NATIONAL INSTITUTE OF

OCCUPATIONAL SAFETY AND HEALTH

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PROPOSED RULE ON

RESPIRATORY PROTECTIVE DEVICE

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INFORMAL PUBLIC HEARING

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FRIDAY,

JUNE 24, 1994

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The hearing was held in the Ballroom of the Vista Hotel, 1400 M Street, N.W., Washington, D.C. at 9:00 a.m., GENE W. MATTHEWS, moderating.

PRESENT:

GENE W. MATTHEWS, Moderator

PANEL MEMBERS:

ROLAND J. BERRYANN
DONALD L. CAMPBELL, Ph.D.
CHRISTOPHER C. COFFEY
RICHARD W. METZLER

ERNEST S. MOYER, Ph.D.
ROBERT J. MULLAN, M.D.
JEFFREY A. PETERSON

ALSO PRESENT:

WENDELL ANDERSON, DOD, Retired

JACALYN L. BRYAN, Association for

Professionals in Infection Control and Epidemiology, Inc.

DR. DAVID K. HENDERSON, Society for Healthcare Epidemiology of America

JEFFREY KILEY, Air Techniques

WILLIAM M. LAMBERT, Mine Safety Appliances Company

TRISH McBREEN, Health Care Association of New York State

THOMAS J. NELSON, American Industrial Hygiene Association

JACK O'LEARY, American Mining Congress

JAY A. PARKER, Glendale Protective Technologies, Inc.

JOE RUMMLER, Tecnol, Inc.

ELIZABETH SOMMERS STREVEY, Greater New York Hospital Association

I-N-D-E-X

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

(9:00 a.m.)

CALL TO ORDER

MODERATOR MATTHEWS: For those wandering in from parts unknown, this is day two of the proposed rule on respiratory protection devices. I'd just like to say we're very pleased with the way the first day went yesterday. We certainly got a lot of very helpful comments on this, and we thank you, thank everyone yesterday for helping us out.

The schedule this morning, two add-ons have signed up in the back: one, Joe Rummler from Tecnol. We were trying to work him in yesterday. And also there's been a Wendell Anderson, retired, DOD.

Both have requested about 5 to 10 minutes each. So those, with time permitting, will be added on after Jeffrey Kiley of Air Techniques in the 10:45 a.m. to 12:00 noon slot.

Again, we still are hopeful that we can proceed expeditiously and be done before lunchtime, but, again, this is not an exact science. So we'll see how it goes. Okay?

First off, then, this morning is Thomas Nelson from American Industrial Hygiene Association. Tom?

MR. NELSON: Good morning. I'm Tom Nelson, Vice Chair of the AIHA Respiratory Protection Committee. We appreciate being given the opportunity to provide testimony regarding NIOSH's proposed rule.

The Respiratory Protection Committee is AIHA's technical committee that deals with issues of respiratory protection. The committee has 30 active members and approximately 10 former members that act as consultants to the committee. The members and consultants come from a wide variety of industries, government and academic groups, providing a broad base of knowledge and experience.

The committee supports NIOSH's efforts to update the filter testing section, Subpart K for certification of filters for respirators. We also support NIOSH's proposed plan to update the entire regulation in a modular process. This process does allow NIOSH to prioritize upgrades.

The committee does have concerns with the

proposal. These are in five broad categories: modular approach, powered air-purifying respirators, isoamyl acetate fit testing, the filter efficiency classifications, and the grandfathering of current filters.

The modular approach. Specifically, even thought we support the approach, we have concerns that this approach has not been tried until this rulemaking.

When modules are developed, how will the effect on other modules be determined? Will the effect on previously published modules be determined? What input will NIOSH utilize in writing modules? There are many groups with a great deal of experience, such as our committee, that can be used to help formulate modules.

We are also concerned that --

MODERATOR MATTHEWS: Excuse me. Could you speak just a little more into the microphones?

MR. NELSON: Yes. We are also concerned that a plan be developed to address the international integration of modules. And, finally, we see the need

for a separate module to be added to the schedule for powered air-purifying respirators, supplied air respirators, gas masks, and combination respirators.

In reviewing the test requirements for PAPR systems, the committee found the requirements difficult to follow. This is the result of combining filter tests with system tests.

We recommend that the test requirements for filters should only address filter performance, that the system performance of PAPRs should be addressed in a separate module dealing specifically with these systems, which are unique to PAPRs, such as performance testing using breathing machines.

Currently NIOSH recognizes only two types of PAPRs: tight-fitting and loose-fitting. The ANSI Z88.2 standard, 1992, on respiratory protection recognizes four types: half mask, full facepiece, loose-fitting facepiece, and helmets and hoods.

A visual examination of the types of inlet coverings would lead one to believe that four types exist. This is also supported by the results of workplace protection factor studies that have found

differing levels of protection for these types of PAPRs.

We recommend, then, that NIOSH should add the ANSI definition of loose-fitting facepieces to the proposed rule and include loose-fitting facepieces as a separate category of PAPRs.

In Paragraphs 181 and 182, NIOSH proposed a tightness test using isoamyl acetate. The purpose of the test is not given, but we believe that it is unnecessary, is not reproducible, provides no benefit.

Fit testing must be done on an individual basis. Prior testing during certification will not assure that an individual receives an adequate fit.

Respirator fit is an important factor in how a respirator performs, so important that ANSI requires that each person who will use a tight-fitting respirator be given a fit test.

OSHA in most of their substance-specific standards also requires that respirator users be fit-tested. However, the tightness test as required by NIOSH does nothing to help assure adequate fits.

In the requirement, NIOSH has not provided

a test that can be reproduced by others. No descriptions of the face sizes and qualities of a test panel have been given.

Unlike the isoamyl acetate fit test, as in OSHA's lead standard, no provision is given to determine if a person participating in the test can sense the presence of isoamyl acetate that leaks into the respirator. The test conditions vary among the two tests for test time and test exercises.

Our recommendation, with an understanding that personal fit testing is a requirement of a respiratory protection program, is that the isoamyl acetate fit test be deleted from the proposal or replaced with a more appropriate and scientifically supported test.

For filter efficiencies, the current respirators provide adequate filter efficiency, as evidenced by the number of workplace protection factor studies. For example, for half mask respirators, the average workplace protection factors have been well over 100, with fifth percentile estimates of over 10.

In changing the filter test, NIOSH is

moving the least efficient respirator filter class from one that would test at 20 to one percent penetration depending on the exact manufacturer to a class with no more than 5 percent penetration.

Since the test is so demanding and since current respirator filters are adequate, a penetration limitation of 90 percent for the lowest class would provide for improved respirators with less of a burden on the people who must use the respirators.

To get higher filter efficiencies will require that filters have more pressure drop that may increase leakage, may make them more uncomfortable and less likely to be used properly, resulting in an overall decrease in protection.

A 10 percent filter penetration during testing is not an unreasonable limit for a respirator filter when the test aerosol is considered. For example, the sodium chloride aerosol is specified to have a count medium diameter of .06 to .11 with a geometric standard deviation of 1.86.

It's highly unlikely that such an aerosol will occur outside the laboratory in any workplace

setting. So the field performance of the filter that passes at 90 percent efficiency will always be more efficient than 90 percent.

I guess yesterday was the one question on: How does this match up? I think you asked 10 percent filter plus 10 percent facepiece. I'd like to add my own explanation for that. I've seen that, and it sort of troubled me.

I think if you look at it, there are two parts. The first part is filter efficiency. In talking a little bit about that, I think it will be better than 90 percent in the workplace.

But assume it's 10 percent leakage for the moment. The other part you look at is the face fitting. The calculations are assuming 10. That 10 comes from the assigned protection factor. The assigned protection factor is derived from studies that include both face fit and filter leakage because with those workplace studies, that's what you're dealing with.

So to be, I think, the right type of calculation, it's a calculation and estimate of

performance that you need to back that filter leakage out for the current filters before applying that face fit number.

Now, I think a more proper number to be used would be 100 for face fit, which would be the minimum required fit factor for using a respirator if you're going to use that calculation. It's either quantitative or qualitative.

And then the form itself, I still don't quite understand where it comes from. I have some understanding of it, but then you're talking about adding 100 and one-tenth, which basically brings you back to the assigned protection factor of 10. So I feel that going to a 90 percent leakage will not really affect respirator performance overall.

The committee's recommendation is that filter efficiencies be set at 99.97, 95, and 90 percent. We feel that this will provide an appropriate range of filters with enough differentiation to meet the needs of workplace protection, including the health care setting.

We are concerned with the length of time

allowed for grandfathering in the proposal. The committee does not believe that a two-year period is the proper amount of time.

Requiring that new applications for approval meet the new requirements of 30 days provides little time for the development of products, performance testing, procurement of testing equipment. This work cannot begin until the final standard is published.

A two-year limit on the sale and distribution of current certified respirators does not provide enough time for NIOSH to process applications considering that development cannot even begin until the final rule is published.

Disallowing extensions on approved certified respirators under 30 CFR Part 11 will limit the supply of equipment, which may cause a disruption in the workplace.

Finally, no provisions have been given to the grandfathering of respirators which may be affected by changes in future modules.

The committee recommendation considering

the range of unknowns is to extent the time line to four years for the sale of equipment currently approved and a two-year limitation for the extension of approvals under 30 CFR Part 11.

If manufacturers are able to obtain approvals under the new procedures and get these to the marketplace sooner than this, manufacture marketing will create a swifter conversion. We believe that the current respirators are adequate and that there is no health-based pressing need to make a faster conversion.

Finally, we are particularly concerned with the effect of the proposal on respirator selection and assigned protection factors. We recommend that the current assigned protection factors remain intact until the proposed module on assigned protection factors is promulgated.

We appreciate this opportunity to testify, and we offer to NIOSH an opportunity to work with our AIHA Respirator Committee in developing future modules, such as that for the assigned protection factor.

Thank you.

MODERATOR MATTHEWS: Thank you.

A couple of reactions. One, your first comment about the modular approach, "How will this fit with the other modules and what type of comment and process in developing the other modules?"; I think we dealt with some of this yesterday.

MR. NELSON: Yes.

MODERATOR MATTHEWS: Clearly we have set out a series of modules which we will do through Administrative Procedure Act notice and comment on all of those.

It is a bit of a chicken and egg problem because we're starting with one and that raises questions for the other modules that have to do with protection factors and workplace and all of the others.

I guess the best view is to go back to Dr. Rosenstock's comments initially that we really are sort of shifting paradigms here to a continuous improvement.

We will be working on this continuously,

the industry, the agency, and the workers' groups, to try to continue to put improvements in. The art for the agency is to do this in a way that we don't suddenly leap out of a black box with a surprise for everyone.

We've got to continue to communicate so that the worker community understands where we're heading and the manufacturers understand where we're heading where we don't run up big R&D costs that are a dead end. So we're trying to be as open as we can be about this given the limitations of our knowledge on some of these issues.

And we can talk about goals. Again, the same discussion yesterday about eventually wanting to merge with a uniform international standard, to say another example.

I have two just technical questions. I don't quite understand your 10 percent APF point. Now, if we're talking about a 10 percent filter leakage, a 90 percent efficacy of a filter, regardless of the mathematical formulas that are used, which I certainly don't understand, it is still intuitively

obvious that also for a half mask or a quarter mask, there is leaking occurring around the face seal.

MR. NELSON: Right.

MODERATOR MATTHEWS: So it would seem like any calculation would lead you eventually to an APF of less than 10 if you've got filter penetration of 10 percent.

MR. NELSON: I guess the question is: Which numbers do you use for assigned protection factor if you look at the studies on half mask? The average performance is somewhere around fit factors or protection factors of 200 to 900.

So you're talking about leaking of one percent or a tenth of a percent. So adding that, then, to a filter efficiency that's 90 percent efficient or 10 percent leakage, you're not adding that much to it.

The calculation that you were presenting was adding 10 percent to 10 percent. Plus, you're adding 10 percent to something less than one percent. So it's not --

MODERATOR MATTHEWS: Your point is that

you're saying it is possible that the face fit would be only a leakage of one percent.

MR. NELSON: Or less, yes. It's tested that way as far as fit testing.

MODERATOR MATTHEWS: Okay.

MR. NELSON: Yes.

MODERATOR MATTHEWS: I understand what you're saying.

MR. NELSON: Yes.

MODERATOR MATTHEWS: The last point. I may have misunderstood you, but I thought I heard you to say that you feel the current respirators are adequate.

We have articulated in both our tuberculosis document and in this rule our concerns about filter penetration on the currently existing DMs and DFMs.

MR. NELSON: Right.

MODERATOR MATTHEWS: Were you embracing that class as well --

MR. NELSON: Yes. I think --

MODERATOR MATTHEWS: -- in your general

comment?

MR. NELSON: -- if I look at the ANSI standard, it has provisions for selection of respirator, which includes looking at particle size as part of that decision. And if you are selecting respirators properly, then they will give you that performance.

If you're taking a dust/mist respirator and using an aerosol that's .1 micrometers in diameter, it's not the proper respirator for that use.

MODERATOR MATTHEWS: Particle size issue.

MR. NELSON: Particle size.

MODERATOR MATTHEWS: Then that leaves -- I'm sorry -- just one last comment. I don't mean to drag this out. You also indicated, if I heard you correctly, that the small particle sizes for which we are testing the penetration levels really don't exist in workplaces.

MR. NELSON: Won't exist as the test aerosol. There are going to be small particles. You're testing with a particle that's a very narrow range. When you get in the workplace, most likely

you're going to see larger particles.

But even if you had small particles, you're not going to find industries where the particle range is such a narrow standard deviation, which means that since you're at the most penetrating particle, any filter penetration is going to be better than that in the real world.

MODERATOR MATTHEWS: Okay.

MR. NELSON: Yesterday I guess there was a comment. And I understand that it's very nice to say what we're going to do is use this most penetrating particle. That way it doesn't take any brains for anybody to go ahead and use a respirator, that anybody anyplace can select a respirator and select it properly.

I sort of disagree a bit with that from the standpoint that I believe that with respirator programs, you have to have knowledgeable people involved.

And the selection is a problem. It's a problem in any industry. You need people who are technically trained available to make those decisions.

MODERATOR MATTHEWS: Right. But one of the union comments that we elicited in the dialogue was it is very, very difficult for employers and employees to know the particle size that exists in a particular environment.

MR. NELSON: It is specifically for that environment, but I think you can do research. And there's probably a lot of published information. You can do it by industries, like paint spray industry.

You know, the particle size in that industry is a very large particle. And a concern over a small particle I don't think is real. I think there is published data on the particle size distribution for paint spray operations.

When you look at other industries, I think you'll find similar. So you can cover a wide range of industries very quickly just saying "We know what this is generally in this industry."

MODERATOR MATTHEWS: Okay. I understand your point.

MR. METZLER: Yes. I have a few questions and comments. Are you representing today AIHA or the

Respirator Committee?

MR. NELSON: The AIHA Respirator Committee.

MR. METZLER: You mentioned that there are 30 members on the Respirator Committee. Could you tell me the percentage of membership that is manufacturers?

MR. NELSON: Offhand, no. There are -- I don't know -- five or six members that are manufacturers.

