NATIONAL INSTITUTE FOR

OCCUPATIONAL SAFETY AND HEALTH

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORIES

TOTAL INWARD LEAKAGE (TIL)

PROPOSED RULEMAKING PUBLIC MEETING

Thursday, December 3, 2009

Commencing at 8:30 a.m. at the Marriott

Inn and Conference Center UMUC, 3501 University

Boulevard E., Adelphi, MD 20783.

MR. HEARL: Good morning. I'm Frank Hearl, and I'm the Chief of Staff for the National Institute for Occupational Safety and Health. And I'm here to welcome you this morning to discuss our proposed rules on Total Inward Leakage requirements for respirators, which were published in the Federal Register on October 30, 2009.

Today's meeting is being held here at the Marriott Inn and Conference Center in College Park, Maryland, and we will be running our meeting today through 4 o'clock, or until after the last presenter has completed and the discussion has closed out, at which time we will close the meeting.

It is being recorded, and transcripts will ultimately be posted in the docket once they are available.

Could I have the next slide?

Okay. First off, I think the most important matter of business to attend to today is to make note of our emergency exits.

We have the three doors here. If you -- if we have to evacuate the building, please proceed to the left and then down the main stairwell. There is also an additional exit stairwell that's marked down the hall.

And then when you get down off to the left, there's emergency exits there and -- actually, in both directions.

Bathroom locations, there's a set of bathrooms out the door and to the right and down the hall and easily accessible. Or if you want to take in the artwork, there's sculpture and paintings down the other end of the hallway, and there is a pair of bathrooms down there as well.

I would ask you-all at this time, too, if you have pagers or cell phones, please either turn them off or put them in the vibrate mode so we don't have interruptions during the day's meeting.

One of the other things that I wanted to mention is that we do have this meeting today being broadcast via LiveMeeting on the internet, and we can hear from our folks on the phone. And I think what I want to do is also -- let me go through here -- talk a little bit about our procedure since this is the first time actually I have run one with LiveMeeting.

But our purpose here is to take oral comments on the proposed rule. And our procedures will be that we will have oral presentations limited to 15 minutes per presentation, and the first priority are the individuals who have preregistered to speak, and we have actually four people who have so registered.

Dr. Phil Eitzman from 3M, Craig Colton from 3M, Daniel Shipp from the International Safety Equipment Association, and Jeff Weed from Weed Respiratory Protection Solutions.

So those are the folks who have preregistered.

As I -- what I want to do now is ask the folks on the phone to identify themselves, who they work for. And if you could indicate if you also want to make a presentation, then we will add you to the list at this time.

And anyone who is here in attendance, we have a sign-up sheet that's outside the door. So far, no additional people have signed up to speak, but we will add you to the list.

And you would be the second priority after the people -- the four people who have already preregistered and anyone we pick up from the phone.

And then the third priority will be -- or the second priority is if any of these four people miss their time.

The third will be people who sign up outside, and the fourth priority will be comments from the floor, which we will entertain after the last speaker is gone, and that we will have the

floor open until 4 o'clock, or until we run out of comments. So that's the order of business for today.

So let me go to the phone and see who all is here.

Everyone else in the room I presume has registered on the sheet and indicated your attendance on the sign-up sheets.

Do we have a location, or just ask someone to speak up?

MR. FRIES: Yeah.

MR. HEARL: Will someone identify yourself and we will begin to take roll from the telephone.

MR. JOHNSON: Yes. This is Dave Johnson. I'm with Kimberly Clark, and I will be an observer of the process. I have no presentation or comments.

MR. HEARL: Thank you.

MR. SCHWIND: Good morning. This is John Schwind, Global Safety First. I will be observing as well.

MS. D'ALESSANDRO: Maryann D'Alessandro of NIOSH.

MS. ARMSTRONG: Mary Armstrong with ODC.

MR. PERROTTE: John Perrotte with NPPTL.

MR. BURGE: Gavin Burge. I work with BMT Designers and Planners, and our customers are OPNAV and the U.S. Navy Safety and Readiness Office.

I had prepared some comments, but I'm not prepared to present them in a public forum.

MR. HEARL: Okay. Thank you.

MR. SPELCE: Hi. This is Dave Spelce with the Navy and Marine Corps Public Health (inaudible).

MR. HEARL: Could you repeat?

MR. SPELCE: Sure. David Spelce with the Navy and Marine Corps Public Health (inaudible).

MR. HEARL: We are not hearing you loud enough. If you could speak up a little bit.

MR. SPELCE: David Spelce with the Navy and Marine Corps Public Health Center.

MR. HEARL: Okay. Thank you.

MR. LEEUW: Hi. This is Chris Leeuw, with Prime Medical Products, and I'll (inaudible).

MR. HEARL: Did you pick up that?

Our recorder didn't pick up your name. Could you say it a little bit louder?

MR. LEEUW: Hi. My name is Chris Leeuw, and I'm with Prime Medical Products.

MR. HEARL: Okay. Thank you.

Is there anyone else that's on by the LiveMeeting who has not identified themselves?

MR. SELL: Yes. Bob Sell with Draeger Safety.

MR. HEARL: And will you be presenting?

MR. SELL: No.

MR. HEARL: Okay, thank you.

Anyone else who is on the line that has not identified themselves?

Well, if I have it correct then, I don't have any additional speakers from the phone that want to make a presentation at this public meeting.

We let me go back here a notch to the NIOSH panel. Today I will be moderating the session, and joining me on the panel to answer questions or clarifications is Jon Szalajda, who is

the Branch Chief for the Policy and Standards Development Branch at the National Personal Protective Technology Laboratory division of NIOSH.

The branch develops and promulgates new and improved PPE, personal protective equipment, related standards and regulations. He holds a BS degree in chemical engineering from Penn State and an MS degree in engineering from George Washington University.

LIVEMEETING VOICE: The conference now in silence mode.

MR. FRIES: Someone was playing something.

MR. HEARL: Someone was playing music.

Okay. I thought I detected that.

He holds a BS degree in chemical engineering from Penn State and a masters degree in engineering from George Washington University and the University of Pittsburgh. He worked in the field of respiratory protections and PPE for 25 years.

