NATIONAL INSTITUTE FOR

OCCUPATIONAL SAFETY AND HEALTH

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORIES

TOTAL INWARD LEAKAGE (TIL)

PROPOSED RULEMAKING PUBLIC MEETING

Thursday, July 29, 2010

Commencing at 8:38 a.m. at the Marriott Inn and Conference Center UMUC, 3501 University Boulevard East, Adelphi, Maryland 20783.

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

MR. HEARL: Well, good morning and welcome.

My name is Frank Hearl, and I'm the Chief of Staff for the National Institute for Occupational Safety and Health.

And we're here today to accept public comment on proposed rules revising Title 42 Code of Federal Regulations, Part 84, entitled "Total Inward Leakage Requirements for Respirators" which is originally published in the Federal Register on October 30, 2009.

Before we begin the substance of the meeting, I want to begin with a few announcements.

First, should there be the need for an evacuation of the building, we would exit through the door at the back of the room and go to the left, and then there's a stairwell that would take us downstairs. And as soon as you get downstairs, there's actually several exits to the outside. So you would move to there if need to be.

The nearest bathrooms are located out the doors and to the right, just down before you get to

the end of the hall. Bathrooms are there.

Third, in deference to today's speakers and in considerations for others attending the meeting, I'd ask that everyone now take a moment to turn off your electronic devices, or at least put them in vibrate-only mode. And hopefully mine won't go off because I didn't do that before I got started up here, sitting over there.

So the purpose of today's meeting is to seek public input and comment on the proposed rules that were published on October 30, 2009, entitled "Total Inward Leakage for Respirators."

NIOSH held an initial public meeting on the rules on December 3rd. And at the request of commenters at the December 3rd public meeting, we extended the comment period from December 29, 2009 until March 29, 2010.

Prior to the close of this comment period, two commenters requested further extension of the comment period for up to one additional year, because they're conducting independent research into the scientific requirements of the proposed rule and its

economic impact.

Because the rule contains only one new performance requirement that the commenters need to analyze, the comment period had already been extended once. The agency decided to extend the comment period to September 30, 2010, to provide sufficient time for comment. Let me move this ahead too.

Okay. So let me begin the program for today's meeting by first introducing also the panel members --

MR. SZALAJDA: No slides.

MR. HEARL: No slides. Well, one moment please while we get that worked out.

MR. PERROTTE: What do you need, Frank?

MR. HEARL: Something to be on the screen.

Okay. Great. Actually I'm going to -- just before I introduce the panel, I'm going to pause. And let me see if the LiveMeeting -- if one of the persons on LiveMeeting could identify whether you're seeing the slides.

LIVEMEETING VOICE: I see them, Frank.

MR. HEARL: Okay. Great. Thanks.

So for today's meeting, I would like to introduce the members of the NIOSH panel that's here today. Jonathan Szalajda.

Jon, if you want to wave your hand.

Jon's current position is Branch Chief for the Policy and Standards Development Branch at NIOSH's National Personal Protective Technology Laboratory, NPPTL.

He's in charge of the development of new standards and standard operating test procedures. And Jon's background includes more than 20 years experience in the field of personal protective technology.

William Newcomb. Bill Newcomb is presently a physical scientist with NIOSH in the Policy and Standards Development Branch and is the project manager for the Total Inward Leakage proposed rule.

Jeff Peterson. Jeff is the lead engineer in the Technology Evaluation Branch which handles the certification.

And Rene Pana-Cryan. And Dr. Pana-Cryan is an economist who works with NIOSH's Associate Director

for Science and as the coordinator for NIOSH's Economics Program.

And in addition, present from NIOSH today and assisting with the meeting are Mr. Les Boord who is the Director of NPPTL.

And I'll see -- we also have Ron Shaffer. Is Ron in here? I don't see him. I thought we did.

John Perrotte, Ziqing Zhuang, Gary Walbert, and Charlene Jennings.

The federal announcement of today's meeting called for participants who wish to speak to notify NIOSH in advance so that we could schedule the presentation. And we have five persons who have registered to speak. And I think I may have a slide on that.

The schedule for presentations today will be in the following order. Dr. Phil Eitzman from 3M for 15 minutes.

I think I'm going to reverse the order so I can put Craig third. And then we'll have Jeff Birkner from Moldex will be the second for 15 minutes. And then Craig Colton from 3M for 45 minutes. Dan Shipp

from ISEA for 15 minutes. And Jeff Weed from Weed Respiratory Protections Solutions for 20 minutes.

We'll begin today's meeting with a presentation by NIOSH staff who will briefly describe the changes that are proposed by these rules and comments that are being sought at today's meeting.

We're then going to invite to the lectern the persons who have preregistered to speak at this meeting in response to the Federal Register Notices I just read off.

If a registered presenter is not present when their presentation is scheduled to begin, we'll continue with the next scheduled presenter. And after the last presenter is heard, participants who missed their scheduled time will be given the opportunity to speak.

We will then have an open comment period when parties who are participating using the audio LiveMeeting conferencing will have an opportunity to comment. And then others from the audience who wish to offer a comment or make a presentation will have an opportunity to be heard.

The meeting will continue until four o'clock p.m. or until there's no further comments offered by the attendees in person or the LiveMeeting conferencing system, whichever comes first.

So I want to point out a few things to you. If you haven't already done so, please register your attendance by signing the sign-in sheets outside the room at the registration table.

Again, if you want to speak but didn't pre-register, if you could let someone at the registration know that you want to speak, I'll be able to call your name. That way I'll check it there before we get to the open comment period.

The meeting today is being recorded and transcripts will be placed on the regulatory docket.

When you get up to speak, please indicate your name, organization, and please do use the microphone so that your comments can be accurately attributed and so that the people who are participating by LiveMeeting can hear what you have to say.

In the request to reopen the record,

commenters asked for additional opportunity to evaluate feasibility and cost associated with the propose ruled. NIOSH encourages presenters and those offering comments today to address feasibility and economic impact. However, any comment relevant to the proposed rule is welcome.

I'd like to now introduce Mr. Bill Newcomb who will briefly describe the proposed rules and will identify some specific issues to be addressed today. Bill.

MR. NEWCOMB: Thank you, Frank. And good morning, everyone.

Back when the Bureau of Mines started certifying respirators back in -- even before I was around, they had some qualitative methods for measuring the face seal leakage performance of respirators. And those were using coal dust and things like that. And they were used until the 70s.

And when the Bureau of Mines promulgated 30 CFR 11, they were changed to make respirators for a particular need to be modified in order to be tested.

In 1995 when Part 84 came about, the

respirators that needed to be modified were no longer tested. This proposed rule would add a requirement for testing of respirators that are made for particular filtering, and in particular half-mask type of respirators which would include what is commonly called "filtering facepieces" today.

This proposal uses some test criteria which was developed at NIOSH using some anthropometric data to update and come up with a panel of faces -- face sizes that are more representative of the population that wears respirators today than was used in the past.

The technology that was proposed uses a CNC technology to measure the penetration of particles into the breathing zone of the wearer. The exercises are those that are typically used in fit testing of respirators in the field.

The proposal also allows a development of Niche respirators which could be made for different ethnic populations or different sizes or different sexes of users who have different facial characteristics.

And the other requirement is that the respirator manufacturer should be able to tell the public who's buying a respirator what type of person that respirator is designed to fit.

In the Federal Register Notice for this meeting, there was two criteria that were asked to be addressed. One was to share the results of new research that may be available or in process in the area of filtering facepieces or other half-mask respirators inward leakage measurement.

And the other was to offer any additional comments on the anticipated economic impact of the proposed rule.

So those are the two main focuses of this meeting. However, as Frank said earlier, any other comments that are pertinent to the rule will be heard as well. Thank you.

MR. HEARL: Okay. Thank you very much. We can now move on to the first of our presentations and Dr. Phil Eitzman from 3M will be first up.