MR. METZLER: Can you tell me the number of members who are labor representatives, laborers, workers?

MR. NELSON: There are no laborers or workers. That's a professional -- you had to be an AIHA member. Nobody from the labor industry has joined the committee.

MR. METZLER: How do you receive your input from workers in setting any guideline documents that you produce?

MR. NELSON: I think that this is being done by the committee members. So it's a professional

organization. The professionals are setting the guidance.

MR. METZLER: Then I have some responses with regard to some of the concerns beyond what Gene had mentioned. With regard to the grandfather periods, where you have expressed a concern that additional module grandfather periods were not mentioned in this first module, it was our intention that grandfather periods may be adjustable and tailored to a particular module and the changes that would be made to the particular respirator type.

With regard to some of the concerns over respirator selection yesterday, it was also discussed, the need for a user's guide of some sort making a transition from Part 11 to Part 84 respirators. We believe that that type of a guide will be needed for each and every module if one is produced.

Your last comment, I believe you were making a suggestion that APF issues ought to be covered in this module. Did I understand that?

MR. NELSON: I'm saying that I think you should use your current APF, or the ANSI assigned

protection factors, until you actually come out with that module, that it should be the guidance so that there is time for input from the different groups.

MR. METZLER: The last point that I would underscore, Gene's remarks about the new paradigm, a greater participation and partnership that was mentioned yesterday, as a first start, it is our intention that the "Federal Register" announcement of the modular approach in those modules which were identified, in addition to comments here and those that will go on the public record, will help us establish priorities and identifying particular modules that would be worked on.

And we do understand the concern that continuous improvement too frequently could actually create additional problems in adjustments to modules that were just promulgated.

And so we will be taking that into serious consideration and looking for public assistance in identifying the modules in schedule for each module.

MR. NELSON: I know that the AIHA Respirator Committee, it's a consensus organization.

So a time line like this one, which I know you have some very good reasons for, it's very hard for us to get our positions together and get all of the necessary approvals. Longer notice would be very helpful for us.

MR. METZLER: I understand.

DR. MOYER: I have two points. I'd just like to ask if AIHA does endorse the ANSI Z88.2 criteria for use of selection of respirators based on the two-micron particle size.

MR. NELSON: The committee has no formal position on that.

DR. MOYER: Okay. And the second point: In your estimation, is there support and recognition that there is a need in the workplace for a solid-only-type filter media.

MR. NELSON: I think from the standpoint of from my understanding of discussions I've had with some of the people that make the filters, that with a solid-only filter, you can do it cheaper. It's a little bit easier to make that type of filter, which means that you'll have filters available, I think.

For most workplaces solids only are what you're dealing with. Having to deal with liquids is specific to some industries. I think my experience in the chemical industry is most of the time it's been solids. You know, it's solids only.

DR. MOYER: Okay. So from your past experience, which has been extensive in related to workplace studies and things of that sort, you think there is a place, then, for a solid-type only-type filter?

MR. NELSON: Yes.

DR. MOYER: Okay.

MODERATOR MATTHEWS: Roland?

MR. BERRY ANN: Yes. Just revisiting the implementation, you made the comment of a 30-day requirement to apply for the new ones. I'd just like to clarify that that effective date allows manufacturers who are ready to apply early, doesn't require it.

The grandfathering clause allows those who are not ready who have not acquired the capability to continue to market the current ones. And we thought

that was important to allow the new technology to get out there for worker safety.

MR. NELSON: Right. I understand that. Thank you.

MODERATOR MATTHEWS: Don?

DR. CAMPBELL: You mentioned a WPF study where the APF was over 1,000. Would you comment on the particle size that was associated with those studies or typically associated with them?

MR. NELSON: One of the things I've done is I've done an analysis by combining several studies. And when you look at the different studies, their average varies from study to study.

But, for example, if you take a look at the HEPA filters only combining data from five or six studies, where HEPA filters were the subject of the workplace study protection, that geometric mean for that filter was 900.

There are studies, like the one we did on lead. It was up over 1,000. I can't remember the individual studies where they are. I can send you a --

DR. CAMPBELL: Yes. If you could submit those details to the record, it would be appreciated.

MR. NELSON: Sure.

DR. CAMPBELL: Also just to clarify one of your recommendations, you suggested deleting the face fit test. And I wasn't sure whether you were recommending that it be deleted from this module or that we, instead, develop a replacement for that to include in this first module.

MR. NELSON: I would think the first choice would be to delete it because I don't think it really adds value. But if it's something that the agency feels you must have in there, then I think you need to go ahead and take a look at developing some other kind of test, changing the isoamyl acetate to more like the real fit test if you're going to do that or use a saccharine fit test for particulate respirators.

But I don't know how that really connects with the workplace. And if a respirator doesn't fit your test panel, what does that really mean?

If someone designs a respirator for a

particular subset of a population, that's very small faces. And it doesn't fit with your panel. So it's not going to be used on big faces because you require fit testing anyway.

DR. CAMPBELL: Now, our intention with this first change was to address the filter penetration issues, realizing that there are a lot of other issues that need to be addressed in the future.

And I'm guessing -- tell me if I'm on the same wavelength -- that the reason that you're recommending this is associated with the fact that when many of especially the disposable types are redesigned with new filter media, they would be fit tested as part of the certification criteria.

And a reason for not doing that would be that your recommendation is that it's not a meaningful test.

MR. NELSON: I think it applies the last numeric phase be consumed, that, again, fit testing is on an individual basis. And whether or not it passes on a panel really has no meaning to an individual worker.

DR. CAMPBELL: Okay. Thank you.

DR. MOYER: One additional question, Tom. In your estimation, from workplace-type studies that you've done, the loading criteria that are presented in this module do, in fact, represent worst case-type loading?

MR. NELSON: From the number of workplaces that I've been in, even for nuisance dust, I think, I would look at that exposures of 20 milligrams per cubic meter of anything would be highly unusual in workplaces.

So if you're talking about a typical day, for 20 milligrams, it would work out to a 200-milligram loading on that filter for a day. So I think that's an upper bound.

Most workplaces you're talking about a milligram is dusty. It's visible. And you don't operate most manufacturing operations with visible dust in the air.

There are some that do. Most I think are not. It's like you're losing too much product is the way I've heard it described.

DR. CAMPBELL: Let me come back to the fit test question again. How would you suggest that we would deal with a respirator that might be submitted that has an obvious fitting problem? In fact, we see some of those from not manufacturers who are currently in the market, but maybe people who are interested in developing a respirator.

And at least the fit tests that we now do eliminates those that are obviously not going to pass any kind of fit test. I mean, it screens out the extremes.

Are you suggesting that we could do that based on a subjective judgment or

MR. NELSON: I guess the real issue is that the fit testing should be part of the regulation for a program and you're trying to control that from certification.

Where is the proper place to control that now? There are people who don't do fit testing. They're violating an OSHA standard, basically. They're selecting a respirator wrong.

It's very difficult to say that for

certification, you should control that part of the program. I guess if the respirator sold and it doesn't fit anyone, they're not going to sell very many and they're not going to stay in business very long, but if that respirator fits a person and that person's happy with it and they pass a fit test, it should be in the marketplace.

DR. CAMPBELL: My concern was, though, that that could put us in the position of certifying a respirator. It would have the NIOSH approval label on it that really wouldn't even pass a laugh test.

MR. NELSON: Yes. But, again, that's supposed to be done in the workplace. If none of them actually do, people can't use it.

DR. CAMPBELL: Thank you.

MR. METZLER: I have a question that's related to the path that Don was on. Do you have any estimates in AIHA Respirator Protection Committee on the number of workers who are without an industrial hygienist or safety professional to assist them in selecting a respirator with a respiratory protection program?

MR. NELSON: No, I don't. No, no figures on that.

MR. METZLER: Okay. We view AIHA's inputs as extremely valuable in helping us formulate our final proposals and future proposals, and we appreciate a continued dialogue in getting additional information from you and in continuing to set the modules.

MR. NELSON: Yes.

MR. METZLER: Thank you.

MR. NELSON: We appreciate any opportunity to help you.

MR. METZLER: Thank you.

MODERATOR MATTHEWS: All right. Next is Jacalyn Bryan, Association for Professionals in Infection Control and Epidemiology.

MS. BRYAN: Good morning. My name is Jacalyn Bryan. I am here today to testify for the Association for Professionals in Infection Control and Epidemiology.

APIC is a multi-disciplinary organization of over 10,000 health care professionals who practice

institutional epidemiology, quality improvement, and infection control in a variety of health care settings throughout the United States.

One of our primary roles is to develop and implement sound scientific strategies for protecting our patients, staff, and the public from acquiring infectious diseases. Our profession relies on scientific data and epidemiologic methods to prevent disease transmission.

We support all efforts to promote standards of prevention which are scientifically sound, realistically achievable, and which service all who encounter the health care environment, including patients, workers, students, and persons from the community. We welcome the opportunity and are pleased to respond to NIOSH's proposed rule on respiratory protective devices.

In September of 1993 APIC responded to OSHA's request for comment on the proposed enforcement policy and procedures for occupational exposure to TB. One of the major concerns we expressed in response to OSHA's proposed enforcement policy was the lack of

sufficient data to support the HEPA particulate respirator mask as a minimum and universal standard for respiratory protection against TB.

The move to such a standard would impose an inappropriate burden on personnel, material, and fiscal resources. We have stressed that the scientific support for these devices is nonexistent.

Respiratory protection has always been acknowledged to be the least important element in the OSHA-supported hierarchy of prevention that relies on early identification of infected cases and implementation of engineering controls as primary prevention strategies.

There now is sufficient scientific evidence to suggest that when primary prevention strategies are implemented, transmission is interrupted.

For example, at the APIC annual educational conference held in May of 1994 in Cincinnati, Ohio, representatives from the Centers for Disease Control, CDC, announced that the outbreaks of multi-drug-resistant tuberculosis which were widely

reported in the media had returned to previous baseline rates. This was accomplished primarily by implementing the requirements of the 1990 TB guidelines published by the CDC.

These guidelines did not include the use of special high efficiency particulate air filtered respirators. Early diagnosis, treatment, and directly observed therapy were the interventions that had the greatest impact in quelling these outbreaks. This finding was predictable.

We are concerned that the disproportionate focus on respirators for controlling occupational exposure to TB created an erroneous impression that respirators are the primary intervention for health care worker protection.

The concerns that we have previously expressed remain and are documented in responses to OSHA and CDC. However, we support NIOSH's proposed rule because it allows manufacturers to develop a broader range of respirators which meet the CDC's performance criteria as outlined in the 1993 proposed TB guidelines.

This proposal essentially removes the earlier impractical NIOSH recommendation to use powered air-purifying respirators and allows options other than the current OSHA-mandated HEPA PRs. In essence, it is a step forward in developing a more scientific approach to the prevention of occupational exposure to TB.

We feel that the new NIOSH performance standards will provide a fair and reliable way of evaluating PR use in the future. APIC recognizes that the certification process finally addresses the health care setting and that Class C filtered respirators with a 95 percent filtration efficiency should be acceptable for most health care worker needs.

We also recognize that fit testing programs will still be required, but the total program should be less costly as a broader range of certified respirators are made available in the marketplace. In addition, we would expect fewer usage problems and greater comfort to the health care worker.

Infection control professionals have an equal concern for both patient and employee protection

and well-being. A science-based usage requirement will enable support for a more consistent approach to prevention of TB among all populations.

We would also like to encourage manufacturers of these devices to not only design safe and effective PRs, but to assure they are nonallergenic and can be worn by persons who wear glasses.

For all of these reasons, we support the proposed standard and encourage NIOSH to continue using scientifically valid strategies for the prevention of occupational TB.

This new generation of respirators is urgently needed. And, for this reason, we urge NIOSH to place implementation of these new regulations on a fast track so the market can expand quickly and users will have a broader selection of certified respirators for TB control.

APIC intends to submit more detailed comments for the written record and has shared this proposed rule with our membership and encouraged them to send written comments to NIOSH in support of the

proposed standard as an important first step in improving the certification process for respiratory protection devices and the protection of health care workers from occupational exposure to TB.

Thank you for the opportunity to share our views.

MODERATOR MATTHEWS: Thank you.

I just have the same question I had yesterday with the Infectious Disease Society. Am I correct in understanding that you're comfortable with the October '93 CDC draft of a 95 percent one-micron standard for tuberculosis in the workplace, again with all of the other wrappings that go with it of a respirator protection program?

MS. BRYAN: In the context of the hierarchy of controls, yes.

MODERATOR MATTHEWS: Okay.

MS. BRYAN: Thank you. Any other questions?

MODERATOR MATTHEWS: Any others?

(No response.)

MODERATOR MATTHEWS: Thank you very much.

Next we have Greater New York Hospital Association, Elizabeth Sommers Strevey.

MS. SOMMERS STREVEY: Good morning. I should probably save everyone time and just say ditto to what she said.

MODERATOR MATTHEWS: Okay.

MS. SOMMERS STREVEY: But I'll take my moment.

MODERATOR MATTHEWS: Sure.

MS. SOMMERS STREVEY: And I'll answer your question, too.

Good morning. My name is Elizabeth Sommers Strevey. I'm the Senior Vice President for Regulatory and Professional Affairs of the Greater New York Hospital Association.

The association represents the interests of more than 167 -- or exactly 167, actually -- not-for-profit voluntary and public hospitals and nursing homes in New York City and surrounding suburbs.

On any given day, Greater New York Hospital Association's members care for more than 800

adults and children with suspected or confirmed tuberculosis in the acute care portion of our membership. And we employ more than 200,000 health care workers, many of whom come in contact with these patients in a variety of ways.

Questions of the level of proper protection, the clinical appropriateness of the current requirements, and issues related to health care worker comfort and compliance have been raised with the implementation of the recent HEPA respirator requirements by OSHA.

We come, therefore, to this hearing on behalf of our patients and our workers to discuss what would appear to be a new positive direction in terms of patient care, worker safety, and cost effectiveness relative to the quality of the respirator protection to be utilized in our members' facilities.

As you likely know, New York State, and particularly New York City, has been at the epicenter of the TB epidemic and, as such, has been grappling with issues related to infection control and TB transmission for some time.

Unfortunately, over time there have been instances of nosocomial TB transmission both to our patients as well as to employees in New York and elsewhere.

In the incidents that have been documented, enhanced, rigorous adherence to traditional infection control practices, the hierarchy of controls, relative to reducing and mitigating transmission of airborne diseases have proved effective in combatting and eliminating nosocomial transmission.

To our knowledge, in none of the outbreaks that have been controlled was the use of the currently required HEPA respirator undertaken as a control measure.

In point of fact, we have gone back to the basics, early diagnosis, isolation, treatment, and the hierarchy, basics we have known about for long periods of time, and by employing the basics in a rigorous and consistent manner have broken the backs of outbreaks both in New York and elsewhere.

Therefore, the hospitals on behalf of

their patients and employees greet NIOSH's new proposed regulatory requirements with very positive and significant interest.

