steps rather than one overall regulation. You have the opportunity for focus in working through regulation and as far as focus on requirements that are best needed at certain times. There's also enhanced workable rulemaking process due to some of this focus as far as resources and available activities, and manufacturing time to develop products that incorporate most current technology, as well as meeting the requirements of updated certification rulemaking.

Through the modular approach, we see benefits to all interested parties again through a more efficient rulemaking process. This should provide us measurable progress through the succession of modules, increase motivation within NIOSH because we'll be able to see or should be seeing accomplishments as we go through the steps, and enhanced external relationships with the regulated community because of these positive, progressive results.

The modular approach does provide focus,

focus on modules perhaps making them easier or more easily understood, this at the user level as well as at the manufacturer level and in the regulated community give us an opportunity to expedite the rulemaking process, focus resources. And this could be focusing resources throughout industry, the manufacturing side, as well as focusing resources within the regulated community and within the regulators. So you've got focus on what task is at hand, and then overall opportunities as far as cooperative development as we progress through modules.

With the modular approach, we see that there are key elements to the potential success of such an approach. And the first is sequence, the second being timing. As far as the sequence, ISEA does support the sequence with some minor modifications, the sequence as published.

We'd like to see the addition of a PAPR module. This will be discussed in more detail later on -- the addition of gas and vapor particulate specific and addition of the airline combination

respirator as a specific module.

A concern as well with the PAPR, gas, vapor and particulate modules, would be to address those prior to APS and the concern here is developing new protection factors without having performance requirements established. We'd like to see the performance requirements so we can develop what the protection factor would be.

As far as timing, we are recommending that a five-year completion schedule is submitted and this so that we have an overall completion of the complete respirator rule that happens within a time frame that gets completed prior to obsolescence. At it gives you then the opportunity to address and update modules in the future as needed. And we propose that NIOSH is the project manager for this and maintains this five-year proposed schedule.

We do have some concerns with the modular approach and that would be with some of the ambiguities as far as we're able to determine from the information that's available to us. We're concerned with how the modules will interrelate. As one module

is established and promulgated, a future module may affect the performance requirements or certain aspects of a specific module that's previously been put in place, and therefore, what type of effect does that have on the definition of what that respirator should be, the performance requirements, perhaps whether it's APS or those sorts of things. There needs to be a definition as far as how they will overlap.

Also as far as the overlap, based on the schedule, it does appear that some modules will be worked on at the same time. And from that standpoint, we're concerned to be sure that the module process continues that there are the appropriate resources to allow these modules to be worked on when there is some overlap in time frame.

As far as the interrelations, the R & D costs and the retooling costs that can be associated at the manufacturing end do create some concern. If there is a future module that may have an effect on a module now in progress, there may be the temptation to wait until the future module comes into play because of the effect one has on the other and the excessive

costs that may be incurred in having to redesign something that was just redesigned and retool a manufacturing facility that had just been retooled.

And then lastly the grandfathering relationships, what will the grandfathering relationships be between modules as modules progress?

Additional opportunities in the modular approach: we see some opportunity for open communications and we would like to submit that open communications, we believe, is key in the development of these modules as we move forward. And that would be communications within the regulated community, within the manufacturing community, the end-user community and the remainder of the respirator community academia and the like.

This would help reduce the potential of R & D costs and laboratory costs. These costs are expensive on manufacturing, as well as on the regulated community or regulators. In open communications, we can all coordinate our efforts towards better development of technology towards the advancement of respiratory protection in the

workplace, and maintain limited -- or focus on minimizing costs in different directions.

Also avoid unrealistic and ambiguous requirements as far as an overall proposed rule requirement or test certification requirements. Focus on R & D, again this can be focused between resources that are available. This should help expedite advancements in technology and protection in the workplace and minimize the end cost impact to the user community.

In the inter-agency coordination, we would like to see NIOSH take a leadership role in the inter-agency coordination. One aspect currently, both OSHA and MSHA have held out their respirator publications, their upcoming rules, and are looking for some input from NIOSH. We'd like to see and promote good coordination between the agencies, and with NIOSH taking that leadership role.

Also just as a note in regard to MSHA and proposals, currently we have a concern as far as MSHA's reference to Z 88.2 (1969). We would propose that that would be referenced to Z 88.2 (1992).

Also inter-agency coordination encompasses all the other agencies, and hopefully I haven't missed any, but there are quite a few. And there are the concerns that there are so many contaminant-specific or use-specific respirator rules out there that it does become very confusing in the workplace, and also from the standpoint of manufacturing for those various requirements.

We'd like to see again that NIOSH take this leadership role and try wherever possible to coordinate throughout agencies.

In line with inter-agency coordination, performance standards and APFs, we'd like to see a link between performance standards to face piece leakage requirements and APFs. OSHA has traditionally handled APFs and we feel that NIOSH is the appropriate agency to evaluate performance in the workplace, and we'd like to see that progress through NIOSH and for NIOSH to determine APFs for respirator classes and this to be done with the input of the users and the input of the manufacturers and the respirator community.

ISEA, as was noted before, has additionally submitted workplace studies and would like to continue to work with NIOSH wherever possible. We would also like to recommend ANSI's Z 88.2 1992 Edition for APFs with more than two dozen workplace and simulated workplace studies utilized for those assigned protection factors, and again to coordinate the APF positions throughout the agencies.

This moves us into a user's guide. It was noted that the user's guide is being planned and we do agree that a user's guide is needed, and we highly support it. And this, to inform the regulated community of the modules as they go through, and specifically with the first module on filter performance, and this to also minimize confusion in the workplace.

We would need to see an indication relative to the new classes and this to be focused at the user level. And it would highlight applications and selections. What will the applications be for the new classes of respirators?

We'd like to see that this user's guide

though would come out with input from all concerned. This would be the worker community, academia, respiratory protection community, people like the AIHA, manufacturing community and also the regulating community including OSHA, MSHA and EPA.

So we'd like to have some review prior to publication to provide this input through some sort of a technical meeting at some point prior to its publication; this to help avoid incorrect interpretation, ensure that there is a user focus to the guide, to ensure ease of understanding since this should be focused to simplify things for the user and their understanding, also to provide a guidance to manufacturers, and again referencing what applications for specific classes of new filter respirators; and then also as a cross reference back to the previous filter requirements.

International harmonization, a globalization goal is supported by ISEA and we'd like to see it as far as being compatible wherever possible, understanding some of the limitations and notations that were brought up before as far as

definition of harmonization and the like. We see some of the benefits as far as lower non-trade tariff barriers from the manufacturing community and potential advancements in export opportunities for U.S. manufactures, also to enhance global understanding of respiratory protection in the workplace.

This would include certification and use standards throughout the modular program, so we'd like to see that wherever possible, there is an effort towards harmonization wherever it is possible, understanding the relevance of the terms.

In quality programs, developing quality system standards such as the basis of the ISO 9000 quality systems. And also as a note in nomenclature, in the respirator or in the filter performance requirements, we would like to suggest that the classes actually be called classes as opposed to types, and they would be in the one, two, and three as far as designation with three being -- or, excuse me, one being equal to Class Three -- or A equal to three.

So it's confusing as I'm becoming --

(Laughter)

MR. PHILLIPS: -- in line with the European standards one, two and three, with three being the highest efficiency.

Industry empowerment, NIOSH programs elements, as have been outlined, requirements are to certify respirators to assure quality, investigate field complaints, provide technical assistance, and obviously developing standards. This is somewhat resource intensive and because of this, there are potential limitations in the certification program; and this through providing increasing demands on NIOSH.

Understanding this, ISEA supports NIOSH's vision for continuous improvement, industry empowerment, matrix management and goal champions; this to broaden the influence of the certification program and to limit additional resource requirements.

As far as focusing on industry empowerment, ISEA strongly supports the idea of industry empowerment; this to expand resources and

expertise including creating partnerships with the private sector, the opportunity of freeing up federal funds; this which would provide an opportunity for other workplace health and safety improvement projects within NIOSH.

Empowerment opportunities we see as far as to take advantage of the private sector as far as its knowledge and its resources, to in turn increase protection of the worker by utilizing consensus standards as highlighted in the OMB circular, utilizing scientific studies, developing through a peer review a formalized peer review process, using qualified labs for performance testing, and utilizing ISO-certified quality auditors for respirator manufacturer quality auditing.

Grandfathering: ISEA does note a need for grandfathering, but ISEA does have some concerns relative to the grandfathering provisions as published. Start off with the proposal of a 30-day limit on 30 C.F.R. 11 submittals. ISEA is in support of this 30-day limit and ISEA does feel that 30 days is reasonable.

The two year limit on sale and distribution as proposed, ISEA recommends that a four year limit on the manufacturer sale and shipment. The reason behind this is experience in the European community showing a three year-plus requirement. A previous proposal of NIOSH of five years without a rationale for the change to two years, NIOSH has limited resources to approve respirators, to ensure that there's an opportunity to approve respirators to the new certification standards.

There's been shown experience as far as time requirements with the Bureau of Mines transfer of certification; filter media limitations and as far as the R & D development requirements for new filter media; and lastly, certainly to ensure that there is a workplace supply maintained in the marketplace from a concern as far as a respirator not meeting new performance requirements and shelves not being stocked with available respiratory protection.

In the proposal, NIOSH will process 30 C.F.R. 11 applications previously submitted for six months. There's no reference made for extensions on

approval. Here the recommendation would be that ISEA recommends two year limitations on extensions affecting filter media. The rationale here is that there may be limitations or effects on respirator manufacturers from the supply of filter media, things that require a change in the filter media that would need to be upgraded.

As far as a time frame that we feel that this time frame is sufficient because of the certification backlog, the product upgrades and changes that would be beneficial if the filter supplier had changed, also provide opportunity for broad-based R & D work throughout the respirator community, and adequate time for manufacturing to make the changes over to the new requirements for that segment.

As far as for limitation on extensions that do not affect filter performance, ISEA recommends a four year limitation on the extensions in this area where filter performance is not affected. And this would be due to the aspects of some sort of requirement to change, whether it's a change of a

color of a seal, the change of a head-strap, the addition of a gas or a vapor to an existing approved respirator.

The purpose of this would be with the four year time period that these respirators should be available for shipment from manufacturing, that there should be an opportunity for those respirators to be enhanced while they are available should the enhancement be made available through additional changes.

This would provide the opportunity for workplace enhancements and keep it in line with the time frame that those respirators are available through manufacturing.

There's also noted in the proposal a two year limit on sales and distribution, and this portion I just want to focus on distribution. We propose that distributors may continue to distribute and users may continue to use. The rationale here is that the certification does not expire with the promulgation of the new certification requirements.

In addition, distribution is not

controlled by the manufacturing community. There is a potential for costly returns if there was a cut-off date on distribution. This would be hardly difficult to regulate, but it could be potentially a return call coming back from the user community and back through the distribution community, which could be highly costly to the marketplace.

We also want to ensure that there's a maintained workplace supply. If there's a belief that a respirator certification were to expire, there's a concern that distribution would not stock appropriate inventory because of the belief that it would become devalued or users would not stock inventory from the fact that it may not -- it may be believed that it would no longer be certified.

In addition to, and as a footnote to all the grandfathering provisions, if there's an opportunity for development and certification in an expedited manner, but quicker than the recommendations here, the market will certainly demand to what direction the respirator requirements become, as far as the purchase requirements of the user community.