MR. EITZMAN: If we could, we sort of got our presentation, our slides together, so if we can

start now.

MR. HEARL: Oh, okay. I moved you back to third since we were having technical difficulties. But if you want to do it that way, that's fine. If you would just be sure to identify yourself from the microphone.

MR. COLTON: Yeah. This is Craig Colton with 3M. The technical difficulties were with both of our presentations.

MR. HEARL: Oh, okay.

MR. COLTON: Because it's one. And so I guess we'll start up here.

MR. PERROTTE: Do you want that turned off?

MR. COLTON: Yeah.

MR. HEARL: Is it showing through the LiveMeeting?

MR. PERROTTE: Yeah.

MR. HEARL: Is it showing through LiveMeeting? It is, okay.

Okay, Craig. Go ahead.

MR. CRAIG: Yeah. Thanks.

I want to thank NIOSH for reopening the

comment period and scheduling this meeting and giving us the opportunity to speak, and Bill I specially like to note that granted me permission to speak. And I'll speak freely if that's okay.

In this presentation, I'm going to start it off and sort of give some overview of what we've learned in this period since the rule was announced and testing to the new standard or the proposed standard test procedure.

And then Dr. Eitzman is going to come up and go through the nitty-gritty details, if you will, of the assessments that we performed. And then we're going to pass the baton again and wrap it up with our recommendations.

This presentation is going to summarize the findings that we've made on studies that we conducted after the proposed rule was made out or the proposed rule was published, and then subsequently the period closed and then when it reopened, we've done some additional work.

So some of this information has already been submitted to the record because we tried to get that

done before the comment period closed. And then we have additional new information that will be shared with you.

Well, as sort of alluded to, a couple of the requirements that I think are the ones that we're going to focus and talk about are listed up here in this slide.

The first point you see there, this requirement to fit persons with various facial shapes and sizes, that's the same requirement that's been in 42 CFR 84, and in fact that language is even in 30 CFR Part 11.

The difference is now how NIOSH is going to assess that. And the proposal is using the standard test procedure that we've all seen for determining compliance and whether they meet it, and then the pass/fail criteria that were suggested and so forth.

The second information is that the user instructions for half-mask respirators need to specify the intended population. But specifically, it states that the user instructions need to identify the facial size or sizes that the respirator is intended to fit.

We take that as being something apparently more -- that is meant more than just small, medium, and large because we've already had that for several years.

Now, when we did our review or started looking at the proposed rule, you know one of the things that stood out in this publication was that there was a statement that approximately 30 percent of this class of respirators, meaning the half-mask respirators or half-facepiece respirators, have face seals that did not perform adequately to achieve a fit factor of 100.

And everything that we looked at seemed to indicate that it was the benchmark testing that NIOSH had performed which allowed them to draw that conclusion.

So when we started looking for information that was available on the record, it became a little bit hard to understand how NIOSH reached that conclusion. One, there was no summary as to how the data were evaluated from the benchmark test and then -- so we were a little bit unclear about things.

However, what we did find in the docket was information that had been presented at a public meeting. And if you look at this slide where you got the penetration criteria there, so 10 percent would be like a fit factor of 10.

LIVEMEETING VOICE: Don --

MR. COLTON: Hello --

LIVEMEETING VOICE: Don, (in audible). How are you?

MR. COLTON: I'm fine.

This is a LiveMeeting. You may be on the wrong call. This is a respirator meeting.

MR. HEARL: Ask him to mute his mike.

MR. COLTON: Yeah. If you could mute your mike, that would be appreciated.

MR. HEARL: Okay. Sorry.

MR. COLTON: Yeah, no problem. Makes it exciting.

LIVEMEETING VOICE: I can't get there now. I'm getting (inaudible) that it can't find RCC router (inaudible) cannot be found.

And what's strange is I tried it yesterday a

couple of times and I was fine.

MR. HEARL: Are we muting this individual?

MR. PERROTTE: Yes.

MR. HEARL: Yeah.

MR. PERROTTE: Sorry about that.

MR. HEARL: Okay. Technical difficulties are -- new technology.

MR. COLTON: Yeah. One of those things. If we're going to learn them, we got to grow with them.

When we looked at this information, though, that was presented, it was -- when they were talking about a fit factor of 20 as a pass criterion, this graph was shown and you can see that basically what it had is indicated that out of the respirators that were tested in the benchmark, about half of them had adequate seals, to use the language in the Federal Register, and the other half didn't.

So what this would seem to say is you got about half of them that were well fitting, according to this criterion and the other half that weren't.

So that seemed to be a pretty big disconnect, at least in my mind, that now if you're

going to raise the fit factor and raise the pass criterion, how is the number of respirators that are going to have -- that will be effected become less.

Furthermore, there's additional information in the docket that was also shown; where here, this is just a slide looking at filtering facepiece respirators.

And if we look at the criterion for what was the closest to being proposed, a 1 percent penetration or a fit factor of 100, and then looking at the red line for pass percentage that they were looking at, this seems to indicate that of the tests in the benchmark, none of them pass, which indicates either that there are no well fitting respirators in this category, and I didn't show the last demerits, but that eliminated quite a few facepieces also, or it can't distinguish between well fitting and poor fitting.

So the benchmark data seemed to be inconsistent to us with the conclusions that had been reached or stated there.

And again, like I say, we weren't clear so

we decided we needed to do some testing which is the reason we've had all these requests for extensions at various times. And we started evaluating first our own respirators.

We reviewed the NIOSH -- NIOSH had nicely provided us with the data, the benchmark testing data from our respirators. So when we evaluated them to look to see how they did at fit factor of 100, it seemed to indicate that there wasn't -- the issue it seemed to support what was shown in the graph perhaps.

So we started conducting the test on several of our products as the STP was proposed, and those results we've submitted to you and Phil will talk about those in a little bit more detail.

Now, we also -- or the ISEA, the International Safety Equipment Association, also conducted a similar study which I think they will be talking about here and did the same thing.

So as we looked at their initial data, it seemed to be that we had data that contradicted the conclusions that were reached or stated in the Federal Register.

Now, NIOSH mentioned that in addition to their benchmark testing, they had looked at some other studies in reference to a couple of articles there, one by Coffey and one by Lawrence. And when we looked at that, that seemed to indicate that there were well fitting respirators and poor fitting respirators on the market.

So we used these studies to help us determine which ones should be tested. And since that, the initial beginning of the comment period up until this point in time, we tested some, what we thought were well fitting respirators. We've also tested a poor fitting respirator as identified in the those articles.

And what our result seemed to indicate is that the proposed fit test isn't capable of differentiating between well and poor eliminates everything, at least when you're looking at filtering facepieces and it --

So based on -- so another part of the information was how well does this predict then what's happening in the field with users. So we did some --

gathered some feedback from people who are using these respirators in the field to see what type of fit testing results they were getting. And that information was also -- has been submitted and Phil will review that with you.

And that showed that we had well fitting respirators, at least when you think of pass rates of 90 percent for our workplace population. That seems to be well fitting, but yet it would have been product that was eliminated by the standard test procedure, the proposed standard test procedure.

So our conclusion here is that as the rule has been proposed that it shouldn't proceed in this present form.

Now, we went and looked to see if there's other information that maybe wasn't gathered by us. There's an article that was in the American Journal Infection Control that was sort of interesting.

They did qualitative fit testing on what I think is a fairly large worker population, 1271 health care workers. They used five different respirators to fit their people. They fitted all of the males and

everyone but six of the females were fitted with filtering facepiece respirators.

What's interesting, though, is the first respirator they chose, the one that was like their default or the one they started with was a filtering facepiece. They got 95 percent of the males were fitted with the respirator and 85 percent of the females.

It's even more interesting to go and look at the data. When they go to the second respirator or to the third one, you find that they -- that respirator was fitting other people who it hadn't fitted. So maybe those are hard to fit people. You had a picking up 80 percent and 70 percent of those people.