As hospitals have attempted to comply with OSHA's requirement for HEPA respirators, they have encountered a series of problems in effecting legitimate and comprehensible communication with patients while wearing the respirator and have also encountered many, many complaints and concerns from employees who find the respirators constraining, difficult to breath through, ill-fitting given the limited numbers of sizes and shapes, and otherwise hot and uncomfortable.

Additionally, many employees have been forced to shave facial hair or utilize higher levels of protection with other attendant problems given the current situation and the rules. Complicating this procedure is a backlog in the supply provision.

As relates to cost, the expenditures being incurred when mounting a fully functional respiratory protection program that includes the use of either reusable or disposable HEPA filtered particular

respirators are extremely high.

While Greater New York had originally estimated an incremental cost of $40 million or more for its members, the cost is more likely to be many, many millions more, perhaps $65 million. These funds come from hospitals mostly with negative or barely break-even margins.

These expenses have diverted and will continue to divert resources from proven techniques for mitigation of disease transmission such as engineering and administrative controls to respirator protection.

Hospitals that spend one-half million or one million dollars more for respirators cannot dedicate that money for re-engineering or re-ventilating presumably risky emergency departments and their waiting rooms, for example.

NIOSH's new proposal offers manufacturers the opportunity to develop respirators that meet the needs of the health care community in terms of disease prevention, ease of use, comfort, and cost.

While we have not yet fully critiqued the

proposed rule from a technical standpoint, the initiative itself and its stated intent are sufficient to suggest to us that NIOSH and the federal government are heading in the direction of reinserting science into this equation while continuing to protect health care workers and marshalling scarce resources for the proven techniques of disease transmission control. We are, therefore, extremely supportive of this change in direction and hope that given the resurgence of TB and the real need for change in the health care environment, this process proceeds most expeditiously.

We plan to submit more formal technical comments by the July 22nd deadline but wanted to be sure that, as we have historically voiced loud complaints about the current OSHA requirements, we are now heard voicing encouragement in moving forward toward more science, more comfort, more compliance, less cost, and more sanity in this area.

We continue to stand ready to work collegially and cooperatively with any and all organizations to ensure that the ultimate result of this process, hopefully expedited, will better ensure

worker safety, high quality patient care and cost-effective use of limited resources.

MODERATOR MATTHEWS: Any questions?

(No response.)

MODERATOR MATTHEWS: We hope we are heading in the right direction, too. Thank you.

We have two for Society for Healthcare Epidemiology of America: Michael Tapper and/or David Henderson. David? Good.

DR. HENDERSON: Mike couldn't be here. He had the choice of being in Switzerland or being here, and I told him that I would be happy to go to Switzerland for him. I ended up getting this assignment instead.

Mr. Chairman, ladies and gentlemen, I am David Henderson, and I am the Associate Director of the Warren G. Magnuson Clinical Center, the hospital at the National Institutes of Health in Bethesda, Maryland.

I am here today to represent the AIDS and Tuberculosis Committees of the Society for Healthcare Epidemiology of America, SHEA, chaired, these

committees are chaired, by Dr. Michael Tapper from Lenox Hill Hospital in New York City.

SHEA is an organization composed of several hundred individuals trained at the doctoral level who are responsible for hospital epidemiology and infection control programs in hospitals and clinics across the United States.

As is the case for the other speakers here today, I come to speak about the proposed rule that discusses certification requirements for respiratory protection devices, specifically as that rule would apply to devices used in the health care environment.

Whereas SHEA shares the concern of the U.S. Public Health Service and other organizations about the marked rise in reported cases of tuberculosis in the United States and we specifically are concerned about the dramatic increase in reported cases of multiply drug-resistant tuberculosis in the cities of the United States, we also have substantial concern about the face of health care in the United States in the 1990s and beyond.

Any strategy that we as a country develop

for the control of tuberculosis in the United States must be grounded firmly in science and must, I believe, be broadly applicable to all health care institutions throughout the country.

Among the strategies that appeal most to us as an organization focusing on hospital epidemiology is the concept of risk assessment. Because of the complexity of the problem presented by the airborne spread of drug-resistant tuberculosis and because of the non-homogeneity of the problem throughout our country, a sensible approach to risk assessment, modeling prevention strategies appropriate to the various levels of risk for each institution appears most sensible to us.

Applying a broad-based "one size fits all" set of recommendations to all health care establishments in the country seems needlessly expensive, quite labor-intensive, and virtually impractical. We believe fervently in fitting the appropriate prevention strategy to a carefully evaluated, definitively determined level of risk.

We concur with the approach initially

presented several years ago by the National Institute of Occupational Safety and Health basing tuberculosis prevention efforts on the implementation of a hierarchy of controls in the health care environment.

We concur with the previously published hierarchy; that is, that administrative controls remain the most important, engineering controls next most important, and that the use of personal protective devices represents the third most important strategy to reduce the risk for transmission of tuberculosis in the health care setting.

Primary efforts simply must be expended on identifying cases of tuberculosis, managing such cases appropriately, and making certain that therapy for active tuberculosis is completed appropriately and under direct observation.

SHEA has been vitally interested in the draft guidelines for the control of tuberculosis in health care settings published in October of 1993 in the "Federal Register" by the Centers for Disease Control. We have felt, that despite the fact that these guidelines emphasize the two crucial concepts

of a hierarchy of controls and a risk-assessment-based prevention strategy, these guidelines, nonetheless, overemphasize the importance of respiratory protection devices as primary prevention strategies.

Further, we have been concerned that only respiratory protection devices that employ high efficiency particulate air; that is, HEPA filters, would meet the criteria published earlier by NIOSH.

We endorse the concept that the Centers for Disease Control has proffered that respiratory protection devices should provide 95 percent filter efficacy of particles 1.0 micron and larger and note that previous testing procedures for other respiratory protection devices; that is, the so-called dust/mist and dust/mist fume devices, were not specifically designed this type of use nor were they designed for use in the health care setting.

We enthusiastically endorse the adoption of these new proposed regulations, which we believe would result in the establishment of a new class; that is, Class C, of respiratory protection devices that would meet or exceed the CDC's published performance

characteristics.

Should this regulation be adopted, we believe that a much broader variety of respiratory protection devices, each of which would offer an appropriate, effective level of respiratory protection for health care workers and would meet these testing requirements, would become available for use in the health care setting.

At a time when all of us are focusing on the dramatically increasing costs of health care, implementation of these cost-effective sensible guidelines seems both prudent and highly advisable.

We also underscore the need for additional clinically based studies which evaluate the true clinical efficacy of all of the prevention strategies that have been advocated by NIOSH, CDC, and others. The need for clinically relevant science is both compelling and dramatic.

We urge the rapid adoption of these regulations and further support the development of a risk-based approach to the management of tuberculosis in the health care environment that is both sentient

and cost-effective.

Thank you for allowing us to present our views. Our organization would be happy to work with NIOSH and CDC in the development of safe and sensible tuberculosis management strategies for the varied health care settings present throughout the United States. Thank you.

MODERATOR MATTHEWS: Thank you very much.

Any questions, comments?

(No response.)

MODERATOR MATTHEWS: Thank you very much.

Next is American Mining Congress. And my understanding is that Jack O'Leary has substituted for Bobby J. Jackson.

MR. O'LEARY: Good morning. My name is Jack O'Leary. I'm representing the American Mining Congress. AMC very much appreciates this opportunity to comment on the proposed Mine Safety and Health Administration and NIOSH joint regulations regarding the requirements for respiratory protective devices.

AMC is a national trade association. It represents mine operators, manufacturers of mining

equipment, including respiratory devices. We have historically been involved with MSHA and 30 CFR 11 and are, therefore, quite interested in this rulemaking and the relationship between the agencies.

In general AMC supports the approach that's taken by the agencies. AMC feels that this well-described and clear regulatory system that's envisioned will be in the best interest of the miner, the mine operator, and the manufacturer of respiratory protective devices.

The transition of authority from MSHA to NIOSH with that latter agency's commitment to the improvement of efficiency could benefit certification programs significantly.

AMC is concerned, however, that there be accountability between agencies as the regulatory transition takes place and after the transition is accomplished.

The memorandum of understanding referred to in the regulations that describes the responsibilities of each agency after the promulgation of the standards is exceptionally important to AMC.

The mining industry faces unique respiratory protection applications, which warrant specific attention; for example, self-contained self rescuers and mine rescue apparatus.

Consequently, AMC requests an opportunity to participate in the development of the memorandum of understanding to ensure that this document serves the needs of both agencies and the mining industry.

While AMC generally commends the agencies' efforts, we have concerns about specific parts of the proposal that could cause difficulty for the manufacturers and users of the devices.

AMC is concerned about the lack of clarity in some of the language in the proposed rulemaking. We are requesting comments from our members at this time to assign priorities and to suggest amendments that can clarify some of the areas that have been mentioned to us by our members as having some ambiguity.

Our written comments to be submitted by July 25th of '94 will expand on that comment. These comments will also address, the written comments will

address, the technical facets that have been told to us. Today I'm only going to address the broader policy issues.

We do support the transfer of the regulatory authority to NIOSH because we feel it will increase the responsibility and accountability for regulations because it will be concentrated in one area, but we also want MSHA to have the strong authority under the memorandum of understanding between the agencies, particularly related to the mine-specific regulatory protection devices.

We also support the modular approach that the agencies are taking in the development of these regulations. Rulemaking that attempts to address all of the issues concerned with regulatory devices would be cumbersome and would likely result in errors and burdensome requirements.

This approach to treat each aspect of the regulatory protective devices discretely will help ensure that each issue is appropriately considered, it is an efficient process, and will yield beneficial results.

AMC supports grandfathering those devices manufactured to current approval criteria. Applications submitted to NIOSH after the rule becomes effective will be accepted for 30 days in accordance with 30 CFR 11 as the proposed regulation is now written.

AMC is concerned about the effect this proposal will have on products already in use and currently available from suppliers, whether manufacturers or distributors.

AMC opposes rules that would immediately or retroactively decertify machine equipment or devices that were previously approved and were manufactured to both government and private specifications.

AMC suggests that the proposed regulation be clarified to ensure that it does not decertify any respiratory protective device that is currently in use or any device that was manufactured prior to the effective date of the promulgation of these regulations if that device is in accord with the approval criteria currently in place at the time of

the promulgation of this rule.

MODERATOR MATTHEWS: Do you mean the old criteria or the new criteria?

MR. O'LEARY: The criteria currently in place when this rule is promulgated.

MODERATOR MATTHEWS: The Part 11 criteria?

MR. O'LEARY: Yes. We don't want that. We don't want retroactive decertification.

MODERATOR MATTHEWS: I apologize for interrupting.

MR. O'LEARY: Oh, no. Please. But we would suggest that a specific reference be included here to preclude retroactive decertification.

In addition, AMC recommends that a separate module be added for the consideration of regulations addressing the issue of powered air-purifying type respirators. They have unique problems dealing with air flow, filter efficiency, and fit and, therefore, deserve special consideration.

In some cases air filtration devices that meet established standards can be engineering-controlled and should be recognized as

such in this and in future rulemaking. We will address this issue also in our written comments in some detail.

In conclusion, I restate that AMC is very supportive of this approach to this important rulemaking. The concept of permitting the agencies to relieve the industry of the burden of intense regulation while maintaining the high level of safety is one that AMC has advocated for quite some time.

We look forward to working with both agencies, both NIOSH and MSHA, to craft regulations that will be of benefit to the miners, to the mine operators, the manufacturers of respiratory protective devices, and will be submitting written comments on many of the issues addressed in the rulemaking.

I appreciate the time to comment.

MODERATOR MATTHEWS: Rich?

MR. METZLER: Yes. Thank you for being here today to represent a mining segment of our industries. You brought up some concerns that we can answer immediately.

As I mentioned in my opening remarks,

there was no intended change to current practice. Actual practice between NIOSH and MSHA is being documented in this rule. We're actually working together in the joint approval processes, as this particular rule describes. So there is no real change in the actual practices between NIOSH and MSHA.

With regard to your concern over the MOU, we do welcome your comments as we will be writing a memorandum of understanding to address how retrofits, recalls will be procedures that we will use in those matters that would be of great interest to you, I'm sure.

MR. O'LEARY: I'm sure, too.

MR. METZLER: Okay. There was also no impact expected on mine emergency equipment, such as SESRs and FSRs and rescue equipment. The technical standards are being transferred from 11 to Part 84. And, therefore, there was no intention to decertify the equipment based upon the transition from Part 11 to Part 84.

MR. O'LEARY: Thank you.

I look forward to working with you on the

memorandum of understanding, too, so that we closely define what devices are under the purview of which agencies.

MODERATOR MATTHEWS: Any other comments, questions?

(No response.)

MODERATOR MATTHEWS: Thank you very much.

MR. O'LEARY: Thank you very much for your time.

MODERATOR MATTHEWS: Last in this segment is Service Employees International Union, Laura Kenny. No Laura Kenny? Not here. Okay. All right.

Well, I will not do to MSA what I did to Moldex yesterday. It's 10:00 o'clock. And rather than have you grope for your slides or your overheads and whatever, it's 10:00 o'clock. Let us take a 15-minute break. We will start back promptly at 10:15 and consider this time gained. Hopefully we will get out of here.

(Whereupon, the foregoing matter went off the record at 10:00 a.m. and went back on the record at 10:19 a.m.)

MODERATOR MATTHEWS: Just one housekeeping function. Again, if you have slides or overheads, if you would give a copy also to Dianne after the presentation. If you have only one copy, then give it to the transcriber prior to the presentation. It makes things go smoother.

Okay. We are now at William M. Lambert, Mine Safety Appliances Company.

MR. LAMBERT: Good morning, everyone. My name is Bill Lambert. I'm MSA's Product Line Manager for Air-Purifying Respirators. I'm here to provide oral comments to the notice of proposed rulemaking, 42 CFR 84.

I'm joined today by Tom Hoetop, our Senior Vice President for the Safety Products Division; Wade Miller, our Director of Product Planning and Engineering; and John Koon, our Product Engineer for Air-Purifying Respirators Development.

Rich, yesterday you indicated that the current filter test is coming up on its 60th birthday and that it's about time that maybe before that birthday celebration we change that regulation.

I'm very proud to say that MSA has been in the respirator business for all 60 of those years. And, in fact, this year we have celebrated our 80th anniversary as a safety equipment supplier to the industry, making us truly the grandfather of respirator manufacturers.

Our company's founders, John Ryan and George Dike, were two Bureau of Mines rescue engineers. They had a vision when they began our company, and that vision was that men may work in safety.

Certainly much has changed over the past 80 years, but one fact has never changed. And that fact is MSA's commitment and dedication to protecting the health and safety of working men and women everywhere.

Over 4,000 employees strong today and operating in 22 countries worldwide, MSA is the world's largest company solely dedicated to producing a complete range of safety equipment and systems for protecting people's health and the environment. And we're very proud of that fact.

MSA welcomes the opportunity to comment at this informal meeting and respectfully submits the following presentation that I'm about to give.

First let me say that we applaud NIOSH's efforts and initiative to date in bringing forth this module sincerely. As the largest safety equipment manufacturer, we do applaud your efforts.