MR. MATTHEWS: Can I just make sure I understand what you're saying in this slide? The Agency proposal is two year sales and distribution deadline.

MR. PHILLIPS: Right.

MR. MATTHEWS: But what you're saying is knock out distribution and use. And in your earlier slide, you're proposing four years on sales?

MR. PHILLIPS: Correct. Correct, on the sales end, yes, four years from the shipment from manufacturer.

MR. MATTHEWS: Sorry to interrupt.

MR. PHILLIPS: Okay, that's fine. Lastly, it wasn't, I think, noted that I would hit this topic as well, but here it is. I have economic impact and the concern with ISEA is basically that the economic impact was underestimated as far as how it was presented in the preamble to the proposed rule.

And this may be understated from the standpoint of limited information that was previously available. ISEA ran an internal survey and from the responding members, we estimate an impact in excess of

$100 million; this based on information that is currently available, estimates on R & D, estimates on plant retooling and estimates on material.

Understanding that there still are a great deal of variables, what ISEA is recommending in reference to the economic impact is ISEA recommends a closer working relationship with NIOSH; this to enable focused resources and cost effective rulemaking and a full understanding of what effect certification requirements will have on the manufacturing and user community.

We're also proposing opening the efficiency ratings; this to meet a larger range of user requirements and also to reduce the overall cost impact. And I'd like to reference in this point that there seems to be some confusion as far as how the cost impact is perceived. Certainly there may be some benefits to the health care industry in going from a HEPA filter requirement to a Type C or Three or One, whatever the classification turns out to be.

There may be some cost potential benefits to the health care community. The health care

community is just one of many communities, respirator communities, workplace communities, that are in need of this protection, and the efficiency rating, as will be discussed a little bit further, may be tighter than needed for some of the other workplace requirements and therefore, adding a great deal of cost to those broad workplace requirements.

That's the end of my segment. I guess I'm here for questions first.

MR. MATTHEWS: It might make sense if we go sort of with respect to your -- and I very much appreciate your overview and your very logical laying out of the issues. As I see it, you've got comments and recommendations on a user's guide, on international harmonization, on the industry empowerment and then the grandfathering and economic impact. Is that about --

MR. PHILLIPS: Right, that's correct.

MR. MATTHEWS: -- the broad categories? It might be better if we try to go a piece at a time on that and see if we have comments -

MR. PHILLIPS: Certainly.

MR. MATTHEWS: -- or questions or responses on that because you've put a very wide set of recommendations --

MR. PHILLIPS: Yes, I understand there are five topics there. Really so, yes.

MR. MATTHEWS: -- in a concise amount of time. But I think probably the group would like to engage on some of these points. If that's acceptable, why don't we -- do we want to talk about the user's guide on that first? Any comments on that, Rich?

DR. METZLER: Well actually, you said a great deal in a very short time. It's difficult to comment on all of your points, but one of the things that impressed me was your call for better partnerships, improved communications among all of the players interested in protecting workers. Some of the points that I note here that actually relies upon a positive, better working, relationship would be with regard to modular approach now, would be the sequence and timing of the modules, the priorities on modules and which modules are picked, the module schedules.

Open communications was a major point with

regard to in the leadership and communication among all the partners and leading up to, at least I thought in the first half of your presentation, was a user's guide plan. This whole philosophy that we have been creating, which is exemplified in the modular approach, is really based upon the belief that safety and health improvements over the years have been made through a number of major efforts.

One of them is labor uniting for a common cause to demand more protective equipment. Another was technological improvements. A third was better training. Certainly a positive impact was felt through better standards and regulations, and we think the future of better quality partnerships will be needed to enhance safety and health.

So we, in fact, do support and agree with your requests and are intending to increase the number of public meetings, increase the forms of our communications, so that we can receive information from all interested parties prior to preparing a proposal.

With regard specifically now to the user's

guide that Gene mentioned, we agree that there is a need for guidelines for, again, many segments of the industry, but particularly workers, in how to transition from Part 11 respirators to Part 84 respirators. And we think that a team partnership among all of the parties to produce that guideline is appropriate.

MR. MATTHEWS: How about -- do you want to just move onto international harmonization? Any other comments on the user guide concept? I think we're in agreement. We clearly need to sit down with the interested parties and come up with a document that doesn't -- it's not in our interest for it to be full of errors and confusing, and it needs to be focused and understood.

So we're -- I think we're in agreement on that.

DR. METZLER: A comment on the schedules, the Institute's interest in making improved protection available to U.S. workers as soon as we can possibly do so, recognizing that foreign workers are already receiving respirators that can perform at the higher

levels and they have the benefit of the greater protection of the respirators in the U.S. which are not meeting these particular standards, do not have that same opportunity for the better level of protection.

With regard to the specific time frames, we think that it is necessary to receive detailed information on the impact to workers and the overall manufacturing community for providing these products in a timely way and yet, meeting worker protection needs as soon as we can get them there.

MR. MATTHEWS: And we understand your point about the nomenclature. We've got to come up with a way so that we ultimately end up at the same place with the European Community. So we hear what you're saying about A, B, and C might be recast Three, Two, One respectively.

MR. PHILLIPS: I understand that they can't be exactly the same because there are some differences.

MR. MATTHEWS: Right. So we hear and appreciate your comment on that piece of it. Industry

empowerment, ISO quality?

DR. METZLER: On industry empowerment, we do agree that Institute resources never seem to be enough to address all of the improvements needed. And we need to find ways that the talents and resources available in the community's private sector: academia, private laboratories, those talents that are out there can in some way form in this partnership so that we can be, in the most timely way, incorporating new technologies and addressing the emerging hazards.

We will be exploring with all interested parties forums for making that empowerment possible.

DR. CAMPBELL: Let me ask one question to follow-up on Gene's earlier comments about the class designations. When we were developing this proposal, we talked about the comparison between the European standard notation one, two, and three, and we actually chose to use the letters because we recognized that these were different standards, and that if we had something that was similar to the European standards, that in fact could cause confusion and possible misuse of the respirators because someone may interpret that

to mean that they were the same standards. And they are, in fact, different in many regards.

I would just ask you to comment on that thinking and had you thought in those terms as well?

MR. PHILLIPS: Right. Well from the standpoint of -- we were discussing it as well as whether it be P1, P2, P3, similar to -- which is very similar. But then again, as I think I brought up, it cannot be exactly the same because they are, agreed, different. But from the standpoint of leaning towards a similar direction, we believe that that will help identify the most efficient, mid-efficiency, lower efficiency range in a similar format and help to create some understanding.

In addition, we have Type C airline respirators. We have other things that come in that could potentially add some confusion in using that type of classification.

MR. MATTHEWS: Okay. Will that --

DR. METZLER: I guess one last comment on your interest in inter-relationships, overlaps and resource availability in identifying and producing the

modules. We agree with you that all of those are legitimate concerns from many points of view and communications in advance and a schedule that is identified so there is a clear target for all of us to work towards, we think may be one way to mitigate those concerns.

We also believe that a process can be established whereby those concerns are taken into consideration in identifying the modules through discussions of this type and others to be able to identify the priorities, schedule them and then everyone will be aware of what targets we're working towards.

MR. PHILLIPS: Yes, I understand. I think also understanding the standpoint that if everything was able to be laid out completely already that the complete rule would be done. So we do understand that this is a new process and not everything has been defined at this point, as the emphasis, again, is open communication with all involved to best develop a system that works and provides the most published protection for the workplace.

MR. MATTHEWS: Well, that now takes us on my playbook up to grandfather. Grandfather is an interesting issue. Clearly I think we're most in agreement with what you say about, we want the marketplace demand to drive the time line here. And we're certainly caught in the dynamic between not wanting to set a grandfather period that is unreasonably short that manufacturers can't meet, there's no product out there, what is the user community going to do? And you've got regulations in place that are making illegal the old equipment. So that is one side of the dichotomy.

On the other side, we don't want to set the time line, the grandfather period, up in such a way that it actually provides a regulatory hinderance to the production of better equipment; in other words, that it artificially keeps the older equipment on the market for use where it really shouldn't be there.

So we're all, I think, striving towards trying to get that timing down in such a way that we encourage as soon as possible the development of the new equipment and the termination of the old equipment

in a way that's as least traumatic on everybody as possible.

But our over-arching goal here is to protect workers and we're all about providing a better product that will protect workers better. So I think we're in agreement on that. Now how we go about that is clearly not an exact science. I understand you to say you're in support of the 30-day clause for non-new Part 11 applications.

MR. PHILLIPS: For brand new -- for complete new respirators.

MR. MATTHEWS: And then if I understand your two slides placed together, you are requesting, instead of two-year limit on sale and distribution, move that to four years on sale and let distribution and use sort itself out --

MR. PHILLIPS: As it's not controlled by --

MR. MATTHEWS: -- downstream from there.

MR. PHILLIPS: Right.

MR. MATTHEWS: I mean, I understand that part of it. With that stage set --

MR. PHILLIPS: Right.

MR. MATTHEWS: -- we have questions about this.

MR. PHILLIPS: Well, I'd like to make a point as well. I think certainly from the standpoint of a manufacturer, it would be -- if I, as a manufacturer, it would be in my benefit to naturally get out the -- to be, say, the first on the block to say I have a 42 C.F.R. 84 filter respirator.

MR. MATTHEWS: And nobody else does.

MR. PHILLIPS: And there's a benefit to that from a single manufacturer standpoint. But when you look at what the limitations may be as far as the full certification process to make a broad range of product available for the user community to enable themselves to have the range of selection that they should have for appropriate fit testing requirements, for the range to support the economic range that may be out there for the user community, and also the limitations that may come up as far as design requirements and filter performance capabilities as the rule is finalized.

So those are the concerns, understanding that there are --

MR. MATTHEWS: If I hear what you just said, it's not just a matter of: is one manufacturer ready to go, but the broader question for all of us is how can we meet the need of the user community?

MR. PHILLIPS: Right, and enabling a broad range of product available for the user community, and also ensure that there is a time frame in there that is sufficient enough for testing, research and development, whether there's field trials or whatever might be. Those things all do take some time and there are still some concerns as far as what the filter performance requirements will be and which will be discussed a little bit further as well.

MR. MATTHEWS: Okay, Rich? Well that takes us then on my notes to economic impact. You indicated an estimate of greater than $100 million based on member survey, R & D costs and plant retooling. Can you give us a little more --

MR. PHILLIPS: Well basically --

MR. MATTHEWS: -- nuts and bolts?

MR. PHILLIPS: -- from the standpoint of the manufacturing end, it's somewhat -- to some extent, it's somewhat difficult to fully define. But I'd like to bring over an example that was brought up this morning about what a user in the health care industry as far as the potential cost for him or his facility from going from one range to another in that very limited user environment.

If you take that and imply what the cost may be for the user of a broad range of respirators now that may be forced up in class, as opposed to what we're looking for as health care coming down in class, the cost implication is extensive.

As far as what we did within the ISEA, there are some limits on information that is able to be shared naturally from the standpoint, of it's a group of competitors in an industry. But we are able to take a look at what was -- based on the information that was available, what did you foresee as a manufacturer as the cost implications based on what you would have to do as far as procuring new equipment, procuring new material, plant retooling and

the like, and then taking that information and compiling it into a number range to give us an idea of what we felt that impact would be.