Bill Newcomb, who is also joining me on the panel, is a physical scientist for NIOSH in the Policy and Standards Development Branch of the National Personal Protective Technology Laboratory, and he is the project officer in charge of this proposed rule.

Bill has had over 47 years experience in respiratory protection, the last five of which have been with NIOSH.

And we also have Terry Thornton in the center there. And he is currently certification analyst with the Technology Evaluation Branch in NPPTL at NIOSH. He is an experienced certification analyst and is very knowledgeable in all classes of respirators certified by NIOSH.

He was integral in the development of the laboratory respiratory protection level facility in Pittsburgh and continues to be very involved with the testing conducted at the facility.

So that's my panel. Gary Walbert, who is listed on the slide, is not with us today.

And at this time, I think I'm ready – I should mention here, too, the docket for written comments.

There's -- after this meeting, you will still have opportunity to submit written comments to the record, and you can do that by one of several means.

One, you can go to the federal e-rulemaking portal, which is found at www.regulations.gov.

You can submit your comments by email to the email site NIOCINDOCKET@cdc.gov, the NIOSH docket. Or you can submit them by mail to the NIOSH docket office at the Robert A. Taft Laboratories at 4676 Columbia Parkway, Mail Stop C34, Cincinnati, Ohio 45226.

The current closing date is December 29, 2009.

And I can tell you that we have received a request to extend the comment period, and that request is under consideration by the department.

So we will go from there. To give you a little bit of a briefing on the rule and a little bit of overview, I would like to ask Mr. Jon Szalajda to please come to the lectern, and he will give us a walk-through on what this rule does.

And I also want to say, too, that anyone who wants to speak or ask a question, you will need to come to the microphone so that the people who are on the LiveMeeting can hear.

So no comments -- even if you say you have a loud voice, we need to have you at a microphone.

So at this time, Jon.

MR. SZALAJDA: Thank you, Frank, and good morning, everyone.

I would like to thank you all for participating in this meeting. And, actually, in looking back and preparing for this, this is the third meeting in the past 12 months that NIOSH has where we have talked about the development of a proposed modification of 42 CFR Part 84.

And looking at this, we are looking to take the existing regulation that was established in 1995 and update that and move it to incorporate and help address evolving technologies in the effort to provide respiratory protection that improves worker safety and health.

Could I have the next slide, please?

Our process to do this, this rule that we are going discuss today and other proposed rules uses an open evolutionary type of process. Some aspects of this process include the use of a publicly accessible docket, stakeholder and informational meetings, and public meetings where NIOSH will share information regarding the development of performance requirements for respiratory protection.

This process also uses benchmark testing that assesses the range of existing technology and how that may perform against anticipated performance requirements. The process also uses concept papers and public meetings that review the benchmarking process and also share in NIOSH's thought process with regard to developing performance requirements.

We think that this process encourages stakeholder participation, which is included as part of our development process.

Today, this meeting is going to provide stakeholders with another opportunity that will provide oral comments on a proposed rule that establishes a Total Inward Leakage requirement for half-mask air purifying particulate respirators.

NIOSH evaluation of Total Inward Leakage performance requirements of these respirators will provide increased assurance to respirator purchasers and users that NIOSH-approved respirators can be expected to effectively protect the user against particulate contaminants when properly donned and used.

This proposed rule also addresses various topics that were identified during our development process and benchmark testing. We anticipate that it will reduce the trial and error associated with workplace -- excuse me -- with workplace fit testing as part of a workplace protection program.

Having a Total Inward Leakage requirement will streamline this process because the respirator will have demonstrated through testing that it achieves a minimal level of performance.

Another aspect of this rule applies to situations where poorly performing Total Inward Leakage respirators are being used without the benefit of complete respiratory protection program, which includes fit testing.

In these instances, a poor fit might not be recognized, increasing the likelihood that a respirator user is not being adequately protected.

Testing and evaluation of Total Inward Leakage performance requirements by NIOSH as a result of this proposed rule will increase the likelihood that workers who lack fit testing will obtain protection by using respirators which are demonstrated to fit intended users when used properly.

This slide in front of you indicates the -- it's about six months old that we had used in a previous briefing, but it also indicates a level of approvals that NIOSH has issued with regard to filtering facepiece respirators.

We currently envision as part of the certification program that, with the implementation of this rule, that the certification time for the respirators will continue to be processed within the 40- to 50-day time period, and also that with the incorporation of this requirement, that inward leakage testing requirements could be accomplished within five to ten working days.

As part of our preparation for this rule, we look forward to working with the manufacturers to be able to identify and fill the panel requirements associated with the rule to ensure that the development of those products can be swiftly moved through our certification process.

And with that, I would like to introduce Bill Newcomb to give a little overview of what the technical requirements are for the proposed rule.

Bill has been our project officer since his employment with NIOSH in development of this proposal.

Bill.

MR. NEWCOMB: Thank you, Jon.

The proposed rule has been in the making for several years now, and we had some public meetings to go over the rule.

First, I think that everybody knows what Total Inward Leakage is, but just in case we have someone who may not, we are talking about the leakage through the filter and through the facepiece, the face seal of a respirator.

We conducted benchmark testing. And as a result of the benchmark testing, we had some concepts. We had a couple of public meetings, and we listened to the comments from those public meetings.

The proposed rule adds new requirements for the minimum characteristics of air purifying filtering respirators, including filtering facepiece respirators.

It uses the newly developed NIOSH fit test panel that many of you are familiar with. It's been published in several publications recently. It was done by the research division at NIOSH to

get a panel which represented more of the working population of the American workers, and it's approximately 98 percent of the working population.

This is the fit test panel that we are proposing to use in the new regulation.

It uses a CNC detection method, which is appropriate for particulate filtering devices. The exercises that are used are those that are defined in the OSHA regulations for conducting fit tests.

We are not developing anything new. What we have done is, in the protocol, defined a little more closely some of the movements, such as does the moving a head up and down occur at -- like you're saying yes, or does it occur like you're actually making movements involved in doing something other than just shaking your head.

So we have sort of put times on the movements to make the test more reproducible from one test to the other.

The proposal also allows the development and approval of niche respirators. If a manufacturer wants to make a respirator to fit a specific population group, then this regulation allows him to do that and to get it certified. It does not have to be a respirator that fits everyone, but it does require that the manufacturer identify the user population.