It has been one heck of an incredible balancing act. We understand that. We were there back in the late '70s, when you were asking for comments on how 30 CFR Part 11 should be changed. We were there in the '80s commenting with you and trying to make this standard evolve to what it has.

We understand the concerns and the issues and the troubles that you have gone through in trying to meet both the industry needs and the user needs and what's best for public health, more than 7 years in the making and maybe even more than that, more like 15 years if you go back to the late '70s, when you first came forward and had the open meetings and said "How do we need to change or evolve 30 CFR Part 11?" and even in '87, when you issued the proposed rule,

taking those more than 270 comments, some of them very, very strong arguments, others maybe not so strong.

There were some pretty hard issues that came out of that. And we can appreciate that. We congratulate your efforts. We really do, and the initiative that you guys are taking.

And, really, the genius behind 42 CFR 84 coming about is this modular approach. We support that modular approach.

I have a four-year-old daughter. My daughter and I were in the front yard watching the caterpillars and the tent worms devour my tree. She asked me, she said, "Dad, how does that caterpillar get to the top of the tree?" I said, "Well, I know that's kind of tough for you and me to get there, but inch by inch that caterpillar is going to make it."

Inch by inch, and even though it's slow, this modular approach is the way to go. And MSA supports that modular approach that you guys are now taking on.

It provides for improvements on a priority

basis so that you can address the respirator needs that are most urgent right now, and we agree with that.

It assures improvements to worker safety are implemented first. And it really facilitates adaptation by not just the manufacturers, but by all stakeholders, including the users. It is a proactive approach that we truly support.

What NIOSH wants from Module 1. As stated in the "Federal Register," there are a number of very specific goals that NIOSH has indicated that they would like to see come about from Module 1 of 42 CFR Part 84: first, -- and these are verbatim out of the "Federal Register" -- to produce significant improvements in the level of protection provided to wearers of respirators; secondly, to enable users to easily discern the level of protection that can be expected when using a respirator; three, enable classification of the filters on their ability to inhibit penetration of particulates of the most penetrating size. MSA agrees with and supports these very worthy goals and objectives.

There was a fourth objective also stated and outlined in 42 CFR 84. That additional benefit was specifically to address health care worker needs, and it said to "address an important public health need regarding the control of TB transmission with six classes of respirators expected to be markedly less expensive than respirators with HEPA filters."

Certainly we've heard from the health care community these past two days, and that is a high priority issue with them trying to balance, on one hand, effective health care costs and, on the other hand, effective respiratory protection for the workers in that health care environment. This is a tough one.

Taking this objective and the three objectives outlined on the previous slide and having those two live happily ever after is tough. And that's something that I think we need to reckon with because I think it's tough and we think it's tough because in some respects, this goal and objective is in conflict with those other three goals and objectives. So what I hope we get to today is a discussion on why we think that's tough and what needs

to be done.

Trying to outline to you our concerns and comments with 42 CFR as written: one, that significant improvements in worker protection won't be achieved; two, that users won't easily discern the level of protection; and, three, that filters aren't classified on their ability to inhibit particulates of the most penetrating size.

We truly believe that the first three objectives, primary objectives, that you outlined for 42 CFR, Module 1 to accomplish won't be realized as written.

Why do we believe that? We believe for three principal reasons. Number one, it's a tiered system, a better-best system that can lead to user misuse and misapplication. The idea of solid-only particulate respirator certifications and liquid and solid particulate classifications and certifications can lead to misuse.

Secondly, the test method can overstate filter efficiency.

And, third, as written, 42 CFR 84 permits

certification of filters that show continued loss of filtering efficiency with exposures to the challenge aerosols.

Providing you with the conclusions right up front and telling you what I'm going to be talking about, these are the three conclusions that I'd like to come to in my presentation: that, just as in 1987, only one certification class be established for respirators; -- that would be liquid and solid -- two, that thermally generated DOP be used as the challenge aerosol; and, three, that, just as in 1987, the testing continue until filter penetration and filter efficiency have stabilized.

First let me address the issue of the tiered approach that we see in the new standard. It is definitely a tiered system, where you have solid-only certification class of respirators, and you have a liquid and solid certification class.

You have the same efficiency ratings, the 99.97, the 99, and the 95 for both the solid and for the higher levels of protection, the higher performance, we should say and probably all agree to,

with the liquid and solid certifications.

How does that lead to misuse? It's been stated. Tom Nelson stated it. It's been talked about within the industry. Solid-only respirators are going to be a lot less expensive. That probably was the reason why or the argument made back in '87 why that was changed now between the rule that we saw in '87 and what we're seeing today in 1994. Solid-only respirators are probably going to be a lot less expensive.

If that's the case, if the user is faced with the fact that he has this 95 percent efficient filter, on one hand, and a 95 percent efficient filter on the other hand, this one being solid, this one being liquid and solid, he's going to look. He's going to take a look at those two respirators, and he's going to say, "You know, they're both 95 percent efficient."

Efficiency will become the decision-maker. That will become the purchasing driver. So now you will have users who will opt for the lower-cost filter, for the filter that's at the 95 percent

efficient level, which is the same over here, but it's a lot less expensive. Misuse, misapplication is going to result.

We all heard Bruce Mahan yesterday indicate that in the real world, speaking for the Chemical Workers Union, in the real world, these guys don't know what aerosols are. He indicated, I think his words were, "They're not sure what the word 'aerosol' means."

They're not measuring the particulates. They take a look, and they classify according to the hazard. And then they apply the respirator according to what they think is there.

Faced with that situation, if this is 95 percent efficient and this is 95 percent efficient, workers are going to opt for the low-cost alternative. That's a concern. That ought to be a concern for all of us.

Two goals that were stated for 42 CFR 84, Module 1: produce significant improvements in protection provided to wearers of respirators, and enable users to easily discern the level of

protection.

Those two will be very, very difficult to accomplish if the user is faced with a solid-only and liquid-solid and, yet, there are the same efficiency classifications within each of those certification groups.

The solution that MSA is proposing and we would like you to very seriously consider is what you proposed and put forth back in 1987, and that is that only one certification class be permitted, that class being liquid and solid, for those special instances; for instance, in the asbestos environment, where we all know the asbestos environment is a solid particulate as classified and probably will have a solid particulate respirator or be classified as a solid particulate.

But the actual use condition where that respirator is being used in the workplace, we know there is water everywhere, water spraying everywhere, to try and control, try and bring down those ambient concentrations of fibers.

What will that user opt for if faced with

that knowing that asbestos is a solid fiber, a solid particulate; yet, the actual use condition in most cases has water spraying everywhere? Clearly a liquid and solid-type approval would probably be the better respirator to use there. We need to address that. We need to give that serious consideration.

Our second point was related to the testing method that's been specified. Bill Newcomb from North talking for the ISEA yesterday touched on that a little bit, and I'm going to touch on it a little bit more.

Our point is that the test method as specified in Module 1 can overstate the filter efficiency. Let's go back to the goal. The goal is to enable classification of filters on their ability to inhibit penetration of particulates of the most penetrating size.

We agree. DOP is the most penetrating liquid aerosol. And we agree, Don, a worst case aerosol should be used for certification testing. To not only protect those workers who are out there working for Union Carbide who have the benefit of a

Safety Department, an Industrial Hygiene Department, who can go out and measure the ambient concentration levels, but for that small business sector of the economy that doesn't have that benefit that's relying on the NIOSH certification label and that TC number to guide them in the right direction, we agree that a worst case aerosol method should be used.

But the question that Bill raised yesterday and we'll raise again today is: How generated, cold nebulized or thermally generated? And the problem again gets back to it gives different results depending on the type of filter construction that you have.

I just want to briefly review these and run through these very quickly. I don't need to spend a lot of time on these graphs because Bill showed them to you yesterday.

For those filters that industry conducted some round robin testing on, those filters approximating Type A filters of the electrostatic class showed this type of performance, where the thermally generated DOP showed significantly higher

penetration than the cold generated, cold nebulized DOP.

Ernie, to address some of your concerns from yesterday, the round robin testing was done with very special attention paid to the test protocol. And we'll be happy to share that with you, with the panel, make them a part of our public comments. But a very specific test protocol was established to eliminate a lot of the things that you indicated yesterday in your discussions.

For those filters approximating Type B performance, again thermally generated DOP showed higher percent penetrations; i.e., lower filter efficiencies than the cold DOP.

And for Type C we saw the same thing. Thermally generated DOP appeared to be a more penetrating aerosol than cold nebulized DOP for all three of these classes or approximating these classes of electrostatic filter medium.

That's an important distinction that needs to be made because under those same test setups, under that same test protocol, the only difference now being

that you're not using electrostatic media, now you're using mechanical filter media, you see very, very close correlation between the results independent of whether you're using cold nebulized DOP or thermally generated DOP.

For those filters approximating Type A performance, you see that they gave almost identical results. We're over into the third place decimal.

For Type B or those filters approximating Type B, again very, very close results, very close correlation between cold and hot DOP; and for Type C, very close.

I think this very closely correlates this study to the studies that you have done, that Ernie has done in your own lab, that show that for mechanical filter media, cold nebulized DOP, thermally generated DOP provide the same result. Where you don't get the same result is on that broad class of filters known as electrostatic filters. And that's a concern.

Graphically showing these two is a telling story. High efficiency -- this is testing not

conducted by the ISEA. This is testing conducted by MSA and an outside lab.

Testing was done using thermally generated DOP on over 30 samples of high efficiency filters, mechanical, a group of mechanical, filtered elements and a group of electrostatic filtered elements. As you can see, the filter efficiency starts to drop off with the electrostatics. And it drops off rather rapidly.

Our conclusions from this are what follows. Number one, this is not across all filter media. As you guys well know, this is a phenomenon to electrostatic filter media.

Two, the cold DOP consistently overestimated filter efficiencies in that broad class of filter media known as electrostatics; that with each type of electrostatic filter, thermally generated DOP was more penetrating than cold nebulized DOP. And, lastly, with each type of electrostatic filter, performance was continuing to decline when the test was stopped.

That's all fine in the lab, talking about

it in what seem to be esoteric terms of whether you're going to generate this cold or hot. Let's try to relate it to the worker, to the user community, to the stakeholder to what we're trying to do today and formulate.

Our goal, 42 CFR 84's goal, was to enable users to easily discern the level of protection that can be expected when using a respirator. The question is: Where is the indicator to the user that the electrostatic filter is losing its efficiency? The user can't detect, taste, or smell the breakthrough in loss of filter efficiency.

What about the user? How does the user enter into this if we're really trying to enable the user to easily discern the level of protection that he can expect when using the respirator? 42 CFR 84 we believe must address this concern. It's a real concern.

Reading to you from a paper issued by Ernie Moyer authored by Ernie Moyer that was distributed at the American industrial hygiene conference and exhibition just a few months ago,

"Electrostatic media have good initial filter efficiencies, but the filter degrades with increased particulate loading. This loading causes a masking or loss of electrostatic charge (filtered degradation) resulting in reduced filter efficiency and increased worker exposure.

"This is possible since there are no end-of-service life indicators for such respirators. Note that the longer the wearer continues to use this respirator under these conditions, the higher the exposure level."

And reading from OSHA's Instruction Manual CPL 2-2.54 from the Office of Science and Technology Assessment, "Only mechanical type high-efficiency particulate air filters enclosed in cartridges or canisters are acceptable for protection against any particulate exposures because efficiency of these filters does not change with dust-loading and ambient conditions."

It would appear that everybody knows about this performance but the user. How can a new certification module go through unless it addresses

this in some fashion?

Some will say that it's just DOP or it is just that oil aerosol that you're using. We would argue it's not just DOP. In a 1986 paper by Blackford, Bostock, Brown, Loxley and Wake entitled "Alterations in the Performance of Electrostatic Filters Caused by Exposure to Aerosols," they showed that silkstone, coal dust, foundry fettling fume, foundry burning fume, carbon brick dust, lead smelting fume, lead battery dust, ammonium chloride, real world stuff, cause a breakdown in electrostatic filter medias.

What they showed were graphs that looked similar to ours, at least characteristically, for those different challenge aerosols, that under the conditions, the test conditions, in the paper, they showed that for all of those challenge aerosols, that the percent penetration increased with exposure to that aerosol.

Quoting from the "Journal of ISRP," July-September 1986, again in an article written by NIOSH, both by Ernie Moyer and a couple of scientists

from NIOSH Cincinnati, "NIOSH is concerned that certain respirator particulate filters degrade under typical use and storage conditions. NIOSH studies have shown significant degradation of electrostatic filter media in coke ovens, Smith 1979, and pesticide environments, Kennedy 1983."

This issue has to be addressed, we believe, by 42 CFR, the Module 1, 42 CFR Part 84. We have all known about it for a while. We're becoming more aware of it, as manufacturers know, but certainly the scientific community has known about it. NIOSH, we believe, must address this.

And you know what? You did. You did in 1987. In the 1987 released 42 CFR 84, it stated that "if filter penetration is increasing when the 100-milligram challenge point is reached, the test shall be continued until there is no further increase in penetration." Therefore, filter efficiency is certified only after performance has leveled off.

You did address it. And you need to address it again, we believe.

What we all want from Module 1, 42 CFR 84,

is to produce significant improvements in the level of protection provided to wearers of respirators, to enable users to easily discern the level of protection that can be expected when using the respirator, and to enable classification of the filters on their ability to inhibit penetration of particulates of the most penetrating size.

To accomplish those goals, those very worthy goals, we recommend the following, that 42 CFR 84 should require: one, that, just as in 1987, only one certification class be established, that being liquid and solid certifications, in order to eliminate or reduce the potential for misuse and misapplication.

Now, a lot of people will say that's OSHA's problem, that's OSHA's problem in the use and application of those respirators. But the mere fact that that certification class exists is an OSHA's problem is something that we can nip in the bud right now with this module release by eliminating that solid-only class and having everything meet the highest level of protection that the government feels it needs to meet.

Our second recommendation is that thermally generated DOP be used as the challenge aerosol. We see with mechanical filter media that thermally generated or cold nebulized DOP give the same result on all classes of filters or very, very close to the same result on all classes of filters.

Thermally generated and cold nebulized DOP do not give the same result on those classes of filters for electrostatic media. There's something else happening there. And if what we're looking for is the most penetrating particle, then thermally generated DOP appears to be more penetrating than cold nebulized DOP, whatever the other influences are that are going on.

And, lastly, just as in 1987, exposure continue until filter penetration and filter efficiency have stabilized. That's to protect the worker. That's what we need that allows the user to easily discern the level of protection that can be expected when using a respirator.

Wow. We do all of that. What about the health care industry? What about the fourth objective

of less expensive respirators for protection from TB? That's suddenly where the conflict arises.

Unfortunately, the cost impact analysis that Bernard Mishkin from Moldex and the ISEA produced yesterday indicated that even if 42 CFR 84 were to go through as is today, there may not be any cost savings at all. In fact, it would be in both cases over a $100 million impact to the user, annual impact. That's significant.

Number two, and a very important question. I think it's echoed this morning from the health care industry. Do we really know enough about TB? Do we know enough about TB that we can take this certification module that's been in the works for 20 years, 15 to 20 years, and now loosen those constraints so that we can meet the need of the health care industry, which, by their own admission, seems to have humped? And the hierarchy of control seems to be taking over, and that crisis seems to have passed somewhat.