We also -- I know there was a reference to an '87 comment from ISEA, I believe, you know it was kind of directed towards Moldex and that was their individual presentation. We can go back and research what that was at that point as well. We don't have that information with us today.

But what I was referencing in this point is that we do feel that it is underestimated. We are concerned about that. And the main focus from that comes up that there are two key things that we'd like to suggest from that and one is a closer working relationship so everybody is aware of where the things are going and what the cost implications may become down the road and the other is the effect on the filter efficiency and what does that actually do to the cost of the broad range users that are out there?

And we'll discuss efficiency again a little bit later on, but the implications on everybody that uses a filter-type respirator and what cost

impact may be expected there. So broadening the efficiency to hopefully provide respiratory protection that exceeds the needs and requirements of the marketplace, but also does not enforce as high an economic impact.

MR. MATTHEWS: Okay. We can go either way. If you want, we can deal with the -- come back and take the cost, economic impact, in the context of the -- you allude to the fact that you're subsequently going to discuss the filter range issue in another presentation. So we can either come back to that later or engage now, whatever you want to do. Rich?

DR. METZLER: I think we can address it further right now. If there's more detailed information that can be provided -- I think one thing I heard this morning was an inherent assumption in the cost estimates that an elastomeric face seal will be needed on every respirator.

And, of course, if that went into the economic impact analysis to produce the figures you're working with, it could significantly mislead what that impact might be. So as a matter of public record on

this rulemaking activity, we need to see specific data in the assumptions that are going into the projections.

MR. PHILLIPS: Well, it's -- and this will have to be discussed and brought up as far as the ISEA's standpoint in written comment, as I don't have that information directly in front of me. There also was a concern within the ISEA organization as far as where the numbers came from from your standpoint.

And it's difficult to comment on whether those numbers are adequate as well or inadequate if what is the information that supports it from that standpoint also; the main concern again being that the communications are kept up between, so that we are best able to focus on what the economic impact will be as future modules develop and so we're all -- as you're just noting there, that we're all working off the same format.

This that was brought up this morning may or may not be a consideration of the range of manufacturers that respond. There are certain things that can be discussed within manufacturers within an

organization and from the standpoint of specific design requirements, that's somewhat that would be proprietary and obviously wouldn't be discussed within or between manufacturers.

MR. MATTHEWS: Okay. What is the next module?

MR. PHILLIPS: Excuse me, our next discussion?

(Laughter)

MR. MATTHEWS: What is the subject? I'm just trying to keep track of time.

MR. PHILLIPS: Okay, the next subject is Bill Newcomb.

MR. MATTHEWS: Okay.

MR. PHILLIPS: Thank you very much.

MR. MATTHEWS: All right, let's go ahead then. Why don't we try to do this next one and discussion and then take a break after that? Does that sound reasonable? After module two --

(Laughter)

MR. MATTHEWS: By the way, they asked me to announce that there's a message board set up

outside, so check it at the break.

MR. NEWCOMB: Thank you. Good afternoon. My name is Bill Newcomb. I'm from North Safety and I am representing the ISEA talking about two subjects: testing parameters and filter efficiencies.

Section 84.184 now is titled "Particulate Instantaneous Penetration Test". We feel that this title is a little misleading since the filter penetration is not taken continuously, nor is it necessarily instantaneous. And it's a small point, but we feel that to readers of the article, it might be misleading.

One of the major topics of discussion within the ISEA since this module was put forth is the method of aerosol generation. The problem that we have found concerns specifically the DOP oil mist penetration requirements. Back to this in a second.

Five members of the ISEA, all having the equipment necessary to generate the particle size as required in the proposal, took samples out of lots of filter material. They were very controlled samples and tested them. These were mechanical filters and

filters that had an electric fabrication.

The mechanical filters were tested with the new proposed test aerosol generator called the AFT and also tested with the old Q-127 DOP generator. And you can see the Type A, Type B, and Type C filter media all gave approximately the same results, no matter which aerosol generation method was used.

The new generation method uses a cold nebulized DOP. The old generation method is the hot DOP. With electret materials and materials that look like a Type A filter, it can be seen running the test. At the end of the test, it was down to about 99.9 percent efficiency.

However, using the hot generator DOP, it was down to less than 99.6 percent. Clearly even though the particle size is the same, the generation method seems to have a different effect on the filter. The same result was noted with the Type B filter material, down to about 98.5 percent with a cold generated and down to less than 95 percent with a hot generated. And as you well imagine, the same thing happens with Type C filters.

The generation method that was chosen was chosen to be the most penetrating particle size and most deterious material to test filters with. This would suggest that there is something wrong with that hypothesis.

Getting back to our proposal, we would like to work with NIOSH, the equipment manufacturers and anyone else that is interested, to come up with a reproducible test that is worst-case, that will satisfy the requirements of the standard.

Going along with that, we also have had some discussion with NIOSH in the past over the reproducibility of the current test in 30 C.F.R. 11 and we certainly would not like to get the same type of problems with this new regulation.

I know there's a lot of figures up there, but again, looking at the round robin tests, one can see that at different test sites, the same media in some cases was much different using one apparatus than it was using another apparatus.

For instance, A-1 initial penetration, .015 percent Test Site A, the same material Test Site

B, similar penetration, Test Site Three, almost doubled, Test Site Four, a little more than half, about two-thirds, and Test Site Five, way out of sight.

If you follow across for Type B media an Type C, you find the same type of penetration results which would indicate that the equipment at the present time does not allow testing at various test sites to get the same results.

This is extremely critical for the manufacturers considering the new requirements for statistical analysis of results. If the inter test variability is more than the standard deviation that we're allowed on filter tests, then we've got a big problem.

Again, ISEA would like to work with NIOSH or with anyone else who is interested to make sure that whatever test is required, it's reproducible on the same piece of equipment in different places in the country or different places in the world.

There are a few things that we feel are left out of the regulation which also could cause

confusion and cause test results not to be reproducible from one test house to the other. One of them is the volume of the containment cylinder or box or whatever that the filter is put in after pre-conditioning.

Our feeling is that if the volume is too large or the filter is left in there too long or not put in there soon enough that any effects that the moisture and pre-conditioning might have could be negated. And in order to make it reproducible, we're suggesting that the volume be specified, the time between conditioning and isolation be specified, as well as a maximum time after pre-conditioning before which the test can be conducted.

Another small point that could cause some confusion is a lack of tolerance on the air flow requirement. Right now it's 85 liters a minute. We're recommending that NIOSH consider two percent tolerance on that.

We are very pleased to see that NIOSH has dropped the requirement for resistance after loading that was in the previous recommendation. However, we

feel that the resistance requirements that are in the present regulation, proposed regulation, are a little tight for a couple of reasons. One is that the filter efficiencies that we're looking at are much higher than they previously have been.

Generally higher efficiency filters are more dense and require greater breathing resistance. In order to keep the filter to a reasonable size, it is requested that the maximum inhalation resistance be moved from 30 to 35 millimeters water column and also that the exhalation resistance be increased from 20 to 25 milliliters.

One of the respirators that the health care workers have been looking at and using does not have exhalation valves. Exhalation valves allow the exhalation resistance to be lower. If you have to breathe back through the filter media as in a lot of DOP respirators, it's felt that this requirement is a little high.

There is also previous history in 30 C.F.R. 11 and other regulations which show that higher breathing resistances are acceptable, such as on

combination filters in the present regulation.

The testing right now calls for loading 200 milligrams challenge on a non-air-powered particulate filter. We have seen in our testing some inconsistencies in the loading characteristics based on external factors that we do not know and can't identify yet. The current equipment only generates about 14 to 20 milligrams, which requires a long test and also is not what the equipment necessarily was designed to do.

We feel that, again, this is a subject where some round-robin testing, some input is needed from the equipment manufacturer, as well as the respirator manufacturers and anyone else who is interested, just to establish where that load should be. This is especially true if you go to powered-air purifying units which will be discussed later.

The method of measuring particle size is the differential mobility particle size counter. This piece of equipment apparently is not available anymore. More modern scanning mobility particle sizer is available and we request NIOSH consider this in the

proposed rulemaking.

That is all I have on testing parameters. I can entertain questions on that now or go onto filter efficiency and can entertain questions at the end.

MR. MATTHEWS: You got a preference? Do you want to maybe do the other presentation and we can take a break and do a few questions? How about that? Why don't you do your other piece?

MR. NEWCOMB: Filter efficiencies, Type A filter: again the proposal to use Class Three rather than Type A, as was previously mentioned -- I do, however, want to address one of Dr. Campbell's comments. A Class A filter in Europe, Australia and many parts of the world right now is an organic vapor filter. Class B filter is an acid gas filter. It's much better to have a 1,2, and 3 corresponding to particulate filters than have people confusing gas and vapor filters with particulate filters.

Type B filter, we would like to see the efficiency of a Type B filter brought from 99 percent down to 96 percent. One of the things that has come

to our attention is that there is very little difference between a 99 percent efficient filter and a 99.97 percent efficient filter.

In order to give the user community a wider range of product to cover a lot of different uses, it's felt that we could go down to 96 percent. This would do a couple things. One, it would give the -- it would more than suffice for the health care workers' 95 percent efficient at one micron requirement. It would also allow particulate respirators to have a -- using this filter to have a protection factor of at least 25.

It is not necessarily true that you can equate the protection factor with the filter efficiency. However, the filter efficiency that we're looking at, the measurement, is a very narrowly dispersed particle size, worst case particle size. And it's not instantaneous, but maximum penetration.

Whereas the APFs for a class of respirators look at what is necessary for a time-weighted average over an eight hour day in a real world which does not, at least not to my knowledge,

have narrowly dispersed, worst-case particle sizes. So it's very -- it's easy to have a respirator that can have a 25 percent leakage through the filter and still have a protection factor, assigned protection factor, of 25.

Type C filter, again we were requesting that the efficiency be lowered from 95 percent to 90 percent. There are a lot of cases where there are relatively inert substances that could use a lower class filtration and most probably a lower cost respirator and still have the ability to have an assigned protection factor of ten and be also usable for workers in the health care setting.

There probably will be a little confusion over that last statement because we're talking about a 95 percent efficiency at one micron for health care workers exposed to TB. Here we're talking a 90 percent efficient respirator against one-tenth micron. The particle size is much smaller, the most penetrating particle size.

There are respirators today that will probably meet the 95 percent, one micron particle size

that meet the current 30 C.F.R. 11 that will not be able to meet this requirement. This is a much more stringent requirement. You can't equate taking what is now a dust/mist respirator which meets the requirements set out for health care workers and say that that respirator will meet the new requirements for a Type C, either as was proposed or as ISEA is suggesting. Thank you.

MR. MATTHEWS: Okay. Our panel has a lot of questions on this, and maybe rather than start into questions and comments, I think maybe it would be better if we took just a quick break now and then pick back up. And that way, we can sort of get through this without an interruption before the half light drops in.

I have 3:11. Let us start back promptly at 3:30. Is that acceptable? Three-thirty we start back with the questions on this presentation. Thank you very much.

(Whereupon, the proceedings went off the record at 3:12 p.m. and resumed at 3:31 p.m.)