So -- the respirator that they were using was also one of those that had been identified as having good fitting characteristics in the article that I have cited there.

In addition, the respirator had been tested in a workplace protection factor and indicated good performance in the workplace. In other words, workplace protection factors in excess of its assigned

protection factor. Yet, this respirator model didn't pass the benchmark, the proposed -- or didn't pass the benchmark test, I should say.

So when we have tested it according to the protocol, the proposed STP, it also didn't pass. So now it seems to us we have a disconnect between a laboratory test procedure that doesn't predict what's going on in the real world, doesn't reflect real world experience.

Here's some information from the OSHA docket when they evaluated or looked at assigning protection factors to respirators, this shows some of the workplace protection factor results.

It's got elastomeric respirators along with filtering facepieces there. But what these data show here is that filtering facepieces and elastomeric, they're achieving good protection in the workplace.

Well, if you believe you got to have fit in order to do that, this indicates that there's adequate or well fitting respirators in order to achieve that.

This is another slide that shows information in a different way where you got the two populations

of elastomeric respirators and filtering facepieces and what they achieve.

Again, for filtering facepieces to perform at this level, they have to be well fitting respirators.

Now, another issue with the current proposal is the topic of individual fit testing. And regardless of how products are designed and tested, it doesn't appear that this protocol proposal is going to ensure that respirators are going to fit people or likely to fit people right out of the box.

Out of the box is language that we've been getting from customers who have been waiting for this that they think that's what this is going to do.

And NIOSH stated the reasons why they wanted the respirators to fit people more likely with a greater percentage without doing fit testing for several reasons. However, I think you need to consider that. Fit testing is more than just finding the size of a respirator that fits one.

In fact, today if you look at things that are written in A and C standards on fit testing in

that, look at the fit test as a part of the training program on how to don it. In fact, it may even be more valuable that way, in my opinion.

But people who don't have fit testing aren't going to have programs. So now you got people where the training is going to be lacking. The user seal checks may or may not be done. Donning can be improper. There's no supervision. So if they have conditions that prevent good face seals like facial hair and other issues that are going to interfere with fit, these aren't going to be covered.

So the idea that someone is going to take these and it's going to increase the number of people are getting fit, I think, is very optimistic.

Also, in the study that we submitted to the docket which I find interesting is one done in the United Kingdom where they were studying elastomeric respirators who had been tested and evaluated over there and marked which had gone through their TIL test, if you will, and the results were published in a journal and the thing -- their point of view at the time this article was done is that since they evaluate

fit during the certification, they don't do individual fit testing. Luckily that seems to be changing, at least, in parts of Europe now.

But when they went and did the survey, of those people who had these respirators, two-thirds of them, about, were not fitting the people that were using them.

So regardless of what happens here to provide effective protection, individual fit testing will still need to be performed and in the context of a complete respirator program.

Excuse me one moment. I forgot a prep.

(Pause)

MR. COLTON: Another issue is that of panel-to-panel variability where our studies have shown that the panel make-up would become very important, in fact more important than the respirator fit characteristics. Therefore, the test method needs to overcome this issue.

Now, one way is to make this test more robust and get rid of some of this variability or do things that can accommodate that.

One would be to dramatically increase the panel size. And based on our testing, the minimum of 105 subjects would be needed to do that. Now, you're really talking about a lot of fit testing.

The other thing to do is reduce variability in the panel cells. Even though we have two different measurements to rely on, you know, there's a wide variety of faces there. In fact, I would say as long as people keep reproducing, it will be basically an infinite number of fits that you could find in a particular cell.

So in order to reduce the variability in the panel cells, one of the things you might do is have standardize faces for each box which is sort of interesting or test tabs are for each cell.

Now, the other criteria is if you don't handle the variability by increasing sample size and making the test more robust, then another alternative is to look at how you -- what you choose for the pass/fail criteria of the test, so you could change that which includes the passing fit factor or passing rate.

The other thing is with all this variability from panel to panel, whether a respirator passes or fails is going to be based on the panel. NIOSH audits are going to be just great because we're going to have -- they'll be very challenging because when we get a product approved in that, we may do nothing to it, it's still produced to plan. And this variability can show on an audit then that the respirator failed the test and without the change to product and change from QA plan.

In fact, one of the things that we know from the benchmark testing is these two respirators were tested. The difference between them is one's got red straps and one has blue straps. And the benchmark testing, one failed, one passed.

We've done enough testing on these two models of respirators, if you will, that the one fit -- fit on one predicts fit on the other in that.

So when we test them, there's no difference in the fit here. Yet, the propose -- or at least the benchmark testing didn't show to be able to separate. They showed either both failed or both passed, you

minutes. So you've got a quarter of an hour for fit tests. You've got a huge number of hours. In fact, if you break it down to hours, that's something about like five man years worth of fit testing. And hopefully the machine is always working. This is just nonstop fit testing. So whether or not implementation period is realistic, it doesn't appear based on that and that information.

And also due to the huge variability in panel results, significant chance of failure will occur with any given respirator model. And so if we design the respirator with no changes here to the proposed, if we start designing the respirators to pass the proposed panel, then this standard becomes basically a design standard. We're designing to the box. And I believe we can fit the box and you could fit the box well. The problem is you don't fit anybody outside the box in that.

So in addition, all the respirator manufacturers in order to add a design to the box is going to reduce diversities from one facepiece to another. So now the people who fit the common one,

but they're maybe not as common about what I call hard to fit people, the respirators aren't going to be there to use as backups as indicated in that health care study that I mentioned earlier.

Small faces are -- the impact on small faces is interesting. The panel moved upward into larger faces which is the trend, I guess, with the U.S. population. But we were already getting complaints from health care workers that small faces were the ones that weren't being covered and taken care of. So this actually by shifting it and as we design to the box, then we even have less chance of fitting those, those people.

With regard to the user instructions, we know that the two dimension facial measurements from the panel do not predict fit. And providing this guidance in the user instructions, that isn't going to assure fit. The people are going to be most likely to think that it does.

The proposed rule also requires that the face sizes will be identified. So if the face sizes are identified, then the users got to identify their

face size to know which one is right for them.

Now presently we have different size people calling. In fact, in the health care study where they used a small and a medium, you know, they held it up to their face and did assessment there and they got pretty good results.

But if we start specifying sizes where we got your face width and face length, they need to be able to measure that. That means they need the respirator -- or employers will need to acquire calipers, receive training on their use -- because variability in the measurement is another issue -- measure facial dimensions for each wearer, acquire the respirators for those face sizes, and then you could fit test each wearer in the respirators that are maybe designed for them.

Fit testing becomes cumbersome and time-consuming.

One of the issues that seem to start this rule making was that people weren't doing fit testing and so this was a way to help with that, at least they'd have respirators that would fit. Now you got

even more -- you may have more people not doing fit testing.

With that, I'll pass this over to Dr. Eitzman.

MR. EITZMAN: Hi. My name is Phil Eitzman, and I'm a product development specialist at 3M Company.

You need me to spell that or --

THE REPORTER: No. Thank you.

MR. EITZMAN: I think you got it. Okay.

And I'll be talking specifically about some additional work that we are still conducting, some of the results that we have.

How do I move it, down here?

MR. HEARL: Yeah.

MR. EITZMAN: Down here?

MR. HEARL: Yes.

MR. EITZMAN: Okay. All right. The stated objective of the proposed regulation change or the modification is to remove poor fitting half-facepiece respirators from the market. That's one of the key objectives.

A NIOSH study, and this is a study that included a number of people from NIOSH, Lawrence -- I won't go through those. But the title of the study was Comparison of Performance of Three Different Types of Respiratory Protection Devices by Lawrence, Duling, Calvert & Coffey, presented test result for a number of different facepieces. I'm going to refer to this. Craig had already talked about it. I'm going to refer to it a couple of times because we used it to identify a poor fitting product that we evaluated.