Do we really know enough about TB and TB concern to now take these regulations and bring them

down to that level to ensure that we have inexpensive respirators for that immediate concern?

Basic fundamental questions, like: Has a safe exposure limit been established for tuberculosis? Does it make more sense for an emergency substance-specific standard from OSHA to help work out way out of the TB issue without taking the respirator certifications down to a point that ensures that we have inexpensive respirators to meet a crisis, which, apparently, by their admission this morning, has passed?

I'm not sure. I'm not a TB expert. We certainly aren't. But we certainly know some of the things that we have read would lead you to some pretty tough questions for answering the question, Gene, as you indicated, to a number of the health care workers, where you said "Do you feel comfortable with a 95 percent efficiency against the one-micron particle size?"

And unanimously all six of those speakers, the people you have asked, certainly, out of that group of six have said, "Yes. We feel comfortable.

We don't want HEPA. We feel comfortable with that" because they've been told, I'm sure, that those are going to be less expensive respirators.

In the CDC's October guidelines, it indicated "Neither the smallest infectious dose of M. tuberculosis nor the highest level of exposure to M. tuberculosis at which transmission will not occur have been conclusively defined.

"The size, the size distribution, the number of particles containing viable M. tuberculosis that are generated by infectious TB patients have not been adequately studied."

And, yet, we're saying this morning and we heard testimony this morning that indicated that they are pleased to see that we're taking a scientific approach in applying respirators to that need, to that health care need. Wow. I don't see the connection between the scientific aspect they're referring to and what the CDC published last October.

Again quoting from that CDC document, "Respirators are typically used in situations where: one, there is an established exposure limit; and, two,

the ambient concentration of a hazardous agent in the workplace is known."

It goes on to say "Neither the exposure limit or the ambient concentrations or a quantitative method for determining the concentration of M. tuberculosis nor a workplace standard has been established for M. tuberculosis."

Our concern to you is: How do we take 42 CFR 84, Module 1? We take those objectives that have been outlined as very worthy objectives for all of industry. Are we watering them down too far to meet this need to the health care industry when we simply don't seem to know very much about how to measure those ambient concentrations, what the safe exposure limit is?

Thank you very much.

MODERATOR MATTHEWS: Thank you.

Let me make sure I understand just for those not steeped in respirator-ese in the audience. When you talk about one class, you're talking about one class of test challenge: solid versus solid and liquid. But you're still presuming there would be

like three levels of filter efficiency, 99 percent, 95 percent, 99.5 percent?

MR. LAMBERT: That's right.

MODERATOR MATTHEWS: Okay.

MR. LAMBERT: And under the proposed rule, you would have two certification classes, I'll call them. You have a solid-only certification class, which includes those three efficiency ratings, and you have a liquid and solid certification class, which would include those three efficiency ratings as well.

MODERATOR MATTHEWS: Could I just draw you out one final point? What is your recommendation for what the agency should do with respect to the TB situation? There's obviously concern in the community about doing something different from HEPA.

And you raise your points. And your last slide is sort of: Well, what about TB? So I'd like to throw the question back to you? What about TB?

I mean, we can weigh and further try to get additional data on TB transmission exposure rates, et cetera, but in the meanwhile is it your recommendation we continue with the current situation?

MR. LAMBERT: Well, Gene, I think that the answer to that question as a manufacturer, as the largest manufacturer of respirators, we have been preaching to people the hierarchy of controls in the workplace.

MODERATOR MATTHEWS: Sure.

MR. LAMBERT: We have been preaching to people that to apply the respirator properly, to go through a decision logic, and if you apply that decision logic to what we know about TB, I'm not sure if you would come to the conclusion that you could use a 95 percent efficient filter against a one-micron particle size.

That is the bridge, chasm, that is hard to cross for us. It would appear that if somebody asked you knowing very little about the hazard or knowing as little as it seems that we do about this hazard and having no way to measure that ambient concentration, -- I suppose there's no way to measure that ambient concentration -- that it's a hard jump for me to say using the lowest class particulate respirator for that hazard. It would make more sense to us that the

recommendations for high efficiency make more sense in that situation.

MODERATOR MATTHEWS: And what is your response, then, to the argument that we're faced with -- certainly, Bob gets this on a daily basis -- of even applying the old 1990 TB standards of a "particulate" respirator, which might even be included by some to include a surgical mask or a DM?

There has been no showing of TB transmission where the 1990 standards have been applied. Therefore, why are you driving us towards what your answer, your response to me just was, continue with HEPA? What is your response, then, to those arguments?

You see, you're saying that there is not enough data from your point of view to make that risk management decision of 95 percent one-micron TB standard.

And what we're also hearing, the countervailing argument, there is a limited data to show, there may be no data to show that at a more relaxed standard, you would not have TB transmission.

Do you follow what I'm saying?

MR. LAMBERT: I follow exactly what you're saying. I don't have an answer for that, Gene. I mean, that's obviously the situation that we're in.

That's why when CDC issued those first recommendations that called for PAPRs or pressure demand airline respirators, that everybody said, "Whoa. Wait a minute. Time out."

And that's why we issued the 95 percent and one micron, which I guess those are based on epidemiological studies. I don't know where those come from.

It's a tough question. I have no answer for you.

MODERATOR MATTHEWS: Okay. Well, I appreciate your comment, and I'm sure we've got technical questions down the line.

Rich, do you want to lead off?

MR. METZLER: Yes. I have a couple of general questions, comments, or observations. One observation is that MSA agrees with testing filters in a certification program with most penetrating particle

size range.

MR. LAMBERT: Yes.

MR. METZLER: MSA agrees with worker concerns over the lack of or inadequacy of monitoring and knowledge of workers to know particle size distribution in the workplace, a position that was represented by ICWU representatives yesterday.

MR. LAMBERT: Right.

MR. METZLER: Does MSA agree that workers need the better protection offered in the standards represented in Module 1 or better with the use of just the liquid challenge?

MR. LAMBERT: Yes, yes. Obviously my presentation hit on achieving those three goals and what was needed to meet those three goals.

MR. METZLER: Is MSA aware that a filter technology exists to provide that better protection abroad, in foreign countries, providing that better protection to workers there?

MR. LAMBERT: I don't understand your question, Rich.

MR. METZLER: The question is: Is the

filter technology available to produce filters that meet Class A, B, or C efficiency levels? And are they available already in foreign countries?

MR. LAMBERT: I don't think that I have that knowledge. I don't have that knowledge to answer that question.

MSA, as I indicated, operates in 22 countries. We have respirators that certainly meet the CEN that are CEN-certified respirators. And I think that trying to bridge what's proposed in 42 CFR 84 to what is required by N143, that bridge can't be made.

MR. METZLER: MSA did not make remarks today about the implementation schedule which has some implications for the technology being available. The absence of any comments on the grandfathering periods mentioned, does that mean MSA has no problem with those schedules, grandfathering periods that were proposed?

MR. LAMBERT: No, the absence of our comments does not mean that we support that. On many issues that were represented by the ISEA yesterday,

MSA endorses, supports, and agrees with those positions and, in particular, the one on the grandfathering provision.

MR. METZLER: All right. Does MSA know of any other competitors who are able to produce economically filters that meet the classes that are being proposed, either as they are proposed or with just the liquid challenge?

MR. LAMBERT: I think that's impossible to answer, Rich. I mean, there's certainly no published pricing information from any manufacturer who is saying that they have respirators that meet A, B, and C to the new requirements.

There is one manufacturer that we are aware of that has literature indicating that they meet the one micron, 95 percent efficient filter. It's currently approved under 30 CFR Part 11 as a dust/mist respirator, but they indicate in that literature that that respirator, in fact, would meet that new requirement, that one micron, 95 percent efficient, which I'm assuming, then, to say -- and I'm making a big bridge here. I'm assuming that that would be a

class E, perhaps a solid-only approved respirator. And that is a very inexpensive respirator.

MR. METZLER: The users' guide that was mentioned in the proposal, is MSA's position that users' guides, information published for workers and IHs, et cetera, is inadequate in providing selection type of information?

MR. LAMBERT: MSA believes that the users' guide is absolutely necessary and urgent to be developed and to be available when 42 CFR 84 rolls off. We believe that is vitally important to have a users' guide that lets people translate what they're currently using in the way of dust/mist and dust/fume/mist and high efficiency respirators to the new classifications.

MR. METZLER: The last question is on innovation. Part of what we're trying to achieve with these standards is to promote greater competition and also to permit greater innovations in filter technology, which we think will lead to better protection overall for workers.

Using the liquid/solid as a single class

for each A, B, and C level, could you give us any of your comments on the kind of filter innovation and technology you see coming on the horizon to provide better protection for workers if, in fact, we do end up going towards the single particle challenge, liquid and solid only?

MR. LAMBERT: No, I don't think I will disclose innovations that MSA is working on currently to meet these requirements, whatever they might be, but certainly we are very actively pursuing that.

With every regulation or certification or consensus standard that has ever been adopted and has ever been promulgated, it has required manufacturers to rethink what they're doing and to innovate and to find solutions to those needs. And under the free market system, the guy that does it fastest and cheapest gets the biggest piece of the pie.

And we support exactly what you're doing.

MR. METZLER: One other question I guess I would have, it seems somewhat unfair just to ask MSA, but I'd like ISEA, other member companies to consider: How is it that since '87 these standards

were proposed and, yet, the industry is found somewhat with the economic impacts that it's indicated today without making some sort of innovation or steps towards these standards that have taken several years to come to this point?

MR. LAMBERT: I don't follow that, Rich. Could you restate that?

MR. METZLER: Much of the concern over the economics that has been represented here is in the cost for transitioning to respirators which will have improved performance above dust/mist, dust/fume/mist, but less than HEPAs, which are already available.

So is there an explanation for how the economics are so significant from that point of view when, in fact, we've known since '87 that these requirements have been evolving and coming?

MR. LAMBERT: Yes. I think that to answer that question properly -- and MSA I don't believe is representative of a large group of those respirators making the types of masks that Bernard Mishkin talked to you about yesterday, where Bernard sees a very strong impact, cost impact. So MSA does not see that

same cost impact with the proposals that we are putting forth here.

MODERATOR MATTHEWS: Can I just sharpen one point three questions back? If I understood you correctly, you're saying that the filter efficiency will become the driver and, therefore, will result in misuse because of the solid-only being less expensive.

And Rich's question to you on that point was that we're going to do things more than simply publish regulatory texts in the Code of Federal Regulations here. We're going to be engaging in a number of different educational processes, including a users' guide and a number of ways of actually communicating to the public what this is all about.

Do I take it that your position is that's not going to be good enough?

MR. LAMBERT: I don't think it will be. I think the example that Rich brought up yesterday where yes, you've got a Union Carbide that has the industrial hygiene worker or staff there to regulate, control what respirators are being used, that will work. That message will get out.

But to that small business sector, that message won't get out. And there you'll see the misapplication and misuse of that respirator to those workers. As Don indicated yesterday and Rich emphasized yesterday, those workers we have to protect as well.

MODERATOR MATTHEWS: Okay. Don?

DR. CAMPBELL: Could you comment on the percentage of respirator wearers that would be exposed to aerosols in a workplace that are degrading? You gave some examples, but one of the things that is of interest to us is how many workers who wear respirators actually need that additional level of protection associated with aerosols that degrade the filters.

MR. LAMBERT: I think you've asked two questions there, Don. You said: What percent of the workforce is using respirators that degrade with exposure? That gets into the mix of market share.

DR. CAMPBELL: Let me rephrase that. I'm interested in the percentage of workers who use respirators in situations where an aerosol may degrade

the filter.

MR. LAMBERT: Certainly that number precisely is not known. My example in the paper that was cited indicated that it's not just DOP or a situation where you have an oil mist, but that those compounds and those aerosols that were measured there that were used in that paper are common aerosols.

I don't know how many industries have those specific aerosols and/or aerosols like that, but certainly those were very representative of what you would find in "the real world."

DR. CAMPBELL: The reason I'm pursuing that is that in response to our '87 proposal, there was a very strong and, in fact, convincing argument that there were many workers using respirators, in fact, a great majority of respirator wearers were using them, in situations where the degradation of the aerosol was not a factor and that to require all filters to have that would be a burden in terms of possibly the cost of the respirator or other features of the respirator that were really unnecessary.

So we have sort of a balancing to do here.

And I'm asking for any input or data that you can provide that addresses that question. And it really gets to how prevalent that problem is in the workplace.

In '87 there was a convincing argument presented to NIOSH that it was not that prevalent.

MR. LAMBERT: I'm not aware of any studies that would give you that answer, Don, that would say "This percentage of the workforce doesn't have that potential to happen" and "This percent doers have that potential to happen." I'm unaware of any studies that have been done along that line.

I'm not sure what studies, if any, were cited by whoever made those public comments to you back in '87, but the idea of attempting to have a standard that significantly improves worker protection, that enables the user to easily discern the level of protection he can expect from that respirator, boy, it would seem to me that if we have degrading filters or degrading performance in that filter, that that respirator for the most part is completely unaware of that today.

He doesn't know. He doesn't know that that's happening and doesn't know that it's happening with not just DOP, which is in the lab, but it seems to be happening with many common aerosols found in industry.

MODERATOR MATTHEWS: Not to beat that horse to death, we went forward in '87, if I understand this correctly, with the proposal that the challenge would liquid and solid only. And then we got --

DR. CAMPBELL: With the liquid only.

MODERATOR MATTHEWS: Okay. Liquid, liquid only. Then we got a lot of comments saying "You need a solid only as well. Bifurcate the class, the challenges."

And now you're saying today "Oh, no. You had it right in '87 originally as a proposal of a liquid challenge." So what we're trying to draw out from you, to your knowledge, or could you submit for the record: Is there something that's changed from '87 to today that reflects this sort of going back and forth in a position?

MR. LAMBERT: Well, I don't know that that position -- there's been no vacillating a position from MSA. Others may have expressed that concern to you.

Clearly today manufacturers, users could use dust-only respirators. And they also get approvals for dust/mist respirators. And I would say that the vast, vast majority of respirators out there -- I don't know what that percentage is, but certainly the vast -- have both dust and the mist approvals.

Now, all of a sudden, you're going to tell the guy who has been using a dust/mist respirator, where he has the dust solid particulate and perhaps a mist environment, now you're going to say to him, "You've got two choices: solid only, liquid/solid."

He's been using dust/mist. So he might wane toward this side. But then, all of a sudden, he's going to realize that this is a little bit more expensive than this. And so he's going to now buy the other less expensive respirator, the solid-only particulate respirator.

I would ask the question: What's in use

today? Are they dust respirators or dust/mist respirators?

MODERATOR MATTHEWS: Well, I don't want to get into sort of a cross-fire here, but I would request that ISEA and the other manufacturers who did submit comments to us on this issue in '87, please in your written submissions for the record address the issue that MSA raises here because we'd like to make an informed intelligent decision based upon the best available comments and data.