MR. MATTHEWS: Okay, if we can -- can we

start back then? Mr. Newcomb, we very much appreciate your comments. I think we've got a good deal of technical engagement we'd like to follow-up on. And I clearly know when I'm over my head. I'm over my head here, so Rich, if you want to take the lead on this?

MR. METZLER: There's a great deal of areas that you presented we'd like to comment on and ask questions for clarification. But I think perhaps two of the most important that were discussed was the concern over reproducibility and differences in results on cold versus hot DOP instruments.

Our scientists here would like to discuss those issues. We have seen some of those in our own laboratory and are aware of some factors that could lead to variation in testing. And perhaps it would be best stated by them to try and clear the issue on reproducibility and differences between hot and cold DOP generation mechanisms before we go into the other areas.

DR. CAMPBELL: In terms of the reproducibility, let me first mention that in our own

laboratories, we have three different sets of test equipment, and we have four different test operators who are familiar with that equipment and are trained to run the tests.

And between the various combinations there of test instruments and test operators, we have developed the test system in our laboratories to the point where it's reproducible between each of those test operators and between each of those systems. And actually, some of the test systems are in different laboratories as well as having different test systems.

But that was not something that occurred in the very beginning of our working with the test. It took some time to develop the details of how to run those tests and the techniques to the point where we were getting reproducible results. And I'm just wondering whether it's possible that the differences you saw were the result of not having a lot of experience with the test systems that we use?

MR. NEWCOMB: Certainly that plays a part in it. Most of this equipment has been purchased since the first of the year, and in some cases, this

was only the second or third time that some of the manufacturers might have conducted tests. And you know, certainly that's a major factor. I'm positive of that.

However, I think what we're requesting is that anything that NIOSH has learned in running these tests be given to the manufacturers so that they will be able to duplicate what you're doing in the lab and run some round-robin tests with the NIOSH machines and the different manufacturers' machines to make sure that we're all doing the same thing with the same type of equipment.

DR. CAMPBELL: Yes, yes. So that's a problem that I think is fairly easily addressed.

DR. MOYER: Okay. In follow-up to that, I would like to kind of address the differences that we have seen and some of the things that can contribute to that, especially differences that might be seen between the different generator methods, all right?

NIOSH knows for a fact that particle size, particle size distribution, has a big effect on

penetration. If the different generation methods do not give you the same particle size and the same particle size distribution, you could potentially see differences. We know that.

We also know that the flow to the filter itself can be critical. If you're evaluating a filter, especially in the case of a respirator-type filter, and you don't have uniform flow to all the parts of that filter in the fixture that you're using in that test instrument, you can get significantly different results. We know that for a fact and we've seen that in the past.

We also know that temperature of the test aerosol can be a factor in these types of studies. We know that a very important factor in the DOP situation is the chemical state of the DOP. DOP does degrade, and I'm sure you're all aware of that. It turns a yellowish color.

We've done some studies where we've done penetration studies as a function of number of times that DOP has been heated, and found out that the actual degradation of the DOP leads to enhanced

penetration through the filter medium all right?

And as little as a few percent degradation product in the DOP can, in fact, enhance the penetration significantly. We also know that proper maintenance of the test equipment is essential to get reproducible results. And in fact, when -- and most of the data that I've seen today is on DOP, but if, particularly with the salt generator systems, if you do not maintain those instruments properly, you will get -- could, as a result of maintenance problems, not get reproducible results.

We're aware of all that. As a matter of fact, on the salt system, we tear it down and clean it on a day-by-day basis, which far exceeds what -- in that particular case, the manufacturer recommends.

We also know that for some of the filters that we're looking at, filter variability is significant, especially with loading. As you all have found in your studies here, if you don't precondition the filters exactly right, your data can be orders of magnitude off, because I saw even in your one table here that the data, which was pre-conditioned for a

longer period of time, the penetrations were orders of magnitude larger than any of the other four sites that tested those particular filters.

We also know that factors like relative humidity, pre-conditioning, levels and concentrations of the liquid in the case of salt in the generator, can have an effect on the actual penetration values that you determine. Yes, we are aware of a lot of factors that can lead to non-reproducibility in results, and we have tried in our laboratories to rule them out.

MR. METZLER: Bill, now that we understand a lot of the key factors critical in the experimentation -- Ernie mentioned a few -- I'll just summarize briefly: particle distribution, flow rates, the filtered area, exposure on the filter, the temperature, the DOP chemical state.

Particularly we noticed large variations in old versus new DOP between cold and hot generation mechanisms and filter pre-conditioning were mentioned. We would be pleased and welcome the opportunity to have the manufacturing community and anyone interested

come in and see what we do and share this information with you in a meeting forum or anywhere else.

MR. NEWCOMB: Thank you. That's really what we're asking for is some feedback as to why we might be seeing these anomalies in the results. We suspect that there are a lot of factors that we don't understand using this new machinery, and perhaps the test protocols that we received were not sufficiently explicit, or perhaps the other things such as the conditioning, might need more tolerances, tighter tolerances, to make a more reproducible test.

We still have a question as to what media, what type of DOP generation should be used, because it's not specified right now and it does seem to be a big --

DR. MOYER: -- could be used if it met those criteria. We didn't want to specifically indicate a generator type because if you make an aerosol and it has the right characteristics, hopefully it will have the same penetration characteristics. We know that for mechanical filters, like you found out in your study, that the results are

pretty consistent

For some of the newer-type electret-type filters, we're not as maybe confident to say that all those factors don't come into play.

MR. MATTHEWS: I mean, clearly it is not our role here to go behind the green curtain and do some magic techniques and then come out and say, "We've got it back there and you guys go through trial and error until you stumble around and figure out how to do it". We want to engage -- it's in our interest to assist the manufacturers to come up to speed as quickly as possible with some procedures that give you confidence that we're all playing out of the same page on this.

And again, we're wanting to get this because as some of the other commentors have said, a number of worker communities need this new equipment quickly. So we'll work with you.

MR. NEWCOMB: We appreciate that. That's what we're asking for. We would like to get these issues resolved though before the rule becomes final because if we've only got 30 days to stop making NIOSH

submissions, we need to have that on board.

MR. MATTHEWS: We agree.

MR. BERRY ANN: I'd just like to add a little bit to that too. The way the rule was written, we did not intend to require any specific generation method. We wanted to leave that open so that any equipment that meets the stated specifications would be acceptable.

We felt that where we could leave it broad enough to allow flexibility, we would do that to allow innovation and advancements. But where there was the requirements to be specific to control the outcome to be reproducible, we tried to do that. As Ernie stated, you know, we're learning some things that maybe we have to be a little more tighter as you've suggested in some of the areas, maybe state some things that we haven't, like make sure the air flow is uniform.

But I think that maybe as you look at your testing and your results and the test protocols that you used, maybe you can give us some insights on that too. But again, you know our intent is not to be

overly restrictive, but specify exactly what we need for that reproducibility without tying everybody in to using the same equipment and the same model number, etc.

MR. NEWCOMB: We appreciate that. We have come out in favor of that in many instances. We don't like to be specific. However, if we felt there was a difference in the generation method, everything else being equal, which we were told was the case, it might not be the case, but with the information that we had, it appeared that the generation method alone was a factor in the results and therefore, if it is, then it should be specified. If it is not, fine.

MR. BERRY ANN: There's one other thing. Ernie mentioned about the temperature of the aerosol being critical and that might be interpreted as hot or cold generation. Actually, the temperature that's specified is at the point of application at the filter and the method of mounting the filter that the aerosol is being put as a challenge agent against, does affect the temperature of the aerosol at that point.

MR. NEWCOMB: I think that was understood,

thank you.

MR. BERRY ANN: Okay.

DR. CAMPBELL: One detail. Your comments about the 200 milligram challenge load, were those comments directed primarily in terms of the reproducibility of the test? Is that what the concern was?

MR. NEWCOMB: Let me refer to my notes for a second.

DR. CAMPBELL: It was the fifth slide from the last one, fifth page from the last one.

MR. NEWCOMB: One of the things that we questioned as being a possible factor in the performance that we were seeing was the amount of aerosol that was being generated and the amount of time that that filter, as a consequence, would be exposed to the aerosol.

If it were generating five milligrams, then you've got a factor of 400 a minute, for instance for five milligrams a minute. Whereas if it were producing 100 milligrams a minute, it's two minutes. There's a large difference in the amount of time that

that filter is exposed and that generation aerosol is not specified right now. It's left open. It has a maximum, I believe, of 100.

DR. MOYER: It has a maximum of 200. I can give you at least one case where that shows that that isn't the case and that's in the case of high efficiency mechanical filters. If you take a high efficiency mechanical filter and you run the test at say 100 milligrams per meter cubed loading at the specified flow rate and you want to load that filter in a hurry, you can jack the flow up to double that, load the filter in half the time, take a final penetration value and you get the same result.

MR. NEWCOMB: But does that hold true for all filter media?

DR. MOYER: I don't know. That might be a point right now, but I can tell you that at least in that case, it does hold. The other point we would have to check on. I must admit that.

MR. NEWCOMB: Thank you.

DR. CAMPBELL: But specifying the loading rate would be, I think, fairly straight forward to do

in this.

MR. NEWCOMB: Well, there are some machine limitations as well at the present time which get --

DR. MOYER: But the limitations are with the sodium chloride, not with the DOP. And I don't think you run into the same problems with the sodium chloride that you do with the DOP when it comes to loading. They are two different beasts.

MR. NEWCOMB: Well one of the things that has been seen in trying to run specifically powered air filters with a 2,000 milligram loading is that the loading characteristics with that much sodium on it, are extremely non-uniform and give completely, many orders of magnitude different results as the sodium is caking onto the filter.

And so I would say that perhaps for some, it's not the case. For others, it might be.

MR. MATTHEWS: Okay. Do you want to talk about filter efficiency classes or do are there other questions on the --

DR. CAMPBELL: I just had one other question about the table.

MR. NEWCOMB: Right.

DR. CAMPBELL: Did you look at the variation or the standard deviation from one test laboratory to another? The reason I ask that is because I thought in your presentation you made some inference about how that would affect the statistical test.

MR. NEWCOMB: I haven't done it yet. We just got this information rather recently. We have not done it. However, if you take a look at what we're talking about for standard deviations, and we'll get into that later when statistics are addressed, it could definitely be a factor in it.

DR. CAMPBELL: Okay.

MR. MATTHEWS: Rich?

MR. METZLER: Well, Gene brought up perhaps the next subject to cover, which is filter efficiency, and I had a couple of questions myself in this area. One is, you did round-robin testing using filters of Class A, B, and C. How many manufacturers produced filters in these classes or have filters in these classes that you use for testing?

MR. NEWCOMB: These were not respirator filters. They were swatches of material that were provided that are commercially available in large -- that would not be suitable to make the type of respirators that we're talking about, the low-cost respirators. They were not respirator filters. They were swatches of material that just happened to be in this filter range.

MR. METZLER: In the surveys that ISEA has conducted with the manufacturing community, do you know the number of manufacturers who can produce respirators at C, B and A classes?

MR. NEWCOMB: I don't personally know. I don't think that information has been asked. Obviously, the high-efficiency filters are available from everyone now. That's not really a question. The lower efficiencies tend to be a little harder to come by.

I am told that there is one filter manufacturer that has a material -- it's just hearsay -- that would be applicable to a Type B, I believe. Other than that, I can't speak for the individual

manufacturers.