Obviously, NIOSH cannot come up with a panel for a product or a respirator facepiece, nor can the wearer know if that facepiece is designed to fit them without some information from the manufacturer as to who that respirator is designed to fit.

It uses a maximum of 35 test subjects. In one of the former proposals, we had suggested 35 test subjects per facepiece, which means that if you had a three-size facepiece that covered the gamut of people, it would be 105 tests.

The new proposal uses 35 for a total. So if you had three facepieces, they would be tested on 35 test subjects, not 105.

So we have listened to the comments that the manufacturers have given us.

The Total Inward Leakage requirement is a maximum of 1 percent, equivalent to a fit factor of 100.

Again, some of the proposals that we had previously had a higher -- lower Total Inward Leakage, higher fit factor.

We have looked at the data that we came up with during the benchmark testing, and we have made a decision that it would be better to use the 1 percent, which is actually equivalent to what OSHA requires for the use of this product. So we are not inventing something new for this type of respirator.

And we have come up with a minimum pass of 74 percent of the test subjects. This might not seem like a high amount, but from the benchmark testing we have done and the statistical analysis, this 74 percent, or 26 out of 35 test subjects, is designed to make sure that a respirator that actually fits well passes the test and also to make sure that a fit -- a respirator that does not fit well does not pass the test.

If you have a niche respirator, the number of test subjects will be less, but the pass criteria will be more stringent. That's an overview of the proposed rule.

And the implementation for the final rule was that 30 days after the publication, that NIOSH would begin accepting applications for approval of respirators that are tested to this rule.

We would give three years for manufacturing and sale of respirators, having approvals at the current time -- approvals that are current at the time of promulgation.

This is very similar to what NIOSH did back in 1995 when we had new types of filters that came onto the market. The N,R and P filters that replaced the old dust, mist, fume and so forth filters.

We gave three years for the manufacturers to phase out the old products and also two years to make changes.

There are always small changes that are made on a routine basis to respirators, and we felt that we would entertain the extension of approval of any old respirators for two years after the promulgation of the new regulation.

Thank you.

MR. HEARL: At this point, we are ready to begin with the first order of business, which is the presentations by those who preregistered to speak, and our first speaker on the list is Dr. Phil Eitzman from 3M.

Dr. Eitzman, if you would like to either use the microphone here on the lectern, that would be fine.

MR. EITZMAN: Well, we will start with Craig, and then I'll go second, if that's okay.

MR. HEARL: That's fine. So the first speaker will be Craig Colton from 3M.

And, as I said, you can either use the microphone in the center of the room or you are welcome to use the lectern. It might be more convenient.

MR. COLTON: Good morning. Thanks, Phil, for switching this around.

First of all, I want to thank NIOSH for the opportunity to add our comments or two cents into the standard at this particular point.

For the presentation, as you – has already been unveiled, there's going to be two of us that are speaking. I'm going to be speaking first, and then Dr. Eitzman is going to be speaking after me, and we both are going to speak on slightly different subjects regarding the proposed rule.

One thing I want to add, though, is that the presentations that we are providing are a summary of some of the primary areas of concern. And we will providing -- as I'm sure NIOSH knows from the past -- detailed written comments to the docket to explain these points.

But at this point, this early on in the rule, we have at least some general concerns that we would like to bring up.

Regarding fit, 3M has a -- what I think is a long experience with respirator fit. I think we have been an advocate -- always been an advocate and innovative leader in trying to advance – in advancing the importance of fit.

3M has developed both qualitative fit tests and quantitative fit test methods so that fit can be evaluated both in the laboratory and by users.

In fact, 3M, before I worked for them, used quantitative fit testing for evaluating fit of half-facepiece respirators, including the filtering facepiece respirators. So it has been going on for at least greater than 25 years, long before this concept came up.

In addition to that, we have performed many workplace protection factor studies that we think is important to the success of these fit testing efforts, in that we have been able to go to workplaces, fit test workers, see that they do fit a wide variety of workers in the workplace. And then once they have fit, go out and have validated that they perform and protect the worker.

And so as part of this -- as this rule making goes, we support the effort to improve respirator fit.

Now, from what our reading has been, it seems most of the conclusions that have been drawn in the proposed rule by NIOSH have been based on the benchmark testing that was done and subsequently published in the Federal Register.

One of those conclusions is that NIOSH states that this proposed rule is not -- while it's a significant regulatory action, it's not considered economically significant. And as I mentioned, benchmark testing appears to be used to support that conclusion.

We believe that NIOSH has erred by using that benchmark testing to substantiate its conclusion with regard to the point on the economic impact of the proposal.

A little bit about, as we have seen, the benchmark testing.

NIOSH states that the testing indicates that the new TIL requirements can be met by current products without additional development or manufacturing costs.

Now, this benchmark testing, at least to summarize some of the major points, there's about 101 respirator models tested. It was I believe a 25-person panel.

At that time, they looked at a pass/fail fit factor, or talked about a pass/fail fit factor of 20 that was an average of three tests, and used the same respirator on all three tests. If it was a filtering facepiece and had a nose clip, then it indicated that that was to be straightened out when present.

One of the comments we raised earlier was to -- about addressing differences between 100 and 95 level filters. And to all indications we know, this was not addressed in that.

Now, if we look at just some -- again, some of the major points with the current NIOSH proposal, we have a different size panel, different pass/fail fit factor of 100.

Now you must pass one person out of the three trials, use the same respirator for all trials, and it doesn't really mention without straightening the nose clip. It talks about that the user would make the adjustments that they seem necessary.

And that for a respirator designed to fit a wide range of people, such as over the entire panel, then it has got to have a pass in every face panel cell.

So, again, with some of those conclusions then, we see that about 30 percent of the half-mask air purifying particulate respirators had eight facepiece seals that did not achieve a fit factor of 100, again, out of the Federal Register.

Our review of the NIOSH benchmark testing of the 3M respirators, at least as we have looked at it, it does not support NIOSH's reliance on the benchmark test data to predict that the proposed TIL requirements can be met without the development -- without development or manufacturing costs.