In comments to the docket, both 3M and ISEA have evaluated some well fitting products that were identified in that Lawrence Study.

In our additional work that is continuing, we have evaluated a poor fitting product that was identified in that study.

Okay. I'd just like to talk kind of about what does it mean to have a well-fitting or a poor-fitting respirator.

And you know, it really depends upon context and who you are. For an individual respirator user, of course, that means you have a well-fitting product

that's something that you can pass a fit test on. So you know, that's one definition.

Really it seems like what we're looking at with this proposed rule is for the employer of a well-fitting product or respirator is a respirator that will fit some workers. And really what we'd like to see is a significant fraction of the people that you would, say, take a product and do some fit testing that you get many of the users to pass that fit test. You don't want a result where basically nobody passes or at a very low percentage.

And we've have to remember that in some cases what might be identified as a well-fitting product may not fit workers at a particular work site maybe because of ethnicity. There could be a number of different factors that could cause low pass rates. But if you're going to call it well-fitting respirator, that should be something that's very unlikely, something that you wouldn't -- you wouldn't normally expect to see.

Craig made mention of this. This is a table that appears in our comments that we submitted into

the docket in March of this year. And it shows the workplace fit test performance or the pass rates of a number of our products at some of our customers. And what we did was we contacted these customers and asked them what their experience was in pass rates. So, you know, real world experience.

And we got five different models here that we've identified with letters. These are the same designations that we use in our submitted comments. And you can see that looking across these we've got pass rates anywhere from 80 to 85 for the Model G. They're up to 100 percent for Model D in the last account or the last work site there, that's Company 6 and -- or 99.5 for that Model C at the Pharmaceutical Account, Company 2.

I'm going to be talking about -- just going to remember a number here. We're going to be talking about the Model A respirator, which is the one that shows that 90 to 95 percent pass rate at Company 3.

All right. What's a poor-fitting respirator?

For an employer, a poor-fitting respirator

is a respirator that fits less workers than they might expect. So if they were thinking they were going to get a 75 percent pass rate or higher, if they get maybe 10 percent or less, that's clearly a poor-fitting respirator. And these respirators do exist.

The Lawrence, et. al paper identified a number of filtering facepieces which had no pass results. And in that paper when they looked at the models, they actually conducted a workplace type fit test with three different types. I think there's a Bitrex and saccharin and the N95 companion test. And then there were a number of respirators that either in one or more than one of those tests had a no pass result. In other words, across panel of people, there were no passes.

So we think that that clearly identifies these as poor-fitting respirators. So that's what we were going to look at. Just kind of -- the question then is, you know, how can we identify well- and poor-fitting respirators?

Now, the NIOSH proposed TIL rule attempts to

do this. And what I'm showing here is just kind of the elements of the test. It uses a 35-member panel which is based on the bivariate NIOSH grid with the exclusion of outliers through a NIOSH PCA panel. And we want to show the test results. We basically followed the parts that -- all the parts of the actual test method.

We use the quantitative fit test which is based on the PortaCount within 95 companion or the PortaCount Pro Plus, depending on which model the instrument used.

And then in the proposed rule, there's a requirement that at least 26 of the subjects out of a 35-member panel have to have one of the fit tests with a fit factor greater than 100 or a TIL less than 1 percent. At least one subject in each cell of the bivariate grid must pass a fit test.

Okay. What we did for additional studies, and this continuing and this is our evaluation of the proposed TIL rule during the extended comment period is we looked at the fit performance of a poor-fitting respirator and we compared it to a well-fitting

respirator.

One of the six respirators with a no pass result was evaluated with three 35-member panels, and I'll go into a little bit more detail of what we did there. But we did follow, as I said. We followed the test procedure that was presented in the proposed rule by NIOSH.

We designated this poor-fitting respirator as Model H. That's just the letter that we hadn't used yet in our designation of 3M model. So I'll be calling that H after this.

And the well-fitting model, as I said before, was that Model A which had the 90 to 95 percent pass rate in that previous table. And that is in -- the data on that Model A is in our previously submitted written comments.

Okay. So this is what we did. For the Model A and the Model H, we did testing on three complete 35-member panels. So we followed the rules for basically assembling those panels in terms of the bivariate grid and the PCA grid. So we did all the measurements we needed to do to verify that they

wouldn't be excluded by PCA.

And for each of the 35 members in the panels, we actually tested them three times regardless of whether they passed. So we didn't stop. If they passed the first time, we kept going and we did all three tests just to collect a full data set.

And then for each of the 35 members -- okay. I already said that. But -- yeah, I think I've got everything there. Sorry.

These are the results that we got for both of the models. And this is a lognormal probability plot. You can see that they do approximately fit a lognormal distribution because they are lying on the lines there.

And I'm presenting the data here with fit factor because we think that's the appropriate way to describe the data since it is a fit test.

For Model A, which are the red points, they have 79 of the 105 test subjects. That is about 75 percent had at least one fit test where the fit factor was greater than or equal to a hundred.

For Model H -- and you can see the one point

here. It's that one point right there. There was one fit test out of the 315 total which is 3 times 105 that was actually over a hundred. The other 314 tests were less than a hundred. And so that one subject who got the fit test with the greater than a hundred pass, and so you had about a 1`percent pass rate with Model H. So looks like they're different based on the data that we collected.

Okay. So what criteria can be used to differentiate between those two Models A and H, well-fitting and the poor-fitting respirator?

We took the data and this 105 members panel or three 35-member panels and we used that data to construct a thousand simulated 35-member panels. We did this by randomly selecting 35-member panels out of the 105 subjects for each model. And those panels were constructed so that we followed the criteria for what was a valid panel.

In other words, they had to meet requirements for the bivariate grid. And as I said, we'd already verified that the PCR outlier rule was met.

And just as a piece of information using the 105 members, you can actually instruct 10 of the 23rd simulated panels that are valid. So there's a large number of simulated panels you can create.

The simulated -- the reason that we did this process was to pick up the variation and results from 35-member panels. And we'll see that as I show some charts.

And then each of these simulated panels was evaluated over a range of approval criterion. Craig already talked about that a little bit looking at -- what we looked at specifically was fit test or fit factor pass criteria and subject pass rate criteria. So we looked at those two things

Okay. So I got some specifics here. I'm forgetting my own slides.

We looked at a range of minimum fit factors of 10 to 100. And we looked at pass rates all the way from 0 percent or zero out of 35 subjects with the passing fit test to 100 percent. That is 35 out of 35.

And a subject passes if at least one of the

three tests that was conducted on them was greater than or equal to the minimum fit factor, so that's that criteria.

Now, we did not look at the one pass per cell. We've submitted extensive comments on this. We don't believe it should be included in the rule. And so the presentation that I'm giving today will not include any discussion of that one pass per cell requirement.

Okay. So this is the first piece of data we're going to look at. And what I'm going to do is I've got four charts and we're going to step through different minimum fit factors.

This is a minimum fit factor of 10. And if you look at the bottom axis, you can see that what we've got is a range of results that we got for each of the thousand simulated panels. And what is indicated is the number of subjects that passed the minimum fit factor on at least one of their tests.

And so if we use a minimum fit factor of 10 as our pass criteria, we can see that for the poor-fitting respirator, which we have identified as

Model H, that actually 35 -- or 1000 out of 1000 panels actually passed the criteria or have fit factors that are greater than 10, I mean.

So it actually -- you know whatever you would put for a requirement for the number of people in the panel but had to pass, this would do it if you had 10 for the fit factor. So it looks like it's too low.

And you can see that it's not differentiating at all from the well-fitting product. So actually this result -- if you were to judge them you'd say, well you can't really tell them apart and there's actually in a couple of situations where the well-fitting product had a couple of people in the panel that weren't passing.