MR. METZLER: In the filter efficiency slides that you used, the recommendation from 99 to 96 and from 95 to 90, I've got two questions. One is with regard to the description of harmonization, how do they harmonize with regard to the CEN standard and also, what applications in the workplace do you foresee these respirators will be used?

MR. NEWCOMB: The harmonization was meant more for the type and class designation than the filtration characteristics. It's kind of difficult to compare the filtration because they're using a much larger particle size, sodium chloride, to characterize the filter penetration efficiencies. So they're not comparable one to the other.

To say that the filters that meet the European requirement for a Class P1 filter or P2 filter would necessarily meet the proposed requirements here, I would dare say that there is very, very little chance of that because of the extreme difference in particle size of the challenge concentration, the challenge aerosol rather.

MR. METZLER: And as the second part of that question was in the suggestion of 96 percent efficient filter class and a 90 percent, has ISEA given consideration to the applications where those respirators would be used?

MR. NEWCOMB: Not specific applications that I know of. What we're talking about is a relatively inert material such as maybe cement dust and gypsum and so forth for a Class C, the 90 percent efficiency and perhaps some fumes or paint spray, pesticide or something along that line at the Class B.

However, that's my own thoughts versus the ISEA's thoughts because that really has not been discussed.

MR. METZLER: Has there been any estimates of the distribution across the market as to the percentage of air purifying filters that will fall in the different classes that you're proposing?

MR. NEWCOMB: Not that I know of.

MR. MATTHEWS: Can I just -- for clarification, again this is probably beyond my realm of competence, but you talk about Type C going to a 90

percent filter. How can you get -- and that would have a protection factor of ten. If you got a 90 percent filtration or a ten percent filter leakage, and then you've got a face seal leakage as well -- and the current estimates, I suppose, is ten percent face seal leakage, a ten percent filter leakage. Why do you not end up as a protection factor of about five?

MR. NEWCOMB: Well first of all, the APF is totalled in with leakage and it considers the filter leakage as well as the face seal leakage. If you take the ten percent penetration of the filter at one-tenth micron, in the workplace where you don't have the narrowly dispersed one-tenth micron particle, you're going to have less than that.

So you're never going to get up to a ten percent leakage in the workplace --

MR. MATTHEWS: Through the filter?

MR. NEWCOMB: -- through the filter. So combining the two, and they're combined not necessarily arithmetically, it is felt that you could have a protection factor of ten, having it totalled in with leakage of ten percent.

MR. MATTHEWS: At what particle size?

MR. NEWCOMB: At a particle size, it would be normally distributed probably in the one to ten micron particle size.

MR. MATTHEWS: Well not again to drag us off into TB land, but we have had presentations already today of a couple of points. One is the reference to the 95 percent, one micron. So what you're saying here is that you would have a 90 percent APF of a one micron to ten micron particle size.

The other piece of it, the testimony from the Infectious Disease Society, is that the route of transmission of tuberculosis is not -- I mean, it's not well known. So when CDC talks about a draft recommendation of 95 percent at one micron, there is still valid comment that can be made to CDC that why aren't you using a more rigorous protective standard? Why 95 percent of one micron?

One of the arguments that we have is that the Class C, as articulated in the NPRM of 95 percent at a three-tenths micron particle size, is providing additional protection in a TB environment of one

micron that goes farther beyond -- it's your same argument of from 95 percent on up to maybe 99.

But when we go to your 90 percent filter, we begin to lose the "safety factor" in what is admitted to be an area of infectious disease science where we don't have all the answers.

MR. NEWCOMB: One of the things that has not been brought out, and I guess is a factor, is even if you have a filter that has 95 percent efficiency against one-tenth micron, if it's a half-mask face piece, it's still only got a protection factor of ten.

So you're not getting the efficiency of the respirator that you had of the filter because you're always going to have some facial leakage in a negative pressure air-purifying respirator.

MR. MATTHEWS: But you understand the other argument that the Agency is faced with about providing some additional safety margin for health care workers in a TB environment?

MR. NEWCOMB: Yes. And if there were still a concern, it could be recommended a Type B at 96 percent.

MR. MATTHEWS: Right, but then other people have other --

MR. NEWCOMB: Yes.

MR. MATTHEWS: -- responses to that too. Okay. Any other comments on that? Okay. Okay, I guess next on your list is PAPRs, right?

MR. NEWCOMB: Yes, thank you.

MR. MATTHEWS: Okay, thank you.

MR. BENNETT: Try and work from this side.

MR. MATTHEWS: You have to turn -- there's a switch on this side of it.

MR. MAHAN: Try and work from this side. Okay.

MR. MATTHEWS: Just please identify yourself for the transcript.

MR. BENNETT: Mike Bennett, Racal Health and Safety, speaking on behalf of ISEA on how their respirators -- and certainly on statistics of test data. I'll start off with PAPRs.

MR. MATTHEWS: You need to somehow get next to the microphone.

MR. BENNETT: I'll try this side.

MR. MATTHEWS: Okay.

MR. BENNETT: Mike Bennett, Racal Health and Safety. PAPRs, why we want to raise this subject in this context. We're talking about filter penetration principally. Well, the subject arises naturally under the proposed regulations because the regulations encompass three major classes of protective systems: the negative full-face mask with canisters and filters, the disposable mask as a separate family and finally powered-air respirators, PAPRs. They inevitably come under the orbit of these modifications.

Why are they important as a type of respirator? Well at one level, they're just another respirator, another product that people can buy for respiratory protection. But they have special benefits and features for the user that very often make them the respirator of choice. They overcome the burden of breathing through the filter and they give the wearer and the use a great deal of possibility and access walking around with the comfort of fresh air often being blown over their face.

They're often the respirator of choice, and this is one of the important issues when we're talking about respirators. It's the respirators that get worn that give protection, not those that are described in the standards and give very good test results in the laboratory.

PAPRs, we believe, are going to play an increasing role in the protection of workers in the States. At the moment though, if you go through the regulations, and as a manufacturer and you try to put forward a PAPR for certification, you have to look hard for the relevant sections. They are included at the end, often it seems as somewhat as an afterthought, perhaps as a modification to the test that's been set up primarily for the other types of systems and filters.

And that's natural because the vast majority of workers and respirators use straight forward negative half masks and filters. However, we estimate that already in the marketplace in the United States, there are of the order of a third of a million PAPRs in use today, and that of course means

continuous reuse with the filters, which are replaced on a regular basis.

So although perhaps not as important as the general respirator classes in use, they are a growing and important class, and we believe they demand further attention in terms of the regulations which are being proposed so that they can be classified more adequately in the future.

We maintain that the proposed regulations don't reflect workers' needs in terms of the sort of equipment they want to wear or the modern technology that is already available in designing and offering to the marketplace PAPRs. The regulations very much reflect perhaps the technology of the last few years. They don't reflect today's technology or tomorrow's. I'll be giving some examples later where PAPRs could be improved.

The proposed tests that we read in 42 C.F.R. 84 are not consistent with the module one objectives, which naturally focus on filter penetration. If you're going to measure filter penetration, you have to know the air flow. If you

consider PAPRs, the measurement of air flow is not a trivial matter.

It is evident that NIOSH has tried very hard to address that issue, but the further you get into it, the more tests you have to specify, the more equipment you have to specify, the more complicated the whole process becomes, and it's not long before you've lost track of where you were going. How can we classify the filters?

What we're saying is we fully support the objective of module one, the reclassification of the filters, for all the reasons that have been explained earlier. There's a great danger. That's why bringing PAPRs into the equation up front -- begin to lose sight of the objective and perhaps fail in its overall purpose.

When we look at the tests, we find that the tests are unclear in their intent to some extent and certainly in their execution. As manufacturers, we need a great deal more information on how to test the equipment in all its variety of forms that it exists today, as well as the systems we'd like to

bring to the market tomorrow.

The consequence of all of that is that the proposed tests in the existing draft regulation are inadequate and we consider design-restrictive in terms of offering to the marketplace systems which will give users genuine protection.

Why are PAPRs different? I've spoken of some of the user side. From a technical side and a design side, which affects manufacturers and certification bodies, there's a unique interaction in PAPRs between filter penetration, air flow and face fit, if I can use the term "fit" in this context of this product line, which is unique to the products.

All three interact strongly. If you vary one, you affect the others and you can't measure one without full knowledge of the others and the interaction of the effects of the change of, for example air flow as a filter load, on the fit. Everything interacts strongly and you have to address the PAPR as a complete system, both obviously in the design stage, but also in the test and certification phase.

This is a major point and it underpins everything that we're leading to in our proposal. I could give a lot of detailed examples, but I think it's fairly evident as soon as you start to look at the subject of certification testing, that the interaction is unique. With negative systems, the proposal that you can separate air flow from penetration is realistic, one can set an agreed level of 85 liters a minute, which is realistic, represents mean breathing rates and peak breathing rates. And you can come to an agreed level of test penetration that has some agreement and meaning.

With PAPRs, it is much more problematic to agree even what a starting point for the air flow measurements should be. Should they be instrument-specific? Should they be class specific? We believe these subjects haven't been properly debated yet and to come up with a particular value, as framed at the moment, would do a disservice to the industry.

We have no intention of going into the details of all the problems that arise from the draft regulations at the moment. I just basically list the

categories of where we see problems of interpretation and understanding, as well as more fundamental questions of design. The filter efficiency levels, that's a question that needs discussing separately in the context of PAPRs from negative systems.

It's not necessary, of course, that you have the same levels. In the proposed regulations, NIOSH has proposed two, consistent with what they ought to be aiming at the health care market, but I think the subject needs more debate. Whether one gets into filter or system testing in module one is an area that is unresolved. As I said in the introduction, the intention of module one is filter testing. But in PAPRs, you end up doing system testing, and there's nowhere near enough thought or discussion gone into the question of PAPR system testing.

Do you measure peak or continuous flow? There are strong arguments for and against. A majority of manufacturers, I think, could come up with a very constructive answer on that, but we feel there's too much detail and this is not the forum to discuss those sorts of issues, but it's an unresolved

issues.

Multiple filter testing, many PAPRs use filters in groups of two or three in parallel. Some systems, in fact, use a pre-filter and the filter in series. The interaction between the two is critical in PAPRs. The testing of multiple filter units needs to be taken into account in a way that perhaps it doesn't on negative systems.

Test equipment, a very big subject. You need very specialized test equipment for PAPRs. It's difficult to specify. It's specified in terms of the tests you're trying to carry out. It's difficult to design. It can be designed by third parties, by test equipment manufacturers. It can be designed by test houses. There are pros and cons.

How do you use the equipment when you've got it? You need agreed protocols. Who can supply the equipment? How many manufacturers are able to supple commercially available equipment? These are all questions which are completely unanswered at the moment and lead us to say that we cannot go forward with PAPRs being in module one with questions like

this completely unanswered.

Air flow measurement is a very difficult area. Some suggestions have been made in the proposal, but even reading what has been written, there are ambiguities of when are the air flow measurements going to be done and how are they going to be done.

It's implied in the regulations in draft form that the air flow will be measured after the filter penetration tests have been completed. But it says in another part of the regulation, of course, the penetration test can be terminated at any stage. All this sort of internal conflict because simply we understand, we believe the work hasn't gone into specifying these tests adequately.