And then regarding economic activity, we submit that it may potentially have an economic impact that would make it significantly significant, and I just list the items here from the executive order that indicate what sort of guides them with regard to economic significance, along with higher cost of product and impact on respirator supplies as we see it.

Now, part of that comes about – the conclusion -- the benchmark testing was based on -- followed one set of criteria, and then we see it is being used to make conclusions about a different type of test method. And at least as we have looked at the study, we haven't seen where that at least our data supports those conclusions.

Now, there is no statement in the Federal Register of how that analysis was performed or – so we are doing it to how we would think the analysis would be done.

A second concern regards the NIOSH proposal with regards to the user instruction -- with regard to the user instructions, and it states there that the user instructions need to specify the information necessary to identify the intended population of users, the face size or sizes that the respirator is intended to fit, and then any additional descriptions necessary to indicate the subpopulation, which I believe is the niche respirator term that Mr. Newcomb used.

One of the issues that drives our concern is that the two dimension -- the two-dimensional facial measurements that are identified in the standard for the panel do not predict fit.

This was pointed out in the IOM study where it's pointed out that the dimensions do not consistently correlate the fit. And we have supplied data and information to the concept docket that the measurements do not correlate to fit.

So providing us guidance will not assure fit, but people will most likely think it does because they are going to see it on the user instructions.

So as such, we believe it is likely to provide a false sense of security by relying on that information. Okay.

Also, identifying the sizes of faces that respirators are to fit, when we put that on the user instructions, may establish an implied warranty.

In doing such, we believe that that will likely result in less fit testing because the packaging and user instructions state that the respirator fits their face size. But because those wearer facial dimensions cannot predict fit, this warranty would be misleading and cannot be made. And this requirement then has the possibility that it can cause manufacturers to eliminate all facepieces from the market.

Another major issue is then how is the wearer going to go what facial size they are? So if you put the size on there and that -- and there's issues with regards to -- logistical issues as well, as how do they make the measurement. Are they going to be qualified to do that?

We sent people to NIOSH to be trained to make those measurements and that, and I don't see, at least right now, how the end users are going to receive that type of training.

Then the question is with regard to the frequency of those measurements, you know, how often are they going to be done.

Whereas fit test is required to be annually, are they going to make measurements annually? And knowing what we know about the measurements, you know, in fact there's a question about whether they would need to be measured annually, but still the question is raised.

And then in doing so, there's a cost to determine the face size which we think negates some of the savings that were mentioned in the Federal Register for not having to guess at the sizes, that you are more likely to get one that fits out of the box, if you will.

If fit testing is not -- and the other thing, if fit testing is not being performed, then why in the heck are they even going to bother with taking facial measurements to find out where they are in the grid in the first place?

So we believe this proposed approach encourages noncompliance with OSHA regulations, which may jeopardize worker safety.

No incentive is provided for workplaces that don't do fit testing to begin doing fit testing because now, as they tell us, they fit better out of the box.

In fact, we have had numerous – or several inquiries where people have gone and said, you know, When is NIOSH going to get that regulation done so they fit right out of the box and

we don't have to do fit testing? And, in fact, some have confused this with the no-fit-test respirator, which is a separate issue.

So hence we have a concern in that area. Then it is also mentioned that one of the reasons for doing it, as you heard, is that for people who don't do fit testing, they have a better chance of fitting the respirator. But there is even a comment that says that the stockpile of respirators might be deployed without a respirator program and without fit testing.

And I would offer that a better solution would be, since the government controls these respirators, it seems like you could put some stipulations on them and say that you require evidence of a program and fit testing before you dole them out.

Then the pass/fail criteria, as you heard, had been one of the changes in that, and some of the reasons why raised some concern.

NIOSH states in the Federal Register that this maximum allowable leakage, this fit factor of 100, is now equivalent to fit test criteria required by OSHA for this type of respirator, okay, and that this technology is identical to that in common use for measuring respirator fit and is accepted by OSHA.

Well, we have a different view of that. In fact, as we read it, the method that NIOSH has proposed is not one of those -- one of the accepted protocols published in the Appendix A of 29 CFR 1910.134, and that's the reference that was given in the Federal Register for this.

The reason we don't is that this rule came out in January, early January of 1998, and did not mention N95 Companion.

If you know about how rules get made, it had to be based on information that was days before that. I mean, it's -- and I'm being generous there. No harm or meant, Jon, but it takes a

while to get these -- in fact, if you look at the issue of how long it takes to get the notice published that you are going to have a public meeting once you do that, it takes time.

So it wasn't -- those protocols had been in the works for some time.

And I have been told that there had been no sales of the N95 Companion until after this date, or about that -- almost corresponding to the same time, but after Appendix A was published.

I'm not aware of any study or publication that's confirmed that the N95 Companion is accurate and reliable as required in by OHSA. And those words, accurate and reliable, come out of 1910.134. And that -- as all new methods are. So if it's a new method, it would need to be evaluated.

So the question is does a fit factor of 100 that's on the Portacount with the Companion as proposed equal a 100 by one of the OSHA-accepted methods? And that was not clear. So the idea that this is being accepted because this is equivalent to OSHA raises questions and concerns.

So it looks like the hundred is arbitrarily chosen, as was, perhaps, the fit factor of 20 that was further. Not that that -- so the conclusion that was reached that it's based on the OSHA protocol we think is in error.

Then comes the concern we have with regards to the TIL. And as Bill knows, I'm a nomenclature freak or nerd. And first of all, I believe that calling this a TIL is going to cause confusion.

In fact, IOM, the Institute of Occupational Medicine, pointed out that the scientific community -- and this is inputting that from their quote, except NIOSH -- refers to the assessment of respirator fit as a fit test, and not TIL.

In a fit test, the challenge aerosol is chosen to match the filtering element in order to measure face seal leakage.

So for N95 level filters, the Portacount measures both filter penetration and face seal leakage, whereas the Portacount with the companion only measures face seal leakage or fit, at least it is chosen to minimize the fit.

The high penetration that you find in an automatic filter tester with maybe a particle size in this range, the same particle size, does not correspond to the high penetration in fit tests with the Companion.