So now as we move along here, we've got the next chart which looks at a minimum fit factor of 20. So we've moved it up a little bit. And now you can see a couple of interesting things.

So as we now say that for a panel to pass or for a subject to pass, they have to have a minimum fit factor of at least 20 on one of their fit tests. You

start to see that there are a number of subjects that are not passing and with the poor-fitting respirator Model H.

And you also start to see the distribution and results which is this panel-to-panel variability that we've talked about quite a bit in both our comments and our verbal and our written comments.

So you can see that now the poor-fitting product is starting to be separated from the well-fitting product. It's starting to move down. But there's still a little bit of overlap.

And just I had some numbers here.

You got a pass rate of between 91 and 100 percent now with the well-fitting product, but you got an overlap because the poor-fitting product has a 57 to 91 percent pass rate, so it would be a little difficult to separate these two.

And you can see that there's a pretty wide range in the pass rate for the poor-fitting product. And this is just the effect of selecting subjects for the 35-member panel.

Okay. So now we're going to go to minimum

fit factor of 50. Now we got more separation. Now the well-fitting product just kind of come off the right axis so you're starting to get failures in that. Some of the subjects are not passing that fit factor of 50 requirement. And we're seeing the poor-fitting product has moved over to the left axis with 0 to 26 percent of the subjects passing and 60 -- for the poor-fitting product of 69 to 100 percent of the subjects passing for the well-fitting.

So now we got this clear separation. And you could put a criteria somewhere in between those two products and that gap in the middle that would -- you know, you could say with a very high degree of certainty that you would reject the one on the left; that is the poor fitting and you would accept the one on the right which is the well fitting.

And then finally, in my last plot we've moved up to a minimum fit factor of 100 and you still see a good separation. Now the poor-fitting product has basically been pushed over the left axis. We still have a large region in between the two. And the well-fitting product has moved down.

So for the well-fitting product, we have between a 54 and a 91 percent pass rate and that's kind of showing that panel-to-panel variability effect that we've talked about quite a bit.

And then also on here I do have a line that indicates where 3M and its written comments I proposed putting the criteria, which is that 60 percent of subjects with fit factors over 100 would be required for product to pass -- for product to be approved under the modified rule.

All right. Our conclusions from this evaluation for possible approval criteria is that a fit factor of 20 or lower, and we did look at other fit factors so -- but you can clearly say that for 20 or below, you really can't differentiate between poor and well-fitting products.

Fit factor 50 does provide good differentiation that allows you to really separate those two. And a subject pass rate kind of in the middle of that area between the two products, that is a 50 percent pass rate, which 18 out of 30, for instance, would be sufficient to reject the really

poorly fitting products that would have little chance of passing a fit test at an employer's work site.

Okay. All right. I think we're moving back to Craig. So we're going to switch speakers one more time and then we'll be done. There's just two more slides and Craig will finish up here.

So thank you for your attention.

MR. COLTON: Thanks, Phil.

So there is an end in sight.

So to wrap up, despite the comments and what tone you thought maybe they had there at the beginning, 3M does support a fit requirement as part of certification. I mean we do. It's just that unfortunately we don't believe that the current proposed fit test proposal will remove well fitting devices -- well, that it will remove well fitting devices from general industry and health care workplaces in its present form.

In order to meet the proposed test method as it's been published, it's going to force redesign of respirators which is going to reduce the diversity of styles and shapes of facepieces among the available

designs, reduce or eliminate respirators that you can go to when you have a hard to fit person and eliminate respirators that fit people outside of the bivariate grid.

And now based on the information not only that we had submitted in the first open comment period, but now with the information that was presented here in the work conducted in the second one, our recommendation would be to replace the percent TIL maximum with a minimum fit factor of 50 and a 50 percent pass rate, remove the one pass per cell requirement, and then change the user instructions to where they could be amended to where user instructions for half-facepiece respirators shall specify information or procedures necessary for the intended population or some population of users in that.

And with that, I thank you for your attention and I'm done.

MR. HEARL: Thank you. Let me just check and see if we have any questions from the panel to the speakers. Bill.

Identify yourself for the record.

MR. NEWCOMB: Bill Newcomb. I have a question concerning the one -- one person per cell. And that is what you propose is I think is a 50 percent pass rate for a respirator that is designed to fit the population, the whole population with one size.

If 50 percent of the pass/fail in virtually all panels were only in cells 8, 9, and 10 or just the middle cells in the large size and didn't fit any of the small sizes in that panel, would you consider that a respirator that fits the total population?

MR. COLTON: I don't think we make a claim that respirator fits the total population everywhere. Even the one size models, in fact -- you know, one that's out there today isn't a one size fits all.

One size is designed to fit as the -- the wording in the standard says is a large number of face sizes and face variety. So it could be depending upon the respirator.

And part of this what ends up being well fitting or not, in this particular case, would be

something that I think has to be determined in part by the user. And the market could end up dictating part of that if people don't like that particular respirator. You know, I wouldn't think they would be buying it.

Phil, do you have comments?

MR. EITZMAN: No.

MR. NEWCOMB: I don't think you answered my question. But thank you.

MR. COLTON: Well let me -- well, if it's well fitting, I don't -- like I say, that's a -- I don't know that the test criteria is a place to decide that. I mean well-fitting respirators is what's in the mind of the user to a large part and they would still need to get -- and then I think we've got two things here.

We've got a fit factor that we're looking at for what I call a populational fit factor here which would be if what we're looking at for passing a respirator. And then we've got the individual fit test which is still the one hundred. And I think those are two different, different things.

MR. HEARL: Thank you. Any other questions from the panel? If not, thank you very much.

And at this point, we'll move on to our next speaker which is Jeff Birkner from Moldex.

MR. BIRKNER: Good morning. My name is Jeff Birkner. I'm the vice president of Tech Services for Moldex.

Moldex Metric is a safety product manufacturer of hearing and respiratory protection equipment. We've been in business for more than 25 years. Moldex takes great pride in its commitment to health and safety of all workers.

We welcome this opportunity to provide comments at this meeting today.

We applaud NIOSH in their efforts to promulgate regulations which ultimately will provide better protection for the public and we will continue to work with them to ensure that the public is properly protected.

Unfortunately, there's been a recent influx of products into the market which we believe are below the NIOSH quality standards and have the less than

adequate fit.

We believe that this has motivated NIOSH to develop the new TIL regulations to some extent.

If this is the case, we believe there are several ways to attack the problem, then ensuring that quality products are supplied to the public.

First and foremost, NIOSH may wish to more aggressively audit all respirator manufacturers through field audits and redouble their efforts for those manufacturers found to have deficiencies.

NIOSH should be equally aggressive in performing their bench test audits of products they're buying from the open market, and then testing in their labs ensure again, redouble their efforts for those manufacturers found to have deficiencies.

We believe that these are the first lines of defense that NIOSH should be using to ensure that certified quality products are reaching the market.

NIOSH has stated that with TIL, quote, The employee is more likely to achieve a good fit from a respirator maker that has been demonstrated through testing to achieve the specified minimum level of

performance. Unquote.

Unfortunately the use of anthropometric test panels is not the best predictor of fit on individuals in the field. During lab evaluations two persons in the same grid being fit tested on a mask can have extremely varied fit test results with one person getting far below the required protection of 100 as the pass/fail criteria. And the other individual achieving the fit in the thousands.

This evidences the fact that the use of anthropometric panels cannot predict good fit on a controlled panel and will be less predictive of the fit of actual users. Thus, it's not likely that a certification requirement such as this will lead to more streamline fitting of individuals in the field as NIOSH has suggested.

We strongly urge NIOSH to look carefully at the data submitted by Dr. Lisa Brosseau and her associates on behalf of ISEA.

We believe that this study proves the lack of validity and extreme variability that is inherent in the use of anthropometric panels to assess fit.