Fit testing, always a contentious subject, but when the banana oil fit test comes on the stage, we consider it a totally inadequate test, and particularly with PAPRs, the relevance has to be questioned very greatly. It would be polite to say that it perhaps relates to one category of product, but it's inconsistent with the range of products which

we believe PAPRs can offer to the marketplace.

My last point is that all the points made so far relate primarily to filter testing. PAPRs, of course, are closely involved with the upcoming module on APFs and we believe that that module in itself will also have implications on PAPR design which will knock right back to filter testing and filter penetration levels. This subject interacts more than perhaps any other.

What I'm listing there are the difficulties that we foresee arising from the draft regulations at the moment. I would like to go into detail on just two issues because we believe that they are particularly important. I'll try and take them one at a time.

Let's talk about today's tests, today's technology, today's test equipment. Most manufacturers are gearing themselves up now to address the filter penetration tests that are in the draft regulations. Machines such as the TSI 8130, which are the typical sort of equipment that's suitable for carrying out these tests are being ordered and

commissioned and, as we heard earlier, some test data is becoming available.

However when you get to PAPRs, we're talking about much higher air flows, typically 160, 170 liters a minute for the open systems. These often run at 200 liters a minute and some tests are often done at those levels. How are we going to generate 200 liters a minute and how are we going to generate a loading at 2,000 milligrams of salt?

We understand it's NIOSH's intention to load 2,000 milligrams of salt onto PAPRs and see how they perform, maybe to look at air flow into that process, maybe to simulate the loading test which we would regret because we seem to have gotten rid of loading tests on APRs. Why don't we get rid of them on PAPRs?

When we take a system like the 8130, we find two problems. It doesn't have the air flow capability and it certainly doesn't have the salt density to enable the test to be carried out in a suitable time. You have to modify the test rate to make 200 liters a minute, or 180 at least anyway, flow

through it and you have to conduct the test for about 20 hours. You get some very strange results when you do that.

So the first point is that the equipment to do the tests which are being suggested in module one is not generally available. I know at least one manufacturer is developing equipment which may be available later this year. That's hardly the basis to go forward on a regulation.

Secondly, some up to date on the effects of one of these tests we believe is the intention of NIOSH to run. We have looked at the effect of loading 2,000 milligrams of penetrating-type salt on four various types of filter media, all in use in PAPRs, although admittedly not all in the United States. Only two of them are at present.

But we're trying to look to the future here. We have found an extraordinary range of behaviors as you load this amount of salt onto the filter media, and I give four examples: one, which is just known as a mechanical filter, basically conventional glass fiber where typically the pressure

drop doubles in the test.

We found another commonly used medium, the pressure drop increased by a factor of seven to one with a roughly 90 percent electrostatic filtering element in it. Another electrostatic material widely used with 30 percent, roughly, electrostatic component in it blocked to a factor of ten to one, and yet another electrostatic medium blocked with a ratio of 30 to one.

The point I'm making on that is there is a wide disparity of behaviors on filtration media being used today which will give enormous results if we just go forward with this one test, which I believe is being proposed in a loading context, and air flow context.

A second and more worrying trend is because we are being required to use equipment that isn't suitable for purpose, we're ending up with 20-hour tests and we're seeing very strange caking effects as this penetrating salt, very, very finely dispersed -- in the case of this test, it wasn't purely mono-dispersed. It wasn't done on the TSI reg.

But there was clear evidence of this particular salt, which is fine for penetration tests, caking and leading to a skin in the filters because of the long life test. When you handle the filter, for example by weighing it, to establish you've got two grams, you find that the cake disappears and the pressure reduces to normal levels.

So introducing spurious results into the test method which has got nothing to do with the product or its use in the field. And we would simply campaign that more efforts and thought and basic tests go into the testing of PAPRs, two specific examples of problem areas.

Having listed the problems, the manufacturers feel all these technical issues can be resolved by discussion and interaction, firstly with ourselves, because a number of manufacturers have a number of years of experience of designing and testing PAPRs. The answers to some of these issues are known and available. And secondly, a number of tests and certification bodies in other countries have wrestled

with these problems and have come up with answers that have satisfied their governments.

We would ask that NIOSH take these things into account. The answers are not too difficult to find. We're not saying you have to take everyone else's answers, but we are asking that you take on board the technology and the test regimes that have already been developed in other countries for the benefit of American systems and workers.

Secondly, we would say that the formal process that we're going through must be supplemented by an informal interaction, particularly between the manufacturers and NIOSH. If the manufacturers can be involved at an early stage, we can pass across the knowledge and experience that we have in resolving these issues, and we very much look forward to a greater informal interaction as well, of course, as the formal process that we take part in to help resolve these issues earlier.

Manufacturers naturally require reproducible and relevant tests to ensure proper use of the resources of the certification body. There's

nothing more frustrating than carrying out tests that give you a different result every day, carrying out tests that give you a pass in the company and then a failure at NIOSH. That frustrates everyone.

It's equally frustrating where tests are carried out, which are not well described and not in the public domain. We ask that we work towards commonly agreed tests which we all understand and we can all work towards getting the same results prior to putting products into the certification testing program.

What that adds up to is our proposal that we put in a new module. We strengthen the proposal we had earlier that there's a module in which PAPRs feature. We are now proposing a specific module to address the requirements of PAPRs leading to a coherent set of tests and certification requirements reflecting modern PAPR design practice and certification practice.

ISEA recommends strongly the urgent addition of a separate PAPR module. And by "urgent", we mean that we believe it should be raised up the

agenda and frankly, initiated as soon as possible so we can get the dialogue going. The other part of the recommendation is that no new tests or test criteria are included in module one 42 C.F.R. 84. The existing 30 C.F.R. 11 tests remain as an interim.

The basic philosophy is that we would rather stay with a test we know and hate rather than put in place tests which we are very uncertain about and we don't understand until we have had time to work through, with NIOSH, a set of tests that are relevant to PAPRs.

We would go as far as to say we would request that the proposed tests outlined in the draft 42 C.F.R. 84 are withdrawn because we believe it will add to the confusion in the interim. And the worst scene of all is that we have three regimes of testing: the old, an interim and a new one.

We would rather stay with the old tests and urgently work with NIOSH to generate a new module leading to a very rapid module for 42 C.F.R. 84.

This does, to some extent, contradict our global statement made earlier that we would be happy

to agree that no further submissions would be made under 30 C.F.R. that are not 30 days. I think for the class of product PAPRs, we would ask that new PAPR designs be certified under 30 C.F.R. 11 during this period before we can get the new module agreed. That's the one class perhaps that we would say is an exception to the general principle.

Finally on this section, I would like to reaffirm that we do consider this as a very positive move. We are not saying we are against what's going on in module one. We totally support what's going on in module one. We want to constructively move forward to a new module and address a lot of elements in it as rapidly as possible.

These are the categories we would suggest can be covered in module two and we would look forward to playing our part in getting them put down on paper and to proper tests and procedures. The module could cover, in the context of PAPRs, a higher protection category. One of the real problems in the existing categorization of PAPRs is they're all given the APF of 25.

Manufacturers are adamant that we can design high protection factor systems. There's a great body of knowledge and experience that shows if you blow more air into the face piece -- sorry if I use European expressions. You know what I mean. If you blow more air into the face piece, you can get continuous positive pressure and higher protection factors than 25.

There's definitely a body of opinion that would like to have a higher protection factor category and the manufacturers would certainly claim they know how to do it. Equally there's another body of opinion that says PAPRs can be a very effective lower protection system. They don't necessarily have to be 25 for everything. We believe there could be a factor lower than 25 without having to specify it. We'll talk about that when we get to the APF module.

This would involve true, loose-fitting systems. The current NIOSH designations don't even distinguish between loose fitting helmets and hoods. They're not the same. You can have truly loose fitting systems that are comfortable to wear,

effective in use, give a lower protection factor, give genuine protection.

The manufacturers would love an opportunity to develop and put on the market such a system.

The third point, reviewing head piece categories, reinforces the two points I made there. The head piece categories do not reflect modern practice in design or use. We must move towards re-specifying these as soon as possible.

The manufacturers can offer breath responsive technology, whereby the canisters last much longer. However, there is no mechanism in the existing standards and tests to meaningfully test such a system. We would like to work with NIOSH to generate such tests.

Appropriate fit tests for the various types of systems -- the test we have at the moment is inappropriate, unreproducible, and leads to a single artificial result, we believe, in many cases, as it does with some of the APRs as well. We would like to develop appropriate fit tests.

New APFs reflecting the design classes I've spoken of, they've come up in the APF module, but perhaps we could discuss it in the module for PAPRs so that we come out with an integrated set of tests at the same time.

Test equipment: can we work with NIOSH to specify the test equipment? Can we get the design specification agreed? Can we give the suppliers a chance to manufacture equipment so that we have a choice of suppliers?

Test protocols: how are we going to use the equipment? These answers can be found quite readily, as I've said before. Filter compatibility with APRs, when we come out with a new range of filter penetration levels for PAPRs, we have to take into account the levels that have been assigned for APRs. In one sense, we have to watch out for the products where you can screw canisters in, which can also be used on negative systems.

We have to take into account both the testing and the workplace use aspects of canisters and cartridges which can be used for both systems. We

have to ensure there can be no accidents, that people use the appropriate canister on the appropriate product. This can be handled by mechanical changes or by labelling and the rest of it.

Air flow indicators: technology is certainly available, but again it comes in a range of sophistications. One goes from the simple quick-look indicator or from mechanical to modern, sophisticated electronic systems which can be built into PAPRs, give a lot of information to the wearer to enhance his protection, but will lead to considerable cost implications in the equipment. We'd like to be involved in the discussion of trade-off of those two issues. Should they be mandatory? Should they be regulated or should they be voluntary? Should the marketplace decide?

And finally, when we're doing PAPRs, let's take into account the chemical cartridge compatibility because they're just as much a feature of the workplace as the particulate filters. So this should very much feature in the module.

In summary then, we would like to move

constructively forward in that general direction. That's the first presentation.

MR. MATTHEWS: Okay, thank you very much. Maybe let's pause here, very thoughtful presentation. Do we have any -- Rich, do you have any comments or questions?

MR. METZLER: Your presentation was very compelling. I recognize concern over the lack of system requirements in the first module, and I believe that you recognize that the changes in the first module were primarily intended for filter efficiency, which would explain the lack of any system requirements for PAPRs.

I also recognize the concern over the length of the test. The test periods are, in fact, lengthy and perhaps Ernie Moyer can comment on that in a few minutes.

With regard to the need for communications, it's been said many times today that we are receptive to and welcome detailed discussions on standards and alternate suggestions, including the suggestions for additional modules and priorities that

ISEA is recommending. I didn't have any specific technical questions myself. Perhaps others might want to comment or ask questions.

DR. CAMPBELL: Would you comment on what you see as the public health implication of continuing to use PAPRs with currently-certified dust respirators or fume respirators?

MR. BENNETT: We believe that the HEPA levels are by and large going to be unaffected because the tests are very similar at the moment and the number of systems are available with HEPA filters. When it comes to the lower levels, it's hard to make a general statement. I think a number of filters which are available today probably wouldn't meet the B or C categories. It's hard to make a general statement, and maybe some of them wouldn't.