So as an example, looking in terms of percent penetration, if I were to -- it's feasible or plausible that I could test a N95 on a Portacount and find that I have like about 2 percent penetration. Whereas if I turned around and tested that with a Companion, on the Companion, I could find that -- I might find that that has only seven-tenths of a percent penetration.

Now, I wasn't a math major, but total looks like 2 is higher -- when I look at total, I look for the highest number, and 2 looks to be bigger than .7 percent, so hence the reason that I don't believe that this is TIL.

While the test may be okay, this is certainly a fit test and not a Total Inward Leakage test. The other part of the confusion comes from the part -- the fact that the work -- there is -- there are places in the world that do have TIL tests that are indeed TIL tests.

So in summary, we support improving respirator fit, but based on the benchmark testing that NIOSH uses to support its conclusions and positions, we have some concerns on how the data were interpreted and extrapolated, and we believe it needs to be looked at more closely; and, as a result, are doing so.

That takes time.

And then there's also a concern on specifying face sizes in the user instructions -- that's what the UIs are -- both from a logistical standpoint and then from its usefulness criteria.

And then we believe the pass/fail criteria has been arbitrarily chosen and does not relate to OSHA fit testing, as implied.

And so to give people the idea that this means they are going to get a 100 as defined by an OSHA fit test is concerning. In fact, one of the issues with the OSHA program, when you do a fit test there, this standard negates or sort of to say ignores rather that a large part of that is based upon the training in that.

So the training that's required by OSHA standards is different than reading the instructions from the manufacturer. In fact, making a respirator that fits perfectly, if a person puts it on upside down, isn't doing to ensure that it's going to fit them right out of the box.

And then based on the standard test procedure, as we see it, this is a fit test and not a Total Inward Leakage test and should be called such. Thank you.

MR. HEARL: Thank you. I think our next speaker is Dr. Phil Eitzman from 3M.

MR. EITZMAN: Thank you. I would also like to thank the Institute for this opportunity to comment on the proposed rule change. Next slide.

First I just want to jump right into some comments on the test procedure. I'm not going to go into explaining that. Bill talked about it. I'm assuming that people that want to know about the details have already reviewed that in the changes that are proposed for 42 CFR 84.

First, as Craig mentioned, each respirator, a single -- for each subject, a single respirator will be used, and it will be tested up to three times.

The use of a single respirator can lead to a situation where, for instance, if a nose clip is misformed and doesn't fit the subject the first time, it won't fit them the second time, and it won't fit them the third time either. So the benefit of doing repeat donnings after that is a big question.

So I believe and we believe that a new product should be used for each time if you are going to do it three times.

Second, as Craig mentioned, there is no requirement to train test subjects on the use of the respirator prior to fit testing other than the review of the instructions. This appears to assume that the respirator will be used in the absence of a respirator program.

We feel that fit test subjects should be trained as they would be under 1910.134.

And then regardless of whether a qualitative or a quantitative fit test is used, panel sizes of 15 to 35 subjects will lead to significant panel-to-panel variability.

So depending on which panel you use and whether a manufacturer does it with their panel or NIOSH does it with their panel, you are going to get different results from panel to panel just because of differences between subjects, and I'll go into that in a little bit more detail. But that has the opportunity to lead to what can be interpreted as erroneous results.

Talk a little bit about the NIOSH grid. First, the development of the new NIOSH fit panel grid was an important advance over the Los Alamos grid, so we do applaud NIOSH on their development of that grid and the work that they did to do that.

Secondly, fit panel grids, whether it's the NIOSH grid or, before, the Los Alamos grid, are appropriate for assembling a sample of a population for the evaluation of a respirator.

Now, as I said, panel-to-panel variability does come into effect with the panel sizes we are talking about. But, in general, to kind of take that a little bit further, fit panel grids are not really appropriate for developing correlations between face size and predicted respirator fit.

Craig already made this comment. I just want to repeat that. And I have got a little bit of data to support that. And I think some of this -- or all of this data has been presented before, but

we just wanted to show it again because the effect -- or the lack of correlation between measured size and grids and respirator fit is an important point.

This is some data on four subjects, and they have in the Los Alamos grid Cell 4, which the Los Alamos grid cells are about the same size as NIOSH grids, but the Grid Cell 4 for the Los Alamos is smaller than the NIOSH grid.

And what we did was we had the test data for elastomeric half-mask respirators -- it's a 3M respirator -- where we had four subjects in the same grid cell and tested them with three sizes to determine which one fit them better.

And you can see that for across these four subjects, the size that fits best depends upon the subject. And it goes from small respirators where -- if you look at Subjects 2 and 3, so Subject 2 would also wear a medium to -- medium perhaps being the best product for Subject 1. And then finally for Subject 4, a large facepiece seems to fit better. So it just shows you that you can't really use that grid size or the grid cell to predict fit.

This is a little bit more information on that. This is now using the filtering facepiece. Again we are using Los Alamos grids.

This is four subjects each in Grid 4 and 7, and these are actually geometric mean fit factors for those subjects when more than -- four or more tests were done on each subject, and you can see as you look across the subjects within a grid that the fit factors vary over a wide range with this one product.

So, again, if you were to assemble a panel and using this maybe as an indication of what might happen, depending on which subject you picked to run a particular panel, you would get one result. And if you used another panel, you could get a completely different result. Maybe one result would show that the product had acceptable fit and another panel would say it wouldn't.

This is just some photos that kind of show the range of differences in facial features and shapes that occur within a NIOSH Grid Cell 4, and you can see, for instance, if we look at the chins, for instance, and focus on that, there are different shapes of chins and jaws and also how -- whether or not the sheets are straight up and down or whether they are at an angle.

So you have a lot of things that can cause changes in fit of a respirator that don't have anything to do with face width and face length.

This is just showing side views to show the differences in cheekbones and chins and noses that occur, again, with five people that fall into the NIOSH Grid Cell 4. So these can all lead to those differences in fit within the cell that I showed earlier.

Just a few comments on the variability of the test itself.

We feel that NIOSH has still not adequately addressed this topic. And it's critical that certification test results properly assess respirator fit and not other factors that might lead to variability in test results.

At least based on our knowledge, there's not use of a test enclosure. We think that this can lead to variability in the test results, and also we believe that reproducibility and repeatability testing needs to be performed to demonstrate that this test is a robust test.