We also strongly recommend that NIOSH perform their own study utilizing a protocol similar to that of Dr. Brosseau which we believe will more clearly demonstrate the inherent variability and validity of use of bivariate anthropometric panels to assess fit.

There's no available data which statistically correlates bivariate grid dimensions and in turn facial measurements to adequate fit of a respirator used in the field.

Furthermore as noted above, there are many examples where someone's face may fit the dimensions of the particular grid and may easily fail the fit test when someone whose dimensions also fall in the same grid may get very high fit factors.

NIOSH also stated that poorly performing respirators are being used by employees and other individuals without the benefit of a complete respirator program that includes fit testing.

NIOSH contends that the TIL would increase the likelihood that these workers who lack fit testing will be protected by respirators that are demonstrated

to generally provide a good fit to intended users when worn properly.

Such stated intentions for the proposed TIL regulations imprudently place NIOSH in the position of encouraging users who do not perform fit testing to continue to be lax in this requirement.

This is contrary to OSHA regulations and contrary to fundamental practices that every health and safety professional must be committed to carry out.

Manufacturers uniformly warn that respirators must be fit tested to ensure proper fit as OSHA requires.

We believe that every respirator required in the workplace must be fit tested on an annual basis, no exceptions.

This even applies to the use of respiratory protection when used for instance, H1N1 or other pandemic situations, even though it requires adequate advance preparation in planning by users such as health care providers.

Some other items of concern in the proposed

regulation are that NIOSH states 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 sizes.

And NIOSH also states if appropriate pursuant to Paragraph A3 of this Section, then the applicant should also specify in the user instruction any additional descriptions necessary to indicate the subpopulations the respirator is intended to fit, such as sex, general facial characteristics, and/or precise facial measurements.

We interpret this to mean that NIOSH is encouraging, if not implicitly, requiring each manufacturer to supply their products with a grid with facial dimensions that a particular individual should have in order for them to use the respirator contained in the particular package.

Presumably this would be based on facial dimensions that were used to conduct the certification testing.

As noted previously, we do not believe that

facial grids will accurately predict the size of a mask that a wearer will fit best.

Additionally, we're not in favor of placing facial grids or similar specific measurement parameters on box of panels -- on box panels of respirators. Doing so is mandating what will be argued to be an explicit warranty of fit to those dimensions which will not be accurate as the factors that contribute to fit are far greater than the limited measurements in the anthropometric grid.

This situation will create some very serious liability issues for manufacturers which could ultimately drive manufacturers off the market.

It's notable that many individuals as well as the Institute of Medicine pointed out to NIOSH in the evaluation of their anthropometric panel that some critical characteristic measurements for their anthropometric panel were missing.

Based on our experience with Asians and some other ethnic groups, we would strongly recommend that NIOSH address the issue of nose bridge height. Although the measure of nasal root breadth is included

in the NIOSH study, our experience indicates that nasal root height may also be a significant factor in determining the appropriate parameters that should be used in developing a fit test panel.

Let me just diverge a little bit in saying that the NIOSH test in the TIL is a bivariate and doesn't even address -- it only addresses two measurements. So that makes it even more difficult. So two dimensional versus three.

It's particularly important in developing sizes for certain subpopulations so in terms of the -- what I'm talking about is the nose measurements. There are likely other parameters which should be considered to correlate facial measurement with respirator sizes.

NIOSH has not evaluated their panels based on the IOM comments provided in the document entitled Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users."

We strongly urge NIOSH to reevaluate relevant parameters of face fit to supplement and improve their existing panel.

Let me just also note that in the Journal of International Society of Respiratory Protection, the most recent journal were NIOSH -- many of NIOSH employees actually wrote that article. I don't have the name of the article. But it does address anthropometric panels.

They note -- the authors note that nose area was found to be frequently correlated to respirator fit. And nose areas may be more significant than other 3D parameters.

So in looking at that, obviously a two-dimensional panel may not address fit at all in any meaningful way.

In the proposed regulation, NIOSH outlines their test procedure using PortaCount Pro Plus, the procedures also outline in Procedure Number RCT-APR-STP-0068.

The NIOSH procedure does not use any type of chamber where the NACL challenge concentration is developed and maintained.

This is a serious flaw in their protocol as the PortaCount does not do simultaneous monitoring and

comparisons of outside concentration CO and inside concentration CI. And therefore rapid concentration change in the ambient environment could easily give highly erroneous results.

Additionally, the protocol calls out in allowable TIL of 1 percent. NIOSH needs to consider the use of a higher TIL number based on an analysis of variability. Although 1 percent is achievable in some cases, the protocol variability may be such that well designed respirators will easily fail.

By raising this number using a quantitative analysis of variation, it will not deleterious effect the evaluation of poorly designed respirators which will likely fail anyway, but will allow the approval of well designed respirators.

If NIOSH wishes to go forward with the TIL, we would recommend that each respirator model be treated as a family of respirators.

When a respirator model is fit tested, all the sizes under that model should be considered as part of the model's family. If a particular size of that model does not fit an individual, the next size

should be used.

If necessary, all sizes in the family of that model should be used on the test subject even if it does not intuitively appear based on facial dimensions of that individual that a particular size of respirator will or will not fit that individual.

From a practical standpoint, we've encountered this under many circumstances when even an individual with a small face fits a size of respirator that clearly would not -- that clearly one wouldn't expect they would fit.

Performing the TIL in this way would optimize the end user's likelihood that they be fitted with a particular model of respirator. Most half-masks come in at least two sizes and some even come in five sizes. This large option almost certainly ensures that a particular model will fit the end user.

Finally, we believe that NIOSH has severely underestimated the cost of this regulation to the manufacturer which would ultimately be passed on to the user. Thanks.

MR. HEARL: Thank you very much.

Are there any questions from the panel?

MR. NEWCOMB: Bill Newcomb.

I wasn't quite clear from your presentation whether or not you were in favor of a Total Inward Leakage requirement or not. However, you started it by saying that the best way to ensure a good product is through an audit. And if there is no test, then the audit will not help any.

Do you have any thoughts on that?

MR. BIRKNER: Well, I think -- I'm talking about the current existing test. I think to some extent NIOSH could use the audits currently available under the regulations to pick out bad product. I'm not necessarily talking about badly fitting product. That's a different issue and that addresses the TIL.

And in answer to whether we're in favor or against the TIL, I think in my opinion they're better ways to determine whether a mask fits an individual.

The most important issue is whether a particular respirator fits a particular individual in the field. And that's addressed through the OSHA

regulations.

Using a test panel with, you know, 10, 20, 30 individuals, I don't think is a predictor of a fit in the field.

And lastly, I think NIOSH to some extent has acknowledged that a bivariate panel doesn't contain all the parameters that are necessary to be a reasonable predictor of a bench test versus what will be achieved in the field.

MR. NEWCOMB: Thank you.

MR. HEARL: I have one question actually just to kind of elaborate.

Each model treated as a family of models idea that you had, would you see there will be an upper limit as to the number of sizes that would be -- fit in each family or is that specific --

MR. BIRKNER: That's market driven.

MR. HEARL: Market driven. Thanks.

Rene Pana-Cryan.

MS. PANA-CRYAN: Hi. This is Rene Pana-Cryan.

Could you elaborate on your statement about

NIOSH having underestimated the costs of their proposal?

MR. BIRKNER: You know, this kind of regulation requires that, that -- although all manufacturers do fit testing. But I mean it's going to require they do fit testing when they're developing respirators and historically, you know, we do very well. But this regulation because of the requirements in terms of actually submitting the panel data and that kind of thing will actually be quite expensive.

MR. HEARL: Any further questions from the panel? Thank you very much.

MR. BIRKNER: You're welcome.

MR. HEARL: Okay. The next speaker I have on our list is Dan Shipp from ISEA.