DR. CAMPBELL: It may also be that Tom Nelson, representing the industrial hygiene community, may have some comments or suggestions to submit to the record that would be relevant to those questions.

I had another, just a technical question, I guess. The two recommendations taken together I'm not quite sure I understand. Specifically I'm wondering that if you were, in fact, to run the test until the filter efficiency stabilized, basically you would be running the test until the electrostatic mechanism had depleted and you had left, then, whatever mechanical, purely mechanical, filtration was

there and that if you were to do that test as the way you suggested, then would the endpoint be the same whether you used the hot or the cold DOP?

MR. LAMBERT: That's a good point, Don. It's exactly the same. So using either thermally generated DOP or cold nebulized DOP if you run the test long enough does get you to the right point.

DR. CAMPBELL: So both of those recommendations are actually inherent in the single recommendation that you've made to run the test until the filter efficiency has stabilized. Is that correct?

MR. LAMBERT: It gets you to the same result. The second recommendation is more related to this, I'll use the term, "arbitrary" stopping point of 200 milligrams or 100 milligrams if the filters are used in a pair configuration.

That point is reached either slower or faster depending on whether you're using thermally generated DOP or cold nebulized DOP. If you run the test until it does level out, until performance levels out, it doesn't matter what you challenged it against.

We saw that with the results of the mechanical filter elements.

DR. CAMPBELL: Okay. I understand.

You mentioned that the solid-only filters would likely be less expensive. Are there other properties that the solid-only filter may have? In particular, I'm concerned about breathing resistance and asking: Is it likely that the solid-only class, as we propose, would have lower breathing resistance?

The reason I'm concerned about breathing resistance is not just in terms of the comfort to the wearer. That's important, but maybe more important is the fact or the relationship between breathing resistance and the total performance of the respirator and that if, for example, you were to reduce the breathing resistance to half, you would be basically reducing to a very good approximation the overall leakage of the respirator by half.

So that the breathing resistance of the respirator is inherently tied to the overall performance of the respirator. And I'm wondering if there is a connection between not only the expense of

the respirator, but the actual overall performance of the respirator.

So even though the filter itself may be better, the overall performance of the respirator would be lower by virtue of the fact that the breathing resistance may be higher. Could you comment on that, please?

MR. LAMBERT: Yes. Obviously those trade-offs have to be made in respirator design. And the solid-only being less expensive, having less filtration media in it potentially is going to have different performance characteristics than a different class, certification class of respirators.

I think the point is well-made. We see that in today's respirators, that depending on what they are certified to, NIOSH-approved to, there's a direct correlation between that aspect per se and inhalation resistance, to give you a example. We see that in today's products.

DR. CAMPBELL: Let me just further explain our thinking behind the proposal as it was made in terms of breathing resistance. The values that were

there were basically there because we thought that they were low enough to eliminate any physiological problems.

We see many respirators that are now produced that have exceptionally low breathing resistance and that we expected that pressures of the marketplace would drive breathing resistance down to lower and lower values. And eliminating the solid-only class may eliminate the low point in breathing resistance for respirators that are available to workers.

So that was the basis of our thinking in terms of breathing resistance. So we're actually hoping and expecting that breathing resistance of respirators that were actually produced on the market would be pushing the state of the art in terms of lower and lower breathing resistance, --

MR. LAMBERT: Right.

DR. CAMPBELL: -- and especially because that's a property of the respirator that is readily apparent to the user.

So what I'm getting at is: If you

eliminate the class of solid-only respirators, would you be eliminating the possibility of very low breathing resistances that would be available or somehow reducing that benefit to workers?

MR. LAMBERT: I don't think I know the answer to that question right now, Don. There are a lot of issues that go into comfort. Wearers choose respirators based on comfort, not specifically inhalation resistance.

Inhalation resistance is a component of comfort, of that feeling that this respirator fits well, feels good, is easy to breathe through, is lightweight. There's a multitude of components that go into that word "comfort."

And so to answer your question directly, I can't answer that directly. I don't know if we would see that.

DR. CAMPBELL: I'm just trying to emphasize that we're concerned with more than just the comfort, but the breathing resistance, the effect it has on the overall performance of the respirator. That's a key consideration that we'll have to

evaluate.

MR. LAMBERT: Okay.

MODERATOR MATTHEWS: Ernie, do you have --

DR. MOYER: Yes, I have a few remarks. First of all, NIOSH recognizes the fact that NIOSH is not intending to test these filters with the worst case penetrating size for each and every filter that is available.

If NIOSH decided to do that, we would, in fact, run a study of efficiency versus particle size for every filter that came in, find what the worst case particle size is for that particular filter, which could vary from manufacturer to manufacturer. That depends on what the properties of the exact filter are.

We would select that worst case size. Then we would do all of our testing at that worst case size with a mono-dispersed aerosol of that particular size and mode.

That is not NIOSH's intention. Because of the fact from cost limitations and personnel-type criteria, we would be unable to run a certification

program doing that. So, instead of that, we tried to select aerosol criteria that were in the worst case penetrating size range. And that was the reason for doing that.

We also --

MR. LAMBERT: Ernie, if I could address that point?

DR. MOYER: Sure.

MR. LAMBERT: We agree with what you're saying. We understand that. We understand that aspect. But, as you remarked yesterday, the intent was that you had these two apparatuses that could produce that worst penetrating particle size range.

DR. MOYER: Okay. I'll get into that. I'll get into that.

The second intent that NIOSH has is not to base this criteria on any particular instrumentation that is presently available. We tried to set up our criteria in such a fashion that it is not design-oriented but is based on performance-oriented. That was our reason for selecting this type of criteria.

The question I would have, then, regarding the instrumentation is: From a theoretical point of view, do you have any reason to suspect that a particle of the same size and the same size distribution and of exactly the same chemical composition would have different penetrating properties?

MR. LAMBERT: I have only the empirical data that shows it does, Ernie.

DR. MOYER: What I'm asking you, then, is: Could you provide to me exact data on the chemical composition of the DOP at the time that the tests were run?

MR. LAMBERT: Our testing protocol that the ISEA used specifically stated that no DOP was used at that test setup. Ernie, I don't understand what's going on there. I don't think you do. I don't think anybody does.

But what is clearly happening and what happened at five test sites, five test sites, -- and if you look at the average of each of those test sites -- cold nebulized DOP gave a higher efficiency rating

to that same filter media out of that same manufacturer's lot code than did thermal.

DR. MOYER: But you can't provide me the chemical data on the purity of the DOP that was used. Is that correct?

MR. LAMBERT: Yesterday the ISEA asked you to do more testing, that we don't know enough about this, that prior to 42 CFR 84 being published as a final rule, that we partner together and try and get our arms around this.

What I'm pointing out is that as written, you can have two different sets of results, depending on what you use.

DR. MOYER: Okay. Well, going on, it's my understanding that in the present scheme of things, if a filter passes by the present NIOSH criteria -- and this addresses the point of dust and mist filters. Most filters are, in fact, certified for dust and mist, rather than dust only.

It's my understanding that in the certification process if a filter is submitted for dust testing and it passes the dust test, it's almost

a given that it will pass the mist test. So it would be crazy for a manufacturer not to submit dust and mist because the mist test is less critical than the dust test.

So, in actuality, workers are not being protected against mist because the test is not critical enough to distinguish between dust and mist. And I think most manufacturers recognize that point.

Also the test criteria for the different levels that NIOSH has proposed being at 95, 99, and 99.97 percent, NIOSH does feel that that would enhance the protection that workers are being afforded because NIOSH is quite aware that there are a lot of dust and mist and dust, fume, and mist respirators which are presently on the market that would not meet the 95 percent criteria. So, in fact, NIOSH by that move is, in fact, trying to enhance the protection to workers, which is a point that you kind of brought up in your thing.

We also have heard this morning -- and one of the questions that was asked was whether there was a need for a solid-only type of aerosol. And there

are people who have performed workplace studies and who are familiar with the workplace who have come forward and said they thought in their estimation that a solid-only type of filter was, in fact, needed.

I understand that the liquid aerosol test is, in fact, more critical than the solid aerosol test. I think we all recognize that fact. And it's from a degradation point of view. And that goes into consideration with the loading. So we understand that, and we would not debate that issue at all because that's a given.

The point, really, that you seem to be making in this is to go back to the '87 kind of criteria, which are in your estimation more stringent than the present criteria that were put forth in the new proposal. Is that correct?

MR. LAMBERT: With regard to which aspect?

DR. MOYER: With regard to using both solid and liquid for testing every type of filter media; right? And also in regard to the loading test which you say should be run out until the loading no longer is at a point where the filter is degrading.

Is that correct?

MR. LAMBERT: That's correct.

DR. MOYER: Okay. So, basically, what MSA is proposing kind of is to limit the type of filters that can be used on respirators to mechanical-type filters. Is that correct?

MR. LAMBERT: No, I don't think that's correct. I think that the marketplace will find a way through innovation to develop filters that meet those criteria. It will happen.

You know, what we're strictly looking at to this point in time and to the test that we've done to date at only electrostatic filter media or only mechanical filter media.

Has anyone presented any data or run any test that shows the performance of hybrid media? I don't think so. I think that we're getting bogged down on this issue of eliminating a class of filter media or potential filter media.

I'm not saying that at all. The focus needs to be on the worker and protecting the worker and making sure that he knows what he can expect out

of that filter. And if that filter degrades with time, doesn't it make sense for a certification test to run that test until the degradation has stopped? That's what we're asking.

DR. MOYER: The issue of degradation I can address the fact that NIOSH has taken that into consideration in this test scheme by, first of all, requiring that all filters be preconditioned before they are tested at very stringent criteria.

Second of all, the loading criteria from '87 to '94 was increased by a factor of two.

And, third of all, the aerosol that is being used to test these filters is neutralized to also try to eliminate any charge effects of the filter medium.

So NIOSH has, in fact, in this criteria addressed a lot of the aspects of charging of filters.

MR. LAMBERT: I think there are a couple of points, Ernie, if I might. Number one, the issue of raising the loading limit by a factor of two 1987 versus 1994 misses one very important point. And that is that in 1987 it was discontinued if that filter was

degrading.

So now while we have arbitrarily chosen 100 milligrams versus 50 milligrams on a pair configuration, now we're saying that "Well, that's okay. That's enough." And I think we need to seriously consider whether that is.

If you take a look at some data that MSA has run in conjunction with an outside lab, this is showing the cold DOP, the cold nebulized/hot DOP. This is on electrostatic media.

You can obviously see from this graph that the cold DOP data is continuing to degrade. That percent penetration is continuing to rise, even when you get to that 23 and a half-minute point where that loading limit is reached.

Well, who says or where does it say that 23 and a half minutes are the right number or that 200 or that 100 or that 50, whatever the milligram load limit is, who says that that's the number?

Doesn't it make sense to keep this graph going out until -- just as shown here, those two are going to come together, as Don indicated earlier.

They will come together. Doesn't that make more sense?

The second point you mentioned with regard to neutralization, I think it's a well-known fact that neutralizing DOP doesn't have any effect on the performance of the test. So when you take DOP and you neutralize it or you keep it in the non-neutralized, reaching that equilibrium really doesn't have an effect on the test result.

DR. MOYER: The neutralization does have an effect in the salt case, though.

MR. LAMBERT: Yes, it does.

MR. METZLER: Bill, I'd like to make one last general point, and that's an observation that we make in the certification program with regard to certification standards in innovation.

We more often find the manufacturing community producing products to meet the standard and, in fact, to reduce performance that is possible down to the standards because of competitive market conditions.

So we see a need for certification

standards to drive technology, rather than limit it, as we often see and have seen with a silica dust test.

MODERATOR MATTHEWS: Okay. Thank you very much. Again, we would appreciate any data that could be submitted with respect to the discussion that has just taken place. It's been about an hour, but it's been very helpful.

MR. LAMBERT: Okay. Thank you.

MODERATOR MATTHEWS: Okay. Could I just ask with respect to Jay Parker in Glendale and Air Techniques, Jeffrey Kiley, are your presentations on the magnitude of MSA? I'm thinking about a break or just going on and finishing up.

I get a "No" here. The rest. Okay. If there's no objection, maybe let's just push ahead and then wrap up. Is that okay with everybody? Okay. Let's go ahead, then.

Jay Parker, Glendale Protective Tech.

MR. PARKER: Good morning. My name is Jay Parker, and I am the Respiratory Protection Product Manager for Glendale Protective Technologies.

Glendale is a manufacturer of

NIOSH/MSHA-approved respiratory protective devices. As Product Manager for Glendale, I have responsibility for all aspects of our product line, including technical issues and testing and certification of respirators.

Glendale is a member of the Industrial Safety Equipment Association and we are in general agreement with the comments provided by ISEA at yesterday's hearing. I will, therefore, restrict my comments to those areas which we feel need further amplification and clarification.

Regarding the proposed types or classes of filters, Glendale's position is that the type should be changed to 99.97 percent, 95 percent, and 90 percent.

In the draft unofficial second notice of proposed rulemaking on 42 CFR 84, NIOSH did propose levels of 99.97 percent, 99 percent, and 90 percent. I believe that it is in the best interests of the respirator users to include a 90 percent level, which would be adequate for many of the low to moderate toxicity particulates and would allow such respirators

to be relatively economical in cost.

The middle level should be set at 95 percent in my opinion. There will not be much difference in cost or actual performance between the 99.97 percent class and the 99 percent class.

The face seal leakage factor will negate most of the improvement in efficiency between these two classes, especially with half masks. The European CEN standard for filtering facepieces allow one percent penetration of paraffin oil for the P3 or higher efficiency class for this very reason.

A 95 percent class would be more economical in cost than the 99 percent class and would provide a true intermediate level of efficiency after allowance for face seal leakage.

The proposed grandfathering period of two years is too short in my opinion. The manufacturers will need sufficient time to develop new filter media and adapt it to respirator filters to meet the new requirements.

Many, if not most, of the respirator manufacturers use media manufactured by separate

companies, whose priorities are not necessarily the same as ours.

NIOSH itself will need time to test and certify all of the new respirators that will be submitted. Although the new tests are faster than the existing tests, there will be an avalanche, obviously, of new approval applications. And the sample size for testing will go from 3 to 30.

There will also be quality assurance documentation that will have to be approved. The last time there was a change in the regulations with the publication of 30 CFR Part 11, most of the existing Bureau of Mines approvals were grandfathered for five years, some longer. And the result was a generally orderly switch-over.

In my opinion, two years is not enough time to develop, test, and certify the new particulate respirators. A precedent of five years was set by 30 CFR 11 when first published. I believe a minimum of four years would ensure an orderly transition to the new approvals.

In addition, I am in agreement with ISEA's

position on two years grandfathering for extensions of approvals for currently approved particulate respirators for changes involving filter media and four years grandfathering for changes involving areas other than filter media.

These changes are sometimes forced on us by circumstances not under our control, such as companies that no longer make certain media that we are using.

The manufacturers need to have the ability to make modifications to their existing respirators, even if they are not ready to submit to the new particulate standards. Otherwise, there may very well be a gap of availability to the users due to this scenario.