I'm not going to read this. These are -- what I did was I went into the Federal Register for the proposed rule change and pulled out all of the questions that NIOSH is asking for comments on.

And so this is not in each case a full question, but it's just the questions that they wanted comments on.

We are looking at all of these questions. We are collecting data and are preparing comments for this. But as my summary slide shows, we would -- we need an extension to the comment period to provide requested comments on the proposed rule changes.

We are currently conducting tests, but it will not be sufficient for us to really make a adequate response to the rule change or the comments, and we need more time to do that.

Just some other points -- and some of these are kind of reiterating things that I said and also that Craig said earlier.

Fit testing of respirator users is a critical component of an effective respiratory protection program. So we believe that fit testing needs to be done by users of products.

The impact of the proposed rule change will be economically significant, again, going back to what Craig was saying.

The use of the term Total Inward Leakage does not correctly describe the fit tests that NIOSH is proposing to use.

And then, finally, the proposed test protocol will lead to significant panel-to-panel variable and will producer erroneous results.

That's the conclusion of my comments. Thank you.

MR. HEARL: Thank you very much for your comments.

Okay, our third speaker will be Daniel Shipp from the International Safety Equipment Association.

MR. SHIPP: Good morning. I don't have any slides.

My name is Dan Shipp. I'm president of the International Safety Equipment Association, ISEA.

ISEA appreciates the opportunity of participating in this public meeting, as we do with all the public meetings on respirator topics regarding the certification procedures under 42 CFR Part 84.

With me this morning, by the way, is Jeff Birkner from Moldex, who is chairman of the ISEA Respiratory Protection Group, and Cristine Fargo, who is ISEA's manager of standards services and provides staff support and prepared these comments as a consensus view of the 12 companies in the ISEA Respiratory Protection Group.

ISEA is the leading trade association representing suppliers of safety equipment, including respiratory protection devices certified by NIOSH.

I want to, as a matter of full disclosure, point out that ISEA is the party that requested the extension to the comment period to get an extension beyond the date of this public meeting.

ISEA develops its comments through a consensus process, which means that we gather the data that comes from companies like 3M, like Moldex, other companies that are members of the association.

These companies are still evaluating the proposal at this time, preparing their own comments, and also participating in the preparation of the comments for the association.

This takes time. And the season coming upon us now doesn't give us as much time as we think is necessary to do this.

Rather than get into a great deal of specifics this morning, what I would like to do is to simply review some of ISEA's concerns with this proposal with the promise that we will cover them in much greater detail in our written comments.

ISEA companies, member companies, believe there are several areas that remain unresolved from the August 2007 comments that we submitted to the criteria included in the current Federal Register notice.

Specifically, manufacturers have concerns with the proposed requirement that states that the applicant shall specify in the user instructions the face size or sizes that the respirator is intended to fit. Pursuant to this requirement, one respirator may be intended to fit all face sizes.

ISEA is not aware of any published statement which statistically correlates facial measurements from bivariate grid dimensions to adequate fit of a respirator.

A manufacturer cannot claim with any certainty that all users within a cell will fit facepieces appropriate for that cell.

To require them to place facial grids on box panels may subject the manufacturer to potential liability issues as an end user may view this information as an implicit warranty.

Related to this concern, that users are expected to identify for themselves the size of respirator to be selected, having them rely on manufacturers' instructions and descriptions of applicable facial shapes and other pertinent characteristics, ISEA believes that this could have the effect of creating work site fit testing procedures that are more complicated and which would have the unintended consequence of less workplace fit testing.

If employers follow the TIL program, they will have to acquire calipers, receive training on their use, measure facial dimensions for each wearer, determine the panel cells each wearer fits into, and acquire respirators for those panel cells if they elect to select respirators in accordance with the information NIOSH may require manufacturers to place on packaging.

Because of the complexity of these procedures and the question of the correlation of grid size to fit, employers will find it more difficult to comply with the required respiratory protection program and their OSHA obligations.

Neither the employee nor the respirator wearers will benefit from any of these new requirements.

Additionally, with respect to testing and the use of the test panel, NIOSH states that concerns will be considered further in the development of testing procedures to be implemented under a final rule.

I apologize about hitting this computer here and making these pictures change.

Manufacturers stress the importance of having the final standard test procedures developed, validated, and available for execution prior to its incorporation of the Registry text.

Specific to this, ISEA members have identified several areas of the testing procedure that are either unclear or incorrect and need to be addressed before final implementation. We intend to elaborate on these items in our written comments.

Finally, ISEA believes that NIOSH should reconsider the proposed implementation scheme with respect to a three-year sell-and-ship period for existing respirators -- for existing approvals.

Clarification must be provided on how the agency will apply this to products already approved but manufactured during the three-year time frame.

It is also unclear if an existing device that fails the TIL test or the fit test could be resubmitted after design tweaks and a request to modify the certification or if it would have to be resubmitted for full testing rather than TIL testing only.

ISEA also believes that the implementation schedule may prove burdensome to NIOSH itself as the agency must ensure that it has all the necessary resources in place to accommodate modifications of existing approvals to include TIL testing.

As the agency seems to consider modifications during the specified time period, we are concerned that the volume of expected applications without adequate resources to handle them could jeopardize the continued availability of current products or protectors that may languish in the queue beyond the two years.

It will also hinder the approval rate anew of new and unrelated products.

ISEA intends to offer alternatives to the schedule in its written comments.

ISEA, as I said, appreciates the opportunity to comment on the proposed requirements, and we will submit detailed written comments to the NIOSH docket by the comment due date which, once again, we hope will be extended beyond the current required due date.

Thank you.

MR. HEARL: Thank you very much, and we are considering the request. Thank you for your comments.

Our fourth speaker is Jeff Weed from Weed Respiratory Protection Solutions.

MR. WEED: Thank you very much. My name is Jeff Weed. I'm with Weed Respiratory Protection Solutions or Weed RPS. But today, I'm representing TSI, Incorporated.

I'm consulting, and I have been contracted by TSI to help them with their interface between NIOSH and TSI regarding the TIL rulemaking issue.

TSI's intent here is to help NIOSH create a document that clearly and precisely specifies the measurements to be made and the instrumentation to be used.