MR. SHIPP: I don't have any slides. So this will be for the next -- the continuation of my presentation, if you will.

Good morning. My name is Dan Shipp. I'm president of the International Safety Equipment Association, also known as ISEA.

As I hope most of you know, ISEA is the

trade association for manufacturers of personal protective equipment, including all kinds of respiratory protection for workers certified by NIOSH under 42 CFR Part 84.

ISEA members in the Respiratory Protection Group are knowledgeable in the design, manufacture, approval, selection, fit testing and use of respirators in all occupational settings.

ISEA appreciates the opportunity for the extension of time given for the consideration of the Total Inward Leakage proposal. We're here to express our views.

As you know, the association has been an active participant in the discussion of this proposed rule since the concept was first presented. I think our initial comments on the concept date back at least three years.

ISEA last December at the first public meeting began a discussion of the proposed rule and what we consider to be some of the shortcomings, or the apparent shortcomings in the test method, and decided at that time to commission an independent

study of the test methods using respirators that had been identified by NIOSH as good fitting respirators.

That study was conducted. It was part of our written comments that we submitted in March. And you will hear a presentation on that study, following my presentation, from Jeff Weed who is a member of the Expert Advisory Panel and one of the principal researchers.

ISEA and its members have discussed and debated this proposal at great length since the close of the comment period in March seeking a way to modify this rule that would make it workable for manufacturers, employers, and users.

You've already heard this morning from two ISEA members. You'll hear the recommendations that came from our expert panel.

As you can see, there are different viewpoints on what would make this work. I remind you that ISEA is a consensus organization. At the end of the day, we keep returning to the one answer on which I believe that ISEA has consensus, and that is does this proposal, does any sort of TIL proposal actually

enhance worker health?

ISEA understands the concept of incorporating fit testing into the certification of respirators. We acknowledge that in a perfect world, any half-mask respirator would provide an adequate seal on any face every time.

Manufacturers invest a great deal of R&D in the development of respirators that will not only pass the stringent filtration efficiency testing necessary for ISEA certification, but will also fit the greatest number of faces. Failure to do this will doom a product in the marketplace, and it should.

But we also know from experience that this perfect universal respirator doesn't exist, because of the variability of face shapes and sizes, coupled with training and user experience in donning and using respiratory protection.

In other words, nothing is going to take the place of fit testing each user as the only way to ensure that the respirator will provide the desired degree of protection.

If we acknowledge that the need to fit a

respirator to the user is not going to change, then we have to question the purpose behind the NIOSH TIL proposal, the methodology proposed to reduce total inward leakage by respirator design decisions, and whether the changes proposed to the certification process will enhance worker protection.

In the benchmark testing of 101 respirator models, NIOSH found that 30 percent of respirators did not provide a fit factor of 100, quote, for substantial numbers of human subjects.

Using this data, NIOSH cites three justifications for the proposed rule. I'd like to address each of these three justifications.

First, NIOSH states that when an employer buys one of the poor-fitting respirators -- and this is a quote from the preamble to their proposed rule. Fit testing of the employees should reveal that a substantial proportion of the employees do not achieve adequate fit.

This presumably compels the employer to purchase other respirators and conduct additional fit-testing on employees, continuing such purchases

and fit testing until respirators are identified, through trial and error, that provide all employees with adequately fitting respirators.

Let's remember that last sentence. We'll hear it again in a minute.

NIOSH writes the proposal as if this would be an ongoing process with the employer buying more respirators and fit testing them until all workers are supplied with an adequately fitting respirator.

ISEA asks if this is as burdensome as it sounds. Putting yourself in the position of an employer, if you buy a supply of respirators and find that they don't provide a good fit to most of your workers, you're not going to buy any more of them. Nor is anyone else.

Why would there be a market for such an ill-fitting product, unless employers are buying them and providing them to workers without fit testing, in clear violation of their legal obligation under OSHA regulations?

Now consider the process using respirators approved under the proposed TIL regulation. The

employer will have to evaluate intended users by facial characteristics, take measurements and find the respirator identified by a manufacturer as suitable for these characteristics.

If everyone in the facility has the same face, the employer gets lucky. But in the real world, it is still likely that one model of respirator will not adequately fit all workers.

To use a phrase from the NIOSH proposal -- and this is the sentence you heard before. This presumably compels the employer to purchase other respirators and conduct additional fit testing for employees, but by mandating that a high percentage of respirators achieve a fit factor of 100 in certification testing. As has already been noted, the employer's choices would be far more limited than they are today.

The second benefit NIOSH finds in its proposed TIL test is that it will provide better protection for users that are not fit tested. It cites a statistic that 40 percent of employers don't fit test workers and that self-employed workers are

even less likely to be fit tested.

ISEA asks NIOSH what in its proposal would force these non-compliant employers to meet their obligation to fit test workers, especially if they are being told that the respirators tested under the new scheme are more likely to fit?

The third justification for the rule is that stockpiled respirators, deployed in the event of a pandemic or other emergency, might be given to workers without a respirator program or fit testing.

In this case, the employer and the user and the worker are presumably not involved in the selection process, and the hazard may be something like a virus for which there is no known PEL or well-defined risk, so fit testing is even more important to assure adequate protection.

Handing out respirators for use in hazardous environments with the hope that they will fit most users is playing Russian roulette with a worker's health.

After all this, NIOSH acknowledges that certification incorporating the TIL test will not

substitute for individual fit testing, respirator training, and other components of the complete respiratory protection program critical to worker protection.

NIOSH claims that TIL will substantially improve the current circumstances by approving only respirators that demonstrate the ability to meet minimum specified performance requirements.

ISEA believes that NIOSH already does this, by testing and certifying respirators under 42 CFR Part 84, in the existing certification regulations.

If NIOSH believes, as we do, that fit testing, training and other elements of a respirator program are critical to worker protection, ISEA is hard pressed to understand why NIOSH is proposing to add a component to respirator testing and certification that appears to be designed to allow employers and users to bypass these critical safeguards.

Ever since NIOSH first proposed incorporating fit testing into respirator certification, ISEA has questioned the wisdom of this

approach.

After the current proposal was introduced, we commissioned an independent evaluation testing respirators using the NIOSH protocol. And you will hear a report in a few minutes on the result of that study presented by Jeff Weed. That study details the shortcomings of the proposed methodology and makes some recommendations for improvement.

But even if the test protocols are improved, and the pass/fail criteria are modified to reflect the realities of respirator design and performance, will they replace the necessity of individual fit testing to determine whether or not a respirator will protect the wearer?

ISEA believes the answer is no.

Given that reality, isn't it better use of NIOSH resources? Is it a better use of NIOSH resources to continue to refine the certification fit test with its inherent flaws or to redirect its efforts toward enhancing respirator fit at the user level?

ISEA believes the institute should focus its

research on improving user fit testing, developing better field fit tests, better exercises that are simple to administer and produce the most repeatable and reliable results.

Concurrently, NIOSH could direct its energy to working with OSHA, MSHA and employers to educate workers and employers about the reasons why respirators have to be fit tested, clearly explaining the function of a respirator in reducing exposure to airborne contaminants to acceptable levels, illustrating the risks of misuse, and encouraging rigorous enforcement of respiratory protection standards and regulations.

Such an approach would do far more to enhance worker protection than adding a complex and unproven set of requirements to certification testing of half-mask respirators.

As always, ISEA and its member manufacturers stand ready to assist in this effort, to achieve our common goal of protecting the health and lives of workers everywhere. Thank you.

MR. HEARL: Thank you very much.

Any questions from the panel?

MR. NEWCOMB: This is Bill Newcomb.

You've pointed out some pitfalls with the requirement for having fit testing as a requirement in 42 CFR 84. But at the present time, all tight fitting respirators with the exception of particular filtering, including all gas and vapor half-mask respirators are fit tested as a matter of certification.