Another issue is whether the grandfathering clause affects sale or sale and distribution. The proposed rule refers to sale and distribution of respirators.

Most U.S. manufacturers sell their products through distributors. In the U.S. there are thousands of small, medium, and large distributors

that distribute safety equipment. And the manufacturers cannot control the sale of product from these distributors.

The grandfathering period should cover sale and shipment from the manufacturers only. When NIOSH banned the sale of chromium-containing sorbents in chemical cartridges several years ago, the question of distributor sales did come up and NIOSH specified that distributor sales were not covered by the ban.

Distributors should be allowed to continue selling particulate respirators approved under 30 CFR 11 after the grandfathering period expires. To not allow the distribution of product after the grandfathering period ends would cause utter chaos in the safety market.

Regarding respirator breathing resistance requirements, Glendale is in agreement with ISEA that the initial inhalation and exhalation resistance requirements should be increased slightly to allow the manufacturers more room to use higher efficiency media.

Efficiency and resistance are related, and

higher efficiency usually means higher resistance. Raising the proposed limits to 35 millimeters inhalation and 25 millimeters exhalation would allow more efficient media to be used and should not present any significant physiological burden.

Currently 30 CFR 11 allows initial resistance, inhalation resistance, as high as 70 millimeters for gas masks. And exhalation resistance of 25 millimeters for single-use respirators without valves for vinyl chloride and pneumoconiosis and fibrosis-producing dusts, and 25 millimeters exhalation resistance is allowed for supplied air respirators.

Concerning the issue of test statistics, Glendale is in agreement with the ISEA position that the one-sided tolerance limit should be based on 95 percent confidence of 90 percent conformance, as was used in the 1987 proposal, rather than the current proposal, which uses 95 percent confidence of 95 percent conformance.

The purpose of this statistical test is for the manufacturers and NIOSH to have more

confidence in the results obtained when testing respirators for certification.

Under the current system, three samples are tested. And if they pass, approval is granted. The three results could all be borderline, but approval is still granted. It is, therefore, understandable for NIOSH to require statistical treatment of the data.

The proposed criteria of 95 percent probability of 95 percent conformance is unnecessarily strict in my opinion and will result in additional costs that will be transferred to the end user, with little benefit.

Glendale would like to see 95 percent confidence of 90 percent conformance because we believe this is sufficiently stringent for the purpose of these tests.

In regard to NIOSH's modular approach to the rulemaking, Glendale understands the benefits to be achieved by such a process. However, there are potential difficulties, such as combination respirators for gases and particulates, which have to

be modified to achieve the new particulate regulations and may have to be modified again to meet the new requirements of a future module on chemical cartridges.

The facepiece fit testing or simulated workplace protection factor testing module may also require further modifications to approved respirators.

Therefore, the modular approach will result in numerous modifications of respirators, which will cause confusion, delays, and expense for the manufacturers and the government.

The respirator users may be totally confused by the endless parade of new approvals to new requirements. However, the benefits of being able to change certain parts of the regulations with speed are not to be overlooked.

I would recommend that the modules be carefully prioritized to achieve the least disruption and to address the areas of greatest concern first.

Another issue is the isoamyl acetate fit tests for all particulate respirators. Glendale is concerned with the feasibility of testing filtering

facepiece-type respirators since the addition of an activated carbon cartridge or a thick layer of non-woven carbon-impregnated media to allow the test to be performed can have a significant effect on the fit of this type of respirator.

It may be meaningless to run a fit test on a respirator that is modified in such a way as to profoundly change the weight and fit characteristics of the respirator, which is what could easily occur with a typical lightweight disposable respirator.

It should be mentioned that the cost of test equipment needed to run the new tests will be over $100,000, not $60,000, as stated in the supplementary information.

The test equipment for running the sodium chloride and DOP tests is about $45,000 per unit, and the scanning mobility particle sizer required in the proposal is about $60,000. More than one test unit may be required for production testing.

I would also question the increased material cost for filters projected by NIOSH as only pennies per filter. I would argue that these pennies

are going to add up pretty fast. I have seen some pretty expensive media out there when one gets up into the higher efficiency levels.

NIOSH also refers to the cost of replacement non-HEPA filters as about one to two dollars each and disposable non-HEPA filters at about one to eight dollars each. I think the new types of filters, especially for a 99 percent efficiency level, may be considerably more expensive than existing non-HEPA filters.

NIOSH states that some currently certified respirators have demonstrated acceptable performance when using the new standards. Is this data available?

A NIOSH study by Stevens and Moyer published in the "American Industrial Hygiene Journal" in May 1989 showed that dust/mist-type, paint spray-type and dust, fume, and mist-type filters from four different manufacturers had initial penetrations of sodium chloride and DOP above five percent using what I believe is pretty close to the proposed test conditions.

NIOSH must also consider the research and

development costs of these new respirators and increased manufacturing costs to make them.

Another huge concern is the selection of respirators with these new classes replacing the existing dusts, mists, fumes, radionuclides, radon daughters, asbestos, paint spray, and pesticide classifications.

Who is going to decide which class to use? Does NIOSH intend on publishing a guide listing all common air contaminants and what class to use? Will OSHA do this? How about existing OSHA and other federal standards that require certain types of current particulate respirators, such as the OSHA cotton, asbestos, and lead standards?

A system must be put in place to address this issue of user guidance in the selection and use of these new classes of filters. This point is of the utmost importance because without the user guidance, the new classes will not serve the purpose for which they are intended, mainly to provide respirator wearers with improved respiratory protection and cost avoidance.

One key area will be the selection guidance for determining whether a solid-only or a liquid and solid approval is needed. The liquid approval will be significantly more difficult to obtain and will require more expensive media because of the prevalence of electrostatic media in particulate respirators. And, as we have heard, electrostatic media is degraded by DOP. And the penetrations are, therefore, higher when tested versus DOP.

On the subject of assigned protection factors, NIOSH is intending to publish a respirator users' notice at the time of publication of the final rule to provide respirator users with new assigned protection factors for the new classes of particulate respirators.

This notice will not go through the public rulemaking process. I understand that assigned protection factors are the next scheduled module, and this notice will apply only in the interim period between passage of the final rule affecting particulate respirators and the final rule on assigned

protection factors. I still think the public should be able to have input in this important area.

This can also serve as a quick start on this module for assigned protection factors and provide a base for this section. This would make final rulemaking easier on assigned protection factors.

In summary, Glendale Protective Technologies as a respirator manufacturer is concerned with this proposal, which needs to be modified as I've explained in order to provide the end users with an improved product at a small increase in cost.

Let's not rush into a new regulation that will cause undue hardship and economic impact to the respirator manufacturers and to respirator users and still not provide end users with affordable improved particulate respirators.

I would like to thank NIOSH for offering me the opportunity to speak here today. Thank you.

MODERATOR MATTHEWS: Thank you very much.

I think we've gone through a good deal of discussion on these issues in the last day and a half.

Does the panel have any other comments or questions on that?

DR. CAMPBELL: Just one comment to clarify the intent of the proposal in terms of the mention of the users' notice. The intention of that was simply to provide the transition information for users between one standard to another.

A number of commenters in the last couple of days have indicated the importance of that, and we agree with that. And that was the intent of that.

The APF values that would be included in that guidance would not only be intended just for the interim period between a new APF module, but our intention was only to address the changes in nomenclature and notation that are associated with this new standard to provide that guidance.

MR. PARKER: Yes. Okay. I understand. Thank you.

MODERATOR MATTHEWS: Okay. Thank you very much.

Next is Trish McBreen, Healthcare Association of New York State.

MS. McBREEN: Good morning. My name is Trish McBreen, and I am a registered nurse deeply involved in occupational health and safety issues at the Healthcare Association of New York State.

Perhaps better known as its acronym, HANYS serves as the principal advocate for more than 400 not-for-profit public, voluntary, and federal hospitals, nursing facilities, home health agencies, hospices, and adult day care programs.

As a representative of HANYS, I am pleased to be able to take the opportunity to make comments to NIOSH today in regard to their proposed rulemaking on respiratory protective devices.

For the past seven years, HANYS has been actively and aggressively involved in providing information and education focused on health care occupational health and safety issues not only for the well over 375,000 health care workers in its member facilities, but for all workers involved in patient care activities in New York State.

HANYS shares the concerns of all of those who have spoken here the last two days for improving

the health and safety of working conditions, and especially for those who are providing care to sick people.

We have, of course, a special concern for health care workers in New York State who are faced with transmission risks while caring for exceedingly high numbers of people with infectious TB.

HANYS supports NIOSH's proposed standards of certification for respiratory protective devices, and we are encouraged that NIOSH intends to replace their 1992 recommendations for health care worker protection against TB with guidelines for the use of particulate respirators that meet CDC's recommended four performance criteria for protection against transmission risks.

NIOSH's certification standards is an important first step toward determining the appropriate level of protection needed for occupational exposure to airborne pathogens.

Just as Mr. Lambert suggested, HANYS proposes that NIOSH continue its research activities directed toward a true understanding of the

transmission of TB.

Once the assessment of risk can be qualified and quantified, since should then be able to define the types or levels of personal respiratory protection necessary to provide increased protection for health care workers in both the presence and the absence of higher levels of protection; that is, administrative, engineering, and work practice controls.

Absent this scientific information, health care employers have been forced to move beyond the surgical mask protection level into a whole jumble of respiratory protective devices, none of which have a grounding in science for protection from TB. And HANYS does have a few questions it wishes to raise after reading this very technical document that we know we don't fully understand.

First, why is NIOSH proposing that filters must demonstrate the ability to remove particles of less than one micrometer in size, thus exceeding the CDC recommendations?

By establishing that capacity as the

baseline parameter, NIOSH essentially guarantees that regulatory agencies will establish this smaller micron size as the minimum requirement particulate respirators must meet in order to qualify as an appropriate PR for health care workers at risk for exposure to infectious TB.

The current HEPA requirement is problematic because it mandates a performance level for respirators that is excessive probably for this purpose.

NIOSH may now be proposing to develop multiple levels of performance standards, but may be requiring construction material that is unnecessarily and excessively impenetrable. The outcome may be no improvement in user comfort and compliance, patient safety, quality of care, and cost.

Second, HANYS is concerned about the definition of a hazardous atmosphere as described on Page 26862 of the "Federal Register." This is a very broad definition. And we urge NIOSH to reevaluate this definition in light of infection control perspectives on disease transmission.

Not all pathogens produce disease through the airborne route. Exposure to pathogens does not necessarily result in disease. Factors such as host, virulence, and the environment itself all play a role in disease transmission.

As currently written, this definition could be interpreted to mean that merely walking into a hospital automatically means walking into a hazardous atmosphere requiring some type of respiratory protection.

And, lastly, HANYS asks how the certification information will be used once the performance requirements have been established and implemented. How will this information be disseminated? And how will it be interpreted and eventually enforced?

We want employers to be able to comply with recommendations or regulations related to providing a safe and healthy working place. And we want both employers and health care workers to be able to make informed decisions about the appropriate level of respiratory protection based not only on these

performance criteria, but also on the level of risk determined to be present in each and every situation where care is provided to persons with infectious or suspicion of infectious TB.

In summary, then, HANYS supports NIOSH's determination to evaluate the efficacy of respiratory devices, and especially those to be used by health care workers, for protection against the risk of TB transmission in health care situations.

We urge NIOSH to continue its research to determine how TB is transmitted and the efficacy of all controls in reducing such risk for New York State and the nation's very vital resource, the health care worker.

Thank you for allowing me this opportunity.

MODERATOR MATTHEWS: If you would like, I think I can quickly, at least, start the response on your three questions. Number one, with respect to the one-micron size, why we're going below, that I think generically arises out of other data about exposure to other aerosols and other particles in the

"normal" workplace environment, the nonmedical workplace environment.

And as you learned, this arises, these regs arise, out of a mining statute and have been used in general occupational settings. That's one piece.

The other piece of it, we are not intending to get into a "TB respirator" certification of one micron, 95 percent because that gets you into and the manufacturers into Food and Drug Administration concerns of medical device, pre-market approval, and a whole cast of issues that could further complicate this process. So we're not going that direction.

Number two, with respect to your definition, we will carefully look at your comments that have been made there on that. With respect to number three, how will the certification information be distributed out to users, we will do this every way we can, basically. And, as you have heard, we are committed to a fairly inclusive process of working with all of the various parties on that.

Rich, have you got a point?

MR. METZLER: Yes. I would only add one point. MSA brought it up in its presentation. And that is some of the unknowns with the transmission concerns in the health care facilities against multi-drug-resistant TB.

It has been brought out that the hierarchy of controls, administrative and engineering controls, there is no real-time measurement of those. The effectiveness of those controls, breakdown of those controls usually is known only after some studies have been done on exposures to health care workers. And, therefore, it is a reactive approach, rather than a proactive approach, to protecting workers.

Some of the concerns over the respirator selection in that particular application would be knowledge of the particular particle size of the infectious aerosol, concern over the ability to actually make a measurement of the workplace concentration to which the health care workers would be exposed. None of those things can be done in real time to know the exposures of health care workers.

A Class C respirator, as proposed in Part

84 here, will provide a margin of safety over that which has been discussed in respirators meeting 95 percent of one micron.

MS. McBREEN: Okay. Thank you.

MODERATOR MATTHEWS: Okay. Thank you very much.

The last scheduled is Jeffrey Kiley, Air Techniques.

MR. KILEY: My name is Jeff Kiley, and I represent Air Techniques. I'm the New Product Sales and Marketing Engineer. ATI is a manufacturer of the Q-127, the thermally generated, mono-dispersed DOP aerosol machine used to test the HEPA filters and other types of filters.

A little bit about my background. I joined the company one week ago. And I'm here now to comment about how these proposals are going to affect our company.

My background is working with chemical surety material. I came from that field into ATI. That background gave me a unique perspective on filters. In some cases the filter might be my only

protection from a lethal dose of nerve agent.

So myself and ATI are committed to providing the best test equipment we can to ensure the worker safety. I share that commitment, and ATI is also committed to that.

Drawing on this meeting so far, we're very concerned about the ISEA result showing difference between the ATI Q-127 and the other instrument manufacturer's aerosol machine. ATI wants to work with NIOSH and the other manufacturers to resolve this issue.

We feel that there should be no bias among test machines, that one test machine should give the same results as other test machines on the same filter media.

We also realize that with the sodium chloride, we do not currently manufacture a sodium chloride tester. There's only, I think, one company that does. And if we do get into that field, we will also be looking to see whether our machine is biased against someone else's.

One thing that I don't know is a

possibility would be whether NIOSH would want to certify the test machines that certify the filters. That's something that we might want to look at.

Specifically, what I came here to talk about was the CFR 84 Part 11, Section 84.184, Paragraph H, where the validation of the particle size distribution is talked about.

The CFR specifies the technology of a differential mobility particle sizer and gives no latitude for any other type of technology. We feel that there are other technologies out there that are equivalent to the differential mobility particle sizer. And this is essentially locking in the user to one machine. And we feel that that needs to be looked at.

We are also concerned that the forward light scattering and equivalent, what is equivalent to forward light scattering for a detection method? For instance, is a flame photometric detector for sodium chloride determined to be equivalent? And how would the maker of the test equipment go about proving that equivalency? That isn't addressed in this

article.