I think as a general statement, that maybe PAPRs, by and large, are the more modern of the products. You know, they haven't been on the market 30 years and maybe some of the filters tend to be higher in performance because they've been designed recently using some of the more recently available

media. So they would tend to be, I'd say, consistent.

If you take the dust, dust/mist media, I'd say they probably are closer to the requirements of B and C at the moment. But I can't be definite on that. It's just a feeling, if you like. This interim situation that we're putting forward is very much a short-term interim. We want to see PAPRs in the health care sector, just as rapidly as the APRs.

We're not trying to put a two-year block into it. We were hoping this could be months rather than anything else, and we get in line pretty quickly. We're just a little bit worried about putting some interim tests in place which may have some rather serious side effects.

MR. MATTHEWS: I understand.

DR. CAMPBELL: One of the reasons I was concerned about the other health implications was that generally the significance of any filter leakage is more important on respirators that the higher APF values, such as a PAPR.

MR. BENNETT: Twenty-five being high, yes.

DR. CAMPBELL: Higher than ten.

MR. BENNETT: Indeed. Well, this is a combination of the filter performance and the general fit and leakage characteristics by and large because of the way they work. The leakage in the fit side is better addressed in PAPRs because you're blowing air into the head area. So it does focus more on the filters and the filters, by and large, are pretty good I would say.

DR. CAMPBELL: Could you give us an idea of what percentage of the market for PAPRs is associated with high-efficiency filters versus the other types? Are they predominantly high efficiency filters in use?

MR. BENNETT: I would say yes, the majority. I'm guessing there. I would believe the majority are and because often the customer would choose the highest level just to be safe, as we have said earlier. And that's equally as true in PAPRs.

Particularly in fact it's often quite an expensive purchase. So if you like, the relative cost of the filters is not such a big factor in the PAPR context.

MR. MATTHEWS: Okay. Do you have another subject you want to cover?

MR. BENNETT: Yes.

MR. MATTHEWS: Go ahead. Please proceed.

MR. BENNETT: Potentially the most exciting subject of the day is test statistics.

(Laughter)

MR. BENNETT: I will try and be brief. I'm not an expert, so you can sit back. There's a very simple and innocuous looking formula in the new regulations. I quote it on the screen there. NIOSH has proposed the test statistic, U, which is the sum of the mean of the readings you get by measuring the filter penetrations and you add to it 2.22 times the standard deviation of the measurements you get. Fine.

That number then has to be less than the given level, depending on the type of filter, A, B, or C. Although it's a very simple formula, it has a very powerful concept behind it. NIOSH was helpful enough to explain very lucidly in the 1987 draft the rationale behind the use of this statistical approach

to testing.

Unfortunately it hasn't been put forward in the current proposal. That presents it with the formula and I would like this opportunity of asking NIOSH perhaps to explain what the rationale behind the appearance of the formula is, what the principles are that they are trying to incorporate by adopting this approach to the selection of test data.

In addition, we would like to highlight two areas of concern we have resulting from the introduction of this type of analysis of test data. Firstly, we have concerns on the validity of parametric testing. Now I'm not an expert in this subject, but what that means is if you get a user formula like this, you've got to be sure that the sort of things your testing fall into the class or distribution that you're applying the formula too. We're not convinced that's the case.

Secondly, implied in this test statistic is a dramatic increase in the acceptable quality level. To use one of the techniques used by manufacturers in assessing the products, they are

letting them go out through the door. This matters. This may come across -- I'm afraid we may inevitably get into a discussion of numbers, but it matters.

What we're talking about is the way manufacturers are being asked to manufacture a filter, test it, and if necessary reject it before it goes out the door. Manufacturers don't like doing that. It costs. It takes time and effort and it means you've got a product you've built which you can't then sell. It puts the cost up dramatically.

Equally, it can mean you have to design the filter to be on the safe side. It leads towards over-design and over-specification of the filter compared with the objective.

The pressure is on the manufacturer, of course, to adjust his processes and his control and his statistics to get close to the boundary. Inevitably, you have to have a certain amount of leeway there to make sure you're on the safe side.

And what this means is that filters get over-specified. They get bigger and they get costlier than perhaps they need be. I wish to just go into

that in a little more depth. But that's what we're talking about. We're not talking about an abstract branch of mathematics here.

The first issue then, the validity of parametric testing, most mechanical filters are extremely well-behaved. They're extremely easy to design in terms of reproducibility. When you measure them with salt or DOP, you get a very nice tight distribution of results. And yes, distributions are normal and everything that NIOSH is intending applies beautifully to mechanical filters which, in fact, dominate the market in terms of numbers.

However, new types of media are coming onto the market. One of the things that's going to happen over the next few years is that media manufacturers are going to offer new media, partly because it offers advantages to the respiratory manufacturers; partly to meet the specifics of the test protocols by the approval authorities.

The improvements are going to come in non-mechanical filters, in the general family of electrostatic and semi-electrostatic materials. We

know -- a number of manufacturers know from years of experience in a different context that these don't necessarily follow normal distributions.

Distributions are skewed. It's not the end of the world, but it's a step away from the assumption that's being made in this statistic. That's in terms of the complete distribution.

Then other things can happen in terms of the sample. You can distort the sample by the way you go about your testing selection process. First of all, not all instruments have sufficient resolving capability to get you the extra decimal place that you need when you're looking at the HEPA filters.

Certainly the modern instruments are capable of giving you that necessary resolution, but a number of manufacturers may have systems that are quite adequate for giving you pass/fail criteria most of the time on a HEPA filter with complete certainty, but when you want the complete distribution, you need the data through the high performance end, and some machines may not give the full distribution.

So it's possible that the instrument

itself doing the measuring that's in the manufacturer's plant are not so concerned here about the tests for certification or the field tests, but the manufacturer's everyday test can distort distribution.

Thirdly, we've got this rather interesting situation that, in principle, the manufacturer is having trouble with his process control and he's finding that some of his filters are going beyond the limit, he may result to 100 percent testing. He would then put the filters below 99.97, he'd put those in the bin.

And there's no way that a product which is not a HEPA filter can go out to the marketplace. On the other hand, when we apply the statistical formula, it is possible -- it's not likely. I'm not going to give you the percentages. But it is possible that you can have a distribution where the mean is correct. The standard deviation is such that when you multiple it by 2.22, you go to the wrong side of the statistic U.

And we are worried about that as a

principle. Put all those features together, what we're saying is in addition to leaving the statistical interpretation of data, can NIOSH add to the pass/fail logic, the decision rule logic, a non-statistical criterion for acceptance of a manufacturer's filters.

We accept that the manufacturer has to make the case. But if we get to the situation where his statistics fail, that the manufacturer be allowed to make the case that for example, he's doing 100 percent testing and that all of the filters are okay.

And we're asking therefore for the possibility of other routes to passing the test statistic.

It's important not just for the module one and filter penetration. We understand, in fact we support in general terms, the move towards statistical testing and analysis of data. We understand that this is going to be applied in other areas, gas-life, cylinder life and SCBA, all the whole gamut of testing and specified product from the manufacturer.

We believe that it's an appropriate technique where the statistics are appropriate. But

in many manufacturing techniques and quality programs, it is not an appropriate selection guide.

The second point is to do with the raising of the quality level, the AQL. We're going to talk about the K factor. That's the number you multiply the standard deviations by when you're trying to get your filters to pass. The bigger K is, the more you have to shift your filter performance down to get past the level.

We want to make a general statement that the new penetration tests, as proposed, are already significantly increasing the performance of filters beyond what's on the market already. There are three dramatic improvements to filter efficiency being called up in this module.

Firstly, the test aerosol itself is highly penetrating by design. It's been reinforced today. This is considered to be one of the most penetrating aerosols that can reproducibly used.

That in itself is pushing the performance levels of filters up. Now we did hear one speaker this morning who said that he is looking for 95

percent of one micron particles. NIOSH is asking for and the manufacturers, at a price, are prepared to respond to the various levels, A, B, and C, of .1 micron penetration particles.

So we already, on the first item, are pushing the performance of filters considerably higher than they have been before. The efficiency levels being called out themselves are high. Pepper, 99 and 95. They are higher, particularly the lower levels which are the ones with greatest interest I know to the health care community, are being raised dramatically from where they were before.

Thirdly, when we introduce the statistical method of sampling, it's not that the filter has to pass 99.97. It has to be some way beyond that. It has to be a multiple of the standard deviation away. So, in fact, we're pushing the level of the filter even higher.

Given that we are now looking at samples of 30, we are increasing the confidence of the data we are using by taking a bigger sample. We consider that K, in the context of everything we're saying, is too

high. We've gone backwards. We don't understand exactly what NIOSH's objective is here. We would ask NIOSH please to give us comments on what it is they're trying to achieve statistically in confidence levels.

Working backwards, we understand that the factor 2.22 can relate to a statement, that 95 percent confidence can be gained, that 95 percent of the filters will meet the test criterion. Now that is one way of explaining where the 2.22 comes from. It comes from statistical tables that lead you to that statement in terms of, "is this filter fit for use."

We believe that's an extraordinarily high level. It's way beyond anything that the industry's been asked for before, and it's even beyond the levels that were argued for in 1987. In 1987, we understood that the request was for 95 percent confidence, that 90 percent of the products would pass the filter level.

Manufacturers are saying, "Okay, we will go that far. We consider that an extremely high level, but we will respond to that, that we will accept that level and we would interpret that as

reducing the K value in statistical terms to a number 1.778."

Now it may seem a small change in number. It may not seem a big deal, but it's one of those things where we're pushing the boundaries further, further and further. We're not quite sure what the objective is. As I've said, the filter penetration levels are being raised high.

If we're talking about manufacturers' quality systems and the way of getting a high quality product out to market with a high confidence level that the product is meeting that standard without enormous testing loads for the manufacturer or for NIOSH, then we need to bring the figure down. We are asking too much.

It is hard to quantify the effect of the distinction between 1.778 and the 2.22, but we believe it could lead to testing regimes and rejection rates and setting of design levels to such an extent that we could be talking millions of dollars extra. Is that scale of investment and loss to the manufacturer, which of course has to passed on in the price of the

product, for no clear advantage?

We believe that NIOSH is asking too much in this context and that we are campaigning that we accept the general principle of this approach statistically, but can we bring the numbers down to more realistic levels? Thank you.

MR. MATTHEWS: Thank you very much. Comments, questions, responses?

DR. CAMPBELL: Let me just make a couple comments to clarify some of our intentions. The intent of the regulation, you said that it wasn't clear to you what our goal was, but you actually stated it quite accurately, and that was to assure the users of these respirators that no more than five percent of the product would fall below that pass/fail line and that we would be 95 percent confident that that was true based on our statistics.

So that was, in fact, the intent of that test statistic. That was the same concept that was applied in '87.

MR. BENNETT: So you are confirming 95/95 or --

DR. CAMPBELL: Except we've now changed it to a 95 percent confidence level and the basis of that was that confidence levels of 95 seem to be generally what is used in making statistical decisions. But it's nothing more profound than that.

MR. BENNETT: Yes but in 1987, the understanding was it was 95 percent confidence that 90 percent of the filters would pass. You seem to have added another five percent in this time around, and we're just questioning whether -- you know, it's getting further and further though we have established a sensible starting point.