They want it to be technically correct, and they want it to be generic because it shouldn't specify a specific commercial instrument for example, the PortaCount. It should be stated in a way that other manufacturers can comply with and that laboratory particle instrumentation in the research grade can be used.

The current rule as proposed specifies the condensation nucleus counter for use, but it's unclear about other things that are often used with condensation counters. And we think that it needs to be very clear and specify exactly what should and should not be used.

For example, it doesn't -- the text of the proposed rule does not mention anything about electrostatic classifier, also known as an N95 Companion, accessory for the Portacount, and also known as a differential mobility analyzer, or DMA in the aerosol science world.

Use or nonuse of an electrostatic classifier has a huge effect on the measurement, especially due to the fact that we dealing with electrostatic media in most cases, with the N95 media.

It also does not mention the use of an aerosol neutralizer, which also has -- can have a major effect on the measurement. And some particle counting systems in the research arena have neutralizers built into the thing. SMPS, for example, that is used at a constant voltage is not just a particle counter. It's a neutralizer as well as a particle counter and will give you much different penetration results on electrostatic media.

We think the current rule as proposed contains some ambiguous specifications regarding the challenge aerosol. And looking at it, we are confused about whether the electrostatic classifier is in there or not since it's not mentioned.

For example, the text on the right talks about a particle size range of .02 to .06 micrometers, or 20 to 60 nanometers, which implies the use of an electrostatic classifier, but it doesn't say that.

There can be other ways to generate aerosol concentrations that will give you different results depending on the way it's generated and the charge that the challenge aerosol has when you are using it with electrostatic media.

And on the left, the rule talks about the ambient challenge concentration of 1,500 to 3,000 particles per cubic centimeter in that particle size range, which to us is confusing because we don't see those kind of concentrations normally when we are using a Portacount and N95 Companion.

In fact, we think there would be performance problems if you had had such a high concentration with the way the instrument is programmed from the factory because the purge times are not likely to be sufficient to clear out that kind of particle concentration between the mask and the ambient measurements.

So it seems like that spec of 1,500 to 3,000 almost seems like a spec that would be for a condensation particle counter or CNC that was not using electrostatic classifiers. So TSI is confused about this.

Also, there is a linearity specification in the rulemaking that TSI is confused about, and we like the idea of having a linearity specification, but we think it needs to be stated differently.

For example, this talks about a concentration range of 70 to 3,000 particles per cubic centimeter in the 20- to 60-nanometer range. Well, the -- if we are going to be measuring en masse concentrations, we are going to be well below 70 in the en masse measurement. This is really just talking about the ambient measurement.

Seventy is a limitation right now on the N95 Companion.

And the 3,000, we don't know where that came from because that is well above what TSI recommends using.

And we wonder if we are ever really going to see that kind of concentration under normal circumstances.

But TSI is concerned about the measurement of TIL instead of face seal leakage alone. They think that measuring face seal leakage simultaneously with filter quality seriously complicates the rulemaking because of the instrumentation that has to be specified and the fact that we are using, in most cases, electrostatic media.

I think that filter efficiency and particle size issues ought to be addressed separately from face seal leakage issues in 42 CFR 84.

This rulemaking should focus on the face seal leakage and not TIL.

Now, the way we understand it, just informally talking with NIOSH, they are intending to use a condensation nuclei counter and an electrostatic classifier.

For example, the PortaCount with the N95 companion or the newer Portacount probe, Model 838 in the N95 mode.

And that's a fit test, not TIL. Because the particle size that's used and the particle charge that's used in this case, because the classifier does not significantly penetrate that filter, so it specifically isolates face seal leakage.

So if NIOSH wants to measure TIL, that's fine with TSI. We would like to help you specify how to do that, but right now, you're not doing that in this proposal.

TSI wants to submit comments regarding all of these issues, and they are doing some laboratory work right now to support those comments, but this work can't be done by the end of December. It's just not going to happen.

So TSI will be submitting a request next week in support of extending the comment period by 60 days or so so that they can finish this work and submit a complete and thorough comment regarding all of these issues with the technical support that's needed.

Thank you very much.

MR. HEARL: Okay. Thank you very much for your comments. I'm looking forward to receiving the written comments in the record.

So we are gone through the folks who have previously signed up to speak today; and to my knowledge, I don't think we have anyone yet who has signed up to speak at the door.

Also no one from LiveMeeting.

MR. FRIES: I have had four more people join.

MR. HEARL: We had four more people join LiveMeeting?

MR. FRIES: Yeah. Do you want me to --

MR. HEARL: Yes. Could we open it up so we could hear that and identify them? So the folks who joined since we did the original roll call, if you could please identify yourself, who you work for, and if you would like to make a presentation today via LiveMeeting.

MR. JARIS: Lieutenant Commander Tim Jaris. I work for the Navy Safety Liaison Office at OPNAV. I don't have any comments. I'm here to listen. Thank you.

MR. HEARL: Thank you. The next person? I understand we had four people sign in.

MR. CARNEY: Dave Carney. The US Army labs in Massachusetts.

MR. HEARL: Could you repeat your name, please?

MR. CARNEY: Dave Carney, C-A-R-N-E-Y.

MR. HEARL: And are you interested in making comments?

MR. CARNEY: Not at this time.

MR. HEARL: Thank you. Next person.

MR. FRIES: Larry Janssen was on and Jim Johnson.

MR. HEARL: Larry --

MR. FRIES: They may not be there anymore.

MR. HEARL: Okay. They have departed.

All right. At this point in time then, we will open the floor. And if there's anyone who is in the room now that would like to make a comment, please feel free to identify yourself and come to a microphone.

Bill, do you have something? Identify your name for the record.

MR. NEWCOMB: Bill Newcomb, NIOSH.

I do have a question or two for our presenters this morning and to the gentlemen from 3M. I would ask that if -- first, I want to clarify something, that there is no requirement in the present proposed rule that there be a grid or any such thing on the packaging or in the instructions for use.

And I would ask if manufacturers at the present time sell product that is marked either S, M, or L, for small, medium, or large, which are size designations.

MR. HEARL: Would anyone like to respond to that? If so, please come to microphone.