So what we currently have on our Q-127 is a tindle awl. Now the tindle awl measures the particle size of the output of the generator, but it doesn't give a count median diameter. It just says that the instrument is performing correctly.

Does there need to be a particle sizer at the manufacturer's site doing the filter testing or can the filter equipment test manufacturer certify his equipment to meet the particle size distribution?

Those are things that need to be addressed also because we feel if you make a company buy a particle-size unit, they're going to have to buy the particle-size unit, train people to use it, and that's going to be a big cost for the filter manufacturer; whereas, if the test equipment manufacturer is ATI, it can certify the equipment to meet the spec and give them a quality control assurance with the unit that it meets the specification, it will continue to meet the specification, that that will lessen the impact of that on industry.

That's all I have to say.

MODERATOR MATTHEWS: Thank you.

Any comments?

DR. MOYER: One comment. In regard to the use of DMPs for measuring particle size, I don't think that was NIOSH's intent to limit it to one particular type of technology and would probably go ahead and say, like we have in the past, "or equivalent," which would address that point. It was not our intent to limit it to one technology.

MR. KILEY: The problem I have is determining how does one determine what is equivalent and what is not. You know, going back and forth between the manufacturer and NIOSH, is NIOSH going to have the say on that or is the manufacturer going to have the say on that as to what is equivalent and what isn't? And that's not really spelled out.

DR. MOYER: Okay. I would think NIOSH in conjunction with the individual would have a say in what is equivalent or what would be projected as being equivalent.

MR. KILEY: And that's where I'm saying NIOSH may be certifying the test machine that it uses

to certify the filters.

MODERATOR MATTHEWS: Okay. Well, we probably aren't going to jump into a test equipment program at noon on Friday. We hear your comment.

MR. KILEY: Okay.

MODERATOR MATTHEWS: All right. Anything else?

(No response.)

MODERATOR MATTHEWS: All right. There were two walk-ons that asked for air time. We have been at this an hour and 45 minutes now. I would ask you to be concise.

The two are Joe Rummler of Tecnol, Inc. and then Wendell Anderson, former DOD, Joe first.

MR. RUMMLER: My name is Joe Rummler. I'm with Tecnol, Incorporated. We are a medical device manufacturer. Tecnol supports the strides forward that NIOSH's proposed ruling presents to the health care industry.

We support the six classifications that include solid and liquid solid classifications. We also express support of the comments presented by

APIC, the Greater New York Hospital Association, the Society for Healthcare Epidemiology of America, and the Healthcare Association of New York.

However, we feel that there are several criteria in the proposed rule which may unnecessarily impede the development and proper use of respirators in the prevention of tuberculosis transmission. These criteria are fit testing, particle size and the nature of the particle use, fluorite, and breathability.

Section 84.181 describes a fit test method for non-powered particulate respirators which we feel is not applicable to disposable respirators. These respirators have no inhalation ports which would allow the attachment of a charcoal filter.

In order to eliminate transmission of an isoamyl acetate through the filter media, the entire surface of the mask would have to be altered in such a manner that any testing for leaks would then be conducted under unrealistic fit conditions. We request consideration of an alternate method: the qualitative saccharine fit test or the same test using Bitrex.

Particle sizes below one micron are not challenges we feel representative of tuberculosis bacteria. Yesterday the problems mentioned with aerosol generation, variability of performance with DOP and sodium chloride suggest that alternative methods, such as those using latex spears of known size, might be more easily performed and controlled. We also request clarification of what constitutes an acceptable alternative to DOP.

We feel that a fluorite of 85 liters per minute does not represent respiratory rates normally achieved in a health care setting. And we suggest consideration of a more realistic end use specific fluorite.

The high differential pressure limits in the proposal designed to allow for the higher filtration filters do not take into account the construction of disposable respirators, which have additional layers in their final configuration, which would add to the differential pressure and decrease the actual breathability relative to the breathability of masks using filters isolated in valves, rather than

incorporated into the entire surface area of the mask.

With the exception of HEPA filters, the result of these standards will be a disposable respirator which is significantly less comfortable than devices previously used in the health care industry without documented increase in protection against tuberculosis.

As with the HEPA, our concern on this point is that some health care workers faced with the possibility of exposure, rather than a certainty, may intentionally fit the mask in properly during routine use, allowing unfiltered air to pass under the chin or around the sides of the mask, or they may rush through procedures which require the use of respirators, causing unsafe conditions.

To summarize, we would like to request consideration of standards for respirators more suitable for use in the health care industry so that needs of the industry can be efficiently met without compromising the standards required in other industries.

Specifically, the standard would include

a lower flow rate, such as 50 liters per minute, a particle size of one micron, and a fit test applicable to disposable respirators, such as the saccharine qualitative fit test.

We feel that this would allow the development of highly effective and affordable devices to protect health care workers from tuberculosis and other airborne bacterial hazards.

MODERATOR MATTHEWS: Okay. Again, the same comments I made with the previous speaker about your last point on a sort of a health care respirator. We are trying to be very thoughtful about how we go about that so the manufacturers don't end up in a pre-market approval for a medical device.

And that is triggered, really, as much on what are the representations made by the manufacturer.

MR. RUMMLER: The reason we're concerned about it is that, in effect, it is going to be used as an approval procedure for the health care workers. And what they're looking for is the respirator since the recommendations by the CDC indicate that.

MODERATOR MATTHEWS: Yes. Okay. I

understand the point.

Any other comments, responses?

(No response.)

MODERATOR MATTHEWS: Thank you very much.

MR. RUMMLER: Thank you.

MODERATOR MATTHEWS: Wendell Anderson?

MR. ANDERSON: My name is Wendell Anderson. I'm retired from the DOD organization. During my service, active service, in that area, I was responsible or involved with the development of the original specifications, most of the development of the filter materials, and most of the test equipment that has been utilized over the intervening 50 years. I don't look that old, but I really am.

(Laughter.)

MR. ANDERSON: What I'd like to call to your attention is that the original military specs have existed for many years. And over the years, DOE has joined forces with the military. And the military has seen fit to incorporate all of their requirements into their given specifications, which are still military-oriented and military-issued.

Just recently IES took the same approach that DOE did, and they came to the group and asked for consideration of the clean room aspects.

MODERATOR MATTHEWS: Excuse me. IES?

MR. ANDERSON: IES. It's Institute of Environmental Sciences.

MODERATOR MATTHEWS: Thank you.

MR. ANDERSON: I have taken over the leadership in the clean rooms. Now, in the clean rooms, they are not specifically interested in the medical aspects of it as they are in the product purity because they have found that small particles will affect their production ratios by deposition on their printed circuits that are used for electronic wizardry.

The pharmaceutical industry has also come and joined up with the group. And they have accepted the tests, the military standards, for both the acceptance of their filters to be used in their production facilities and their clean benches or their benches, the pharmaceutical benches, that they use.

ASTM has again come out with a revision

of theirs, and it is pretty much in line with --

MODERATOR MATTHEWS: I'm sorry. ASTM for the unwashed here?

MR. ANDERSON: I think it's American Association of --

AUDIENCE PARTICIPANT: American Society for Testing Materials.

MODERATOR MATTHEWS: Thank you.

MR. ANDERSON: And at the same time ASHRAE now has included a special area where they now address it.

Now, what I'd like to do is concentrate specifically on the higher efficiency areas and not with respect to the medical aspects of it. This is because the DOD has primarily decided and found by experience that the filter materials that are based on the electrostatic effect will not exist in the military environment.

Because of the long lead time between production and actual use by the troops, because of the storage conditions in warehouses and under areas, because of the use against toxic gasses, which can be

aerosol in form and are highly toxic, and because of the fact that radioactivity will very quickly discharge, and including humidity, they do not permit plastic fibers to be used in their applications for a gas mask. So I would prefer just to keep my comments in the area of the high efficiency area.

In summary, what has happened over the years, all of these groups have accepted two separate tests for the determination of the efficiency of filter materials. The penetrations affect particle size. All of the physical parameters of the filters are clearly defined in the military specs.

One is a nearly mono-dispersed aerosol generated by the hot method or the condensation method, as we refer to it. And we use either photometers for gross or single particle counters for individual use in this area.

Now, the photometer can be used very adequately in the QA/QC area for specific measurement of penetration. The single particle size counter can be used if you are interested in efficiency pertaining to particle size.

The other area is one that has been referred to here as the cold smoke or the air-operated generator. We refer to it as a poly-dispersed mode because it has a broad spectrum of sizes.

It has an average light scattering diameter of about .75 microns in diameter. It has a count median diameter of closer to .5 micron, perhaps maybe even a little lower.

By the way, the thermally generated smoke or the condensation smoke has a light scattering diameter of about .3 micron in diameter. If you go over to the count median diameter, it is closer to .22 or .23 in diameter.

These have been adopted for the area of testing all the way from the media clear through the unit manufacturer, then into installation in systems and actually in-place testing and evaluation of the efficacies of these systems. We have tested systems as low as a few liters a minute up to 100,000 CFM, primarily with the poly-dispersed mode.

It is interesting to note that a lot of the things that we refer to today have taken on a

different context. For instance, the loading characteristics for DOP and sodium chloride are entirely different.

The sodium chloride will deposit on the fiber as a single crystal and preferentially, then, but not always, the next deposition will be on the crystal itself and not on the fiber. It results in a dendritic structure that goes out through the open areas of the filter. And that is one of the reasons why it is so effective.

The liquid aerosol now will collect as individual particles on the outside of the fibers. And when a sufficient number have accumulated, it will wet the fiber. And it will form a coating on the outside of the fiber.

Now, what this does, it insulates the electrical effect from the electric-type material and prevents it having contact with the aerosol itself. It also provides a leakage path for the electrical content and electrostatic effect of the PAPR. And that's why we do not use it in the military applications.

We also do not use the plastic materials for other reasons. One is we have found that we would like to have a heat barrier or a reference barrier for fire-fighting and for isolation of compartments which are not necessarily directly related with the fires aboard ship but which will have the use of the ventilation systems that will distribute smoke into the area.

And we have found that the standard gas mask canister will provide that effect for them, and even going through three and four changes of canisters because the canister in the military is adapted so that it can be changed with one breath of air. You hold your breath, and you can change the canister from one over to a new one.

I would like to clarify a couple other things which I heard during here in the program. Efficiency by itself means nothing. You must specify what the velocity and the size of efficiency is.

Over and above that, if you want to take a look at the solid versus liquid, you'll find out that the filter doesn't care what kind of a material

that comes into it. It will be a characteristic of the aerosol, of the filter material itself, and the conditions of test.

And in the aerosol area, you will find that it's the particle size, a particle size distribution, and even the density of the particle. For instance, plutonium, which has a density of roughly 20 and is very highly toxic, can be effectively removed in very small particle sizes which exist in the processing for nuclear applications.

We have evaluated the system actively by using viruses, by using phages, by using bacteria, by using pollens. And we have effectively covered the range from perhaps as low as .01 millimicrons all the way up to 20 microns in diameter.

We have found that it really doesn't make any difference whether it is liquid or solid, whether it is pathogenic or nonpathogenic, whether it is viable or nonviable. The criteria that is most important is the characteristics of your challenge and also the fibers in the filter itself.

For instance, we have discovered that if

you want to remove a one-micron particle effectively in the filter by a process of filtration, all you need in that filter is a one-micron fiber. If you want to effectively remove plutonium, then plutonium exists down in the micron, tenth of a micron and below range, then you need those smaller fibers in there in order to effectively give the removal, physical removal, area that we have.

What we're suggesting is that you might consider certain elements. For instance, the present military standards have no provision for using sodium chloride. And by using sodium chloride in your directives, you will find that you are walking alone in that area because most of the other people, both the manufacturers of media and the filter test groups, already have our equipment installed and use it on a daily basis.

The second thing is sodium chloride equipment is very expensive. And it is estimated that to comply with your rules and regulations, it would cost a small manufacturer or a large manufacturer for that case in excess of $100,000 by the time he got

the new generator, he got the new aerosol, he got the new mobility analyzer, he got the new diluter, which would be required for diluting the upstream concentration to the downstream concentration because the photoelectric system particle counter will not process more than 30,000 particles per cc. So it would be an undue burden on these individual manufacturers.

Another thing which we would recommend that you consider is that you use your highly specified or specifications for only the filter manufacturing process. And you could certify the filtering manufacturer material so that it could be used then by the person or the company who is making the canisters.

We have found that most of the testing done at the canister level reveals only the leaks in the system, the damage that has been taken care of in the process, and it is really not meaningful if you're looking at the overall performance of the media.

I thank you for your consideration.

DR. MOYER: I have two questions,

basically. One of the questions is a question I asked earlier and I would like to address to you. From a theoretical point of view, if you had an aerosol, that same particle size, same distribution, and same chemical composition, and was made by different generation methods, should it produce the same penetration results?

MR. ANDERSON: If it was used under the same conditions of test now, you know, if you're using the same velocity and you have the same operational tests, you should expect that.

DR. MOYER: Yes. Okay. Fine.

The second question is -- it's not really a question. I understand all of the work that you have done, and I respect it and was wondering if, in fact, a lot of the information that you and your group generated when you were with the Army would be available to be looked at and could be submitted to the docket.

I know a lot of that information was classified because a lot of it had to do with biological agents in the past. I know some of that

data has become declassified and that from my point of view, it has been extremely difficult to get our hands on that.

MR. ANDERSON: I think that you will find that almost all of the reports have now been declassified.

DR. MOYER: Okay.

MR. ANDERSON: And if you have specific titles or specific numbers that you want, that can be obtained from the Documentation Center over in Virginia.

DR. MOYER: Okay. The reason for saying that, unless you know the specific document number and title, which is not readily available to us, it's almost like being a classified document. That's why I said that.

I have tried to get a hold of some of those, have even had people who have worked at Agewood Arsenal, trying to find out document numbers and titles. It's held very hush-hush.

MR. ANDERSON: Right. Well, there are two other areas which you might want to consider

exploring. One is in the area of DOE. They have published a handbook on aerosols, which gives you the basic parameters of aerosols. And they have now published a handbook on air cleaning.

If you don't have those available to you, you can get them from AEC, or DOE now.

DR. MOYER: Right.

MR. ANDERSON: If you have specific ones, in my inventory of documents which I have retained, I might be able to give you the exact numbers that you could get from the Documentation Center.

DR. MOYER: Thank you very much.

MODERATOR MATTHEWS: Thank you, sir.

Larry, there weren't any other sign-ups, were there? Okay. Any other comments from the panel?

(No response.)

MODERATOR MATTHEWS: We very much appreciate the patience, the time, the energy that everyone has put into this. We certainly will give very thoughtful consideration.

Clearly we've got to work out the technical aspects, as has been drawn out in the

discussions, both ISEA and MSA presentations. And we clearly will work with all of the parties in coming up with the appropriate type of user information before we go to the final on this.

Rich, do you have any other comments?

MR. METZLER: Thank you all for coming. We appreciate it very much.

(Whereupon, the foregoing matter was concluded at 12:21 p.m.)