You know, I think the manufacturers would respond if you came back in two years' time and said that we're finding too many filters out there that don't meet the need. But we believe that 95/90 is an extremely high level and is consistent with modern practice and manufacturing methods.

But to go to 95/95, you're starting it off at something a bit special suddenly.

DR. CAMPBELL: Okay. That was the intent of the proposal. The other difference was that in

'87, there was sequential testing which was permitted, which we've eliminated because of some concerns that statisticians have about the validity of that.

But let me get back to your recommendation of using some non-parametric test; that is, a simple pass/fail test. Are you suggesting that a non-parametric test would be appropriate when a manufacturer has 100 percent testing incorporated into their quality assurance plan?

MR. BENNETT: Yes. I would call it a common sense test. If a manufacturer can convince you that 100 percent of his filters are below the number you require, simply because he's measuring them all and throwing the bad ones away, you accept that as being a pass in terms of the product going to the market.

Never mind the statistics of it. I'm talking about common sense. For example, as one of the ways out of it -- I think the manufacturer has to make the case. We're not asking NIOSH to be creative on the manufacturer's part, but we are saying, please can you open the door to the manufacturer coming back

when he has a failure and making a reasonable case that you would accept.

In other words, the statistical test is not the only criterion.

DR. CAMPBELL: Just a comment about your comments about the normal distribution that, in many cases, that's not accurate of many products. The statisticians who advised us on this suggest that this test is what they call "robust". That is, the outcome is not -- the validity of the outcome is not critical upon the actual distribution unless you have some extreme variations.

And if you were doing some screening tests to eliminate failures, than that would be a reason to go to the non-parametric test as you suggest. We understand that.

MR. BENNETT: I accept that and the manufacturers certainly support that. The majority of products do fall well within that sort of approach to sampling and analyzing the data. The distributions do behave properly. And even when they don't you still come up with means and deviations that enable you to

pass the test statistic that you're calling for.

It is, perhaps, extreme circumstances, and the one that we can think of that would lead to the most grossly distorted distribution would be 100 percent salting and testing where you may throw away, heaven forbid for the manufacturer, 50 percent of his product. It's the principle that we're worried about here.

We believe that the vast majority of filters, in particular in the context of module one, will be satisfactorily handled by the test statistic that you're asking for.

DR. CAMPBELL: One practical comment concerning 100 percent testing, in terms of the tests that we have proposed in Part 84, in this proposal, those are basically destructive tests. The Part 11 tests are not destructive tests and I can understand how you could do those 100 percent, but I'm not sure I understand exactly what you're proposing in terms of doing a test that is destructive and doing that 100 percent. I mean, you're not going to have anything left.

MR. BENNETT: It depends how you do the test. Manufacturers don't necessarily carry out the test in exactly the same way for quality purposes --

DR. CAMPBELL: And that's why I'm asking exactly what your proposal is in that area. What test would you do?

MR. BENNETT: There are various penetration tests. I think they use similar media, salt and DOP, but they can be used at levels that often don't affect the performance of the filter. They're quite routine and used widely in filter manufacturing.

DR. CAMPBELL: The tests that are proposed here measure two characteristics of the filter. One is the inherent efficiency of the filter or the initial penetration.

MR. BENNETT: Penetration, yes.

DR. CAMPBELL: And the other is the ability of the filter to resists degradation. And I can understand how a screening test or a spot check, such as you just described, could be used to assure that the inherent efficiency was appropriate. But

unless you extend the test, I'm not sure how you would get to that second product.

MR. BENNETT: I can't conceive that a manufacturer is ever going to do 100 percent life testing. That is done on a back basis. That's a design issue. What's measured in practice is often penetration and pressure drop.

DR. CAMPBELL: But what about degradation of the filter efficiency that occurs because of exposure to the aerosol?

MR. BENNETT: In the context of production and quality testing?

DR. CAMPBELL: Yes. How would you know that the product you're producing has the desired ability to resist degradation?

MR. BENNETT: By experiments and measurement. These things are well established. I mean, particularly in the military context where filters have to be measured on a 100 percent basis and get stored for years with no effect on their life, for example. Filter testing is a well researched subject in terms of manufacturing large numbers, provided you

limit the tests that you do.

It is possible to carry out meaningful tests relating to penetration and pressure drop which don't have any detectable effect on the performance of the filter.

MR. CAMPBELL: Are you going to be making some specific recommendations along those lines?

MR. BENNETT: These are not in the context of certification. I'm just reflecting that these are standard practices today for many manufacturers. What we're debating here is the probability of 30 filters coming up with a strange result, as a result of the normal practices carried out by the manufacturer in the context of a certification test or perhaps a field audit.

DR. CAMPBELL: I understand the concept as it applies to the initial penetration or the initial efficiency. I'm still having a little bit of difficulty understanding how you can screen 100 percent of all products to assure that they are resistant to degradation and --

MR. BENNETT: No, that's not the proposal

that we're making. That's not a proposal we're making. That would never be cost effective and technically feasible. You would never destroy the filter. I can't see that situation arising. That would be done on a design-proving basis and on a batch basis and you would destroy the filters.

MR. METZLER: I have a general comment about the process of quality assurance versus performance testing. I think we will certainly give careful consideration to your comments and tests after statistics indicate that a respirator conforms to standards.

We definitely will give careful consideration of that. Please provide your comments for the record.

Our interest was in dividing or separating performance statistics from reliability engineering from quality assurance processes at the manufacturing site. And a lot of your discussion started to deal with the manufacturing process controls and the quality assurance aspects of manufacturing in addition to the performance testing statistic mentioned here.

While there is some overlap, we really intend to introduce quality assurance provisions in the quality module that was planned. Overall, our requirements were intended to take a system of today, where we're using three samples, in AQL levels which place the risk of accepting non-conforming products on the worker and placing a greater risk on the manufacturers for rejecting those non-conformances.

So essentially, we are trying to achieve a greater balance between the manufacturer's risk of having additional waste at the manufacturing site, versus workers consuming or having a greater risk of accepting non-conforming products.

MR. BENNETT: Indeed. It always seems a matter of balance. It's simply the way that --

MR. METZLER: Right. Your response to that was that it would involve cost and technical complexity of the equipment.

MR. MATTHEWS: Okay?

MR. BENNETT: Okay.

MR. MATTHEWS: Thank you. Let us -- we've been at this for an hour and a half. Could we take

just a quick, say ten minute, break? I would like to finish ISEA today. We have one more presentation from Don Wilmes. Don? Yes, how long do you figure it would take you?

MR. WILMES: Five minutes.

(Laughter)

MR. MATTHEWS: We've heard that before. What's the vote? Ten minute break or five minutes from Don Wilmes? Come on down.

SPEAKERS: Five minutes.

MR. MATTHEWS: Come on down.

MR. WILMES: I do have a very short presentation. I originally had two subjects. One was fit testing. The other was assigned protection factors, but I believe Barry addressed assigned protection factors in terms of the respirator user notice in his comments.

Just half a second on that issue again which he didn't cover is that ISEA would recommend that NIOSH seriously consider the assigned protection factors in the 1992 ANSI standard when it develops these interim assigned protection factors prior to

developing its assigned protection factor module.

Getting back to the first subject I was going to cover is fit testing. Section 84.181 and 84.182 of the proposed regulation require fit testing during certification of all particulate respirators.

As we had done in 1987, ISEA recommends that fit testing not be used as a condition of certification. Fit testing as part of certification, we feel creates a false sense of security to the respirator user. We think it also discourages fit testing in respirator use, which we believe is the only place that is really important.

To date, no one has really made any relationship between fit testing on a group of people in Morgantown as compared to what will happen in a particular work force.

In addition, OSHA requires as a part of respirator use, that every person be fit tested on each and every type of respirator that they'll be used in actual use, which we think is the only real meaningful fit test that is done.

Secondly, in the proposal, the requirement

for fit testing uses isoamyl acetate, which is an organic vapor. And these are particulate respirators, so therefore, there's going to have to be substantial modification made to them to make them capable of removing organic vapor.

To do this, you're going to have replace, for example, the media on a disposable respirator with a substantial amount of carbon in order to perform this test. And I guess we feel that the product that is going to be actually fit-tested will in no way resemble the product that's actually going to be used. We don't feel it's a meaningful test.

Other types of particulate respirators with cartridges, this is less of a problem. The filters can be replaced with cartridges, but then there is concern about using an organic vapor fit test when indeed the actual application is a particulate.

ISEA recommends that no fit testing be done as a part of certification, but efforts be made to reinforce fit testing as a part of respirator use. However, if fit testing is to be done, we would recommend that a particulate fit test agent be used in

terms of Bitrex, which is a qualitative fit test that can be used following the saccarine qualitative fit test protocol contained in the Lead Standard, or perhaps a large particle fit test using a particle of approximately two microns.

Secondly, in the standard, NIOSH makes a distinction between respirators with replaceable filters and respirators without replaceable filters. In a nutshell, what it requires was a two minute isoamyl acetate test for a disposable respirator and a five minute test with exercises for an undisposable.

We see no rationale for making such a distinction since their uses will be essentially the same. If there is going to be a distinction, it would be probably better to make the distinction based on the type of respirator. And what we would recommend if you're going to have two types of fit test protocols, is that perhaps your current Type C would be used with the two-minute version, versus Type A and B with the five-minute version with exercises.

You could perhaps justify this on what their anticipated use would be and that A and B would

probably be used in more hazardous atmospheres. Thank you, that's all I have. And I think it was under five minutes.

MR. MATTHEWS: Questions, comments?

DR. CAMPBELL: A quick question. You mentioned the large aerosol fit test as an alternative.

MR. WILMES: Yes.

DR. CAMPBELL: I'm wondering with the new filters that are proposed, would you really need a large aerosol to do a fit test?

MR. WILMES: I guess that would depend on what your pass/fail criteria was going to be. Generally it's accepted these days with a half-mask respirator that the generally used fit tests require a fit leakage of no more than one percent, which could present a problem with like a Type C respirator, for example.

DR. CAMPBELL: But if you could account for that, it might be possible to --

MR. WILMES: I don't think you can mathematically account for it because the penetration

is based on the challenge rate. And when you're wearing a respirator, your breathing patterns fluctuate continuously and so you're going to get unmeasurable fluctuations of challenge.

DR. CAMPBELL: Okay. All right, thank you.

MR. MATTHEWS: Rich?

MR. WILMES: Thank you.

MR. MATTHEWS: Okay, thank you. I had mentioned Technol, but I may exercise the prerogative of the chair to roll Technol over until tomorrow to prevent you from otherwise being stoned or mobbed. I do promise though that you will have air time tomorrow at the end of the presentations.

Given that, I thank everyone for their patience. We feel very pleased the way this has gone. We appreciate all the hard work demonstrated by all the presenters and we will kick off at 9:00 a.m. tomorrow morning with Thomas J. Nelson of American Industrial Hygiene Association as the number one hitter at 9:00.

Have a good night. See you in the

morning. Thank you.

(Whereupon, the hearing was concluded for the day at 5:10 p.m., to be resumed the following day, Friday, June 24, 1994, at 9:00 a.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

in the matter of: NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
INFORMAL PUBLIC MEETING

Before: GENE MATTHEWS, MODERATOR

Date: JUNE 23, 1994

Place: WASHINGTON, D.C.

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.

Michael Stern