MR. COLTON: Craig Colton with 3M.

And Bills knows, the answer is the manufacturers do have product marked in those sizes or with those designations to indicate that they are different from other ones that are sold, but there is no indication as to which one is going to fit an individual.

And when it comes to taking the sizes on there, just reading the proposal directly and the quote was, face sizes are sizes that the respirator is intended to fit in the user instructions.

So that's sounds like some way you are going to be telling them how that -- you know, that their face matches up with a specific model whereas, even though we have small, medium, and large or other sizes, there's no indication -- or no statement saying do that. In fact, the way you find which one fits you is by performing the fit test.

MR. NEWCOMB: Thank you.

A question for Phil. On the panels that -- the subjects that you showed --

MR. EITZMAN: Yes.

MR. NEWCOMB: -- were these subjects screened using a PCA panel as NIOSH has proposed doing?

MR. EITZMAN: Yes. We used the PCA panel to exclude outliers.

MR. HEARL: Any other questions? If there's no other -- are there any other --

MR. COLTON: Craig Colton 3M. I have a question.

As I look at the NIOSH docket page, there are two dockets, one that seems to be -- that was established for when it was the concept and one for the proposed rule. And then the question is are those -- is the information from both dockets going to be combined into the final one, or are they separate dockets and will be considered separate and kept independent?

MR. SZALAJDA: I think the short answer is yes, that -- I'm sorry, Jon Szalajda with NIOSH.

The short answer is Docket 36, which was done for the concept page, will still exist, but there will be a link on Docket 137 that takes you to all of the comments that were provided in 36.

So 137 will be a repository for any of the comments regarding the proposed rule at this stage, but there will be a link there that takes you to 36, and those two will be permanently linked.

MR. COLTON: So the record will be considered to be both --

MR. SZALAJDA: Both dockets.

MR. COLTON: -- both dockets?

MR. SZALAJDA: Right. That's correct.

MR. COLTON: Thank you.

MR. HEARL: Are there any other comments that anyone would like to offer from the meeting room here today?

MR. COLTON: Craig Colton, 3M, and, yes, I have a comment now.

We also were one of the people who sent in a request for an extension to comment. What's been driving that is the ongoing study that we have currently designed and have up and running to evaluate the rule.

And things -- and we are trying to go fast due to the short time period that we have, but, you know, with the deadline date and the holidays and all of that.

But from the time we submitted that, we have continued to get more data, of course. And one of the things we have noticed is that the results of these ongoing tests indicate that if we were to do it today, we would request even additional time than what we had done there.

Now, I realize that the request for extension of the comments needs to be balanced between getting good information and not dragging out the rule extremely long.

But considering how long this has been going on, we probably -- if we were to request a day, we would request 180 days instead of the 90 days that we did.

So that's my comment. Thank you.

MR. HEARL: Thank you very much.

Anyone else from the LiveMeeting connections? If you would like to -- if you like would like to make a remark, the lines are open. We would like to hear from you now.

Well, I think without further remarks, if you can put up the docket submission slide again. Yes, that's good. The slide that's up right now shows the details for how to submit comments to the docket.

Again, it can be submitted by going to the website, which is www. regulations.gov. Submitting by email to the address NIOCINDOCKET@cdc.gov, or by mail to our address at 4676 Columbia Parkway, Cincinnati, Ohio and making reference to the Docket number 137.

Those are the means of submission. The current closing date is December 29, 2009. And, as was mentioned several times, we are taking under consideration and working with the Department of Health and Human Services regarding the requests for extensions for the time period to submit comments.

At this time, with no further hands going up -- oh, just as I say, we have one.

MS. DEMEDEIROS: One additional question.

MR. HEARL: If you could identify yourself.

MS. DEMEDEIROS: Edna DeMedeiros, Honeywell Safety Products.

I wonder, if I go to Docket 137, am I going to see everyone's comments up until this point, or is that just where I can post comments?

MR. HEARL: That's right now just where you can post comments.

MS. DEMEDEIROS: All right. So I can't see anyone else's comments? I can only go back to the prior docket. What was it? 36 or whatever? And --

MR. HEARL: I'll let Jon answer that.

MR. SZALAJDA: Edna, the way it's set up is that when you go to the web page for Docket 137, as the docket office receives comments regarding the proposed rule, they will be posted in that docket.

There's also a link there to Docket 36 which was used for the concept phase that has all of the prior submittals regarding the development of the proposal.

But the docket office posts comments. Everything is open in the public forum. And there is a little bit of a lag time from the time that the docket office receives a comment till the time it's actually posted. But eventually anything that is submitted to the docket office will be posted verbatim, and you will be able to see any comments that were submitted.

MS. DEMEDEIROS: Okay. So as comments --

MR. SZALAJDA: As comments come in, they are posted.

MS. DEMEDEIROS: They will be --

MR. SZALAJDA: They will be publicly available.

MS. DEMEDEIROS: Okay. Thank you.

MR. SZALAJDA: You're welcome.

MR. HEARL: I think the most timely way to look at it would be to travel to the docket office, which is the way it used to work. We now try to get these things posted as time permits.

MR. NEWCOMB: You will find that the request for extension has not been posted yet, even though it was received a couple of days ago. There is a timeline between the time that something actually gets received in email and gets posted on the web. But everything will be posted there, yes.

MS. DEMEDEIROS: Okay. Thanks.

MR. HEARL: Seems if I wait a little bit, I get more comments.

I want to make sure that everyone has a full chance to be heard, but it seems that we may have exhausted the comments available for today. And so on behalf of NIOSH, I want to thank you the presenters for offering their comments. We would like to encourage you to submit the comments in written form to the docket.

I would like to thank my colleagues from NIOSH and those who helped to set up this meeting here today at the University of Maryland conference center, and I would like to thank everyone for attending and for your attention. And with that, I will close this public meeting and thank you all and travel safe back home.

(Whereupon, the proceedings in the above-captioned matter were concluded at 9:54 a.m.)

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CERTIFICATE OF REPORTER

I, Joseph A. Inabnet, do hereby certify that the transcript of the foregoing proceedings was taken by me in Stenotype and thereafter reduced to typewriting under my supervision; that said transcript is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

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Joseph A. Inabnet

Court Reporter