Are you suggesting that these pitfalls that you've identified are therefore in all of the other types of respirators that NIOSH presently certifies?

MR. SHIPP: In the certification testing of those types of respirators that you mention that include fit testing, is the user told that this is a respirator that will provide a fit for a certain face size? Is the user given the instructions and the guidance that would be proposed under this proposal?

The difference I see is at the user end, do you believe that having that fit testing in those respirators reduces the amount of fit testing that may be done at the user level?

That's probably an answerable question.

MR. NEWCOMB: Yeah. I don't think that I want to debate these issues at the present time. That was just a question.

MR. SHIPP: I think you understand my perspective here and point of view.

The point of view, I believe, of the manufacturers, the consensus view within ISEA is that yes, we understand fit testing. Yes, we understand the certification process.

But in this particular incident will -- including the fit testing actually -- will including a fit component in the certification actually at the end of the day provide better fitting respirators and reduce the likelihood that an employer, whether or not they provide better fitting respirators, will they reduce the likelihood that an employer will fit test the workers which we find to be a dangerous thing? That's my answer.

MR. NEWCOMB: Okay.

MR. HEARL: Okay. Thank you.

MR. SHIPP: Anything else? Thank you.

MR. HEARL: Any other questions? Okay.

In this case, we're ready for our last scheduled presenter is Jeff Weed from Weed Respiratory Protection Solutions.

MR. WEED: Thank you very much.

I'm here today because I'm a co-author of this paper which is sponsored by ISEA. The principal author is Dr. Lisa Brosseau and was unable to be here today.

I'd like to acknowledge the participates in this. The principal contractor was Environmental Health and Safety, Incorporated; and the Project Management was conducted by Ron Pearson. The Advisory Panel consisted of the primary researcher, Dr. Lisa Brosseau of the University of Minnesota and myself. Statistical analysis was provided by Christopher Pulling and Stacia Kraus of Integra Group, LLC.

The study goals that we had is twofold.

First was to evaluate the variability in subject pass rates for half-facepiece air purifying respirators following the proposed NIOSH test protocol.

And also secondarily to determine the probability of the subjects will attain fit factors ranging from 20 to 100.

And during the study, we had two sets of data. In this presentation, I'm calling experimental data the data that we took as -- fit testing we did as part of this study. And we also did analysis on the NIOSH benchmark data that was obtained.

I'll cover some findings first and then get into some details.

We found that the proposed test criteria were very stringent and will exclude almost all filtering facepiece respirators, which I refer to as FFRs here, and 50 percent of the elastomeric respirators, referred to as ER, from the marketplace.

And we found that 25 percent of the filtering facepiece respirators and 80 percent of the elastomeric respirators would be certified if the fit factor criterion were reduced to 20 instead of the hundred that's in the proposal.

55 percent of the filtering facepiece respirators and 90 percent of the elastomeric

respirators would be certified if the fit factor criterion were reduced down to 10 which is the assigned protection factor.

Requiring that at least one subject in each cell receive a passing fit factor is very stringent and handicap cells with small numbers of subjects. And, for example, because of the number subjects, there was a 50 percent chance of failure in certain cells and 25 to 33 percent chance in other cells and 11 to 14 percent in the cells that have more subjects.

We thought -- we found a proposed NIOSH protocol would be more statistically or less variable, I'd say, if there were more than 35 subjects in the panel, more than one panel of 35 subjects, a similar and larger number of subjects in each cell, for example, greater than 5 per cell and using multiple donnings of the respirator on each subject.

We did bootstrap analysis which is similar to what the 3M presentation where we create virtual panels randomly and statistically analyze those.

And we found that a bootstrap analysis would lead to more informed decisions about the probability

that a respirator will fit a population of users. And this would require multiple panels or multiple donnings of a single respirator on each subject.

We found a consistent approach for testing multi-size respirators is needed.

We recommend using approach that we used in this study which included a preliminary qualitative evaluation of each size through assisted donning. And what that is is really the -- if you look at the Appendix A of OSHA 1910.134, the advice there is to have the person hold each size respirator up to their face and kind of do a self-evaluation of which one they think is likely to fit them the best. And that's what we did in this study.

The NIOSH benchmark tests were not strictly relevant to this certification protocol. We analyzed them anyway. But they didn't use the 35 subjects. They used 25. The test panel appeared to us to be the Los Alamos criteria.

And also NIOSH tested each size respirator with a separate panel. In other words, the whole panel. They didn't select a size first like we did.

And what happened then is they were testing gross mismatches in their study. A person with an obvious should face was tested with a very large respirator and that affected the data.

In our study, we only used the respirator that the person felt was most likely to fit. So we didn't have these gross mismatches.

The methods we used, the experiments with the filtering facepiece respirator was we chose a single cup shape respirator that was available on a single size. We used the Lawrence study to choose a respirator that was a very good fitting respirator. According to the study, it was available now and it also came in one size.

And the reason that we selected one -- it only came in one size -- is because we were under a time constraint. This study was done in January, February, March 2010. And the closing of the comment period was at the end of March at that time. So we had to be finished and had to have it submitted by then.

I think if we had known that the comment

period was going to be reopened three weeks later and had more time, we might have designed the study a little bit differently. But we had three months to do many hundreds of fit tests.

The filtering facepiece respirator was tested with one panel of 35 subjects on three different days. They donned the respirator one day. We tested -- we did three fit tests on that day. And then on another day, we took the same make, model, and size respirator and three fit tests with that respirator. And then the third day repeated that again.

We took also took a filtering facepiece respirator and tested it with three different panels of 35 subjects. Panel 1, each subject dons the respirator three times. Panel 2, new set of subjects. Each dons the respirator three times. And then panel 3, the same thing. New subjects, three fit test each.

Experiments with the elastomeric respirator which was available in three sizes. We did a similar test with one panel of 35 subjects, three separate

days, three fit tests on each day, same make, model, and size.

And this case the size respirator that was chosen was selected by allowing the user to examine all three sizes, put them up to their face. They didn't put the straps on. They just hold it to their face and do a little preliminary kind of a user seal check and pick the one that use best.

And that respirator was used for the rest of the measurements. And we had our procedure set up so that if the person couldn't get 100 on any one of the three fit tests, then they would have to go back and select another size from the two remained.

And if they couldn't pass one time with that, then they'd have to go to the third size.

We found it unnecessary to use that procedure, though, because everybody was able to get at least one fit test above 100 with the first size that they picked.

We analyzed the NIOSH benchmark test data for filtering facepiece respirators and elastomerics.

ISEA members requested the data from NIOSH

and then gave it to us to study. We were unable to get it directly from NIOSH. So we ended up with data for 17 filtering facepiece respirators, 2 of which were multi-size and 20 elastomeric respirators.

The NIOSH study was conducted with a separate panel for each size. So there was gross mismatches were allowed and the distribution was a Los Alamos criteria rather than a bivariate.

The instrumentation was a TSI PortaCount Plus Model 820 with a N95-Companion. We used a special fit test software that did not have the upper limit of 200 which is part of the commercial fit test software from TSI.

We had a test chamber with a controlled atmosphere with approximately an average of 2500 particles per cubic centimeters of the size that is seen by the N95-Companion which is about 50 nanometers.

The aerosol was sodium chloride, generated with a 6-Jet Atomizer. We used the exercises that were in the TIL proposal and we had 60-second mask sample time. Data was recorded every second.

And these test subjects did have previous experience donning respirators.

That data analyses we determined the geometric mean, geometric standard deviation and did an analysis of variance. We looked at between-subject vs. within-subject variability in fit, pass rates for filtering facepiece respirators, and elastomerics separately. And we did predictions of fit using bootstrap analysis filtering facepieces, three panels and using the NIOSH benchmark data.

Just an overall summary of some of the numbers we got for the filtering facepiece single panel done on three days. All days combined, we had a geometric mean fit factor of 30.

On Day 1 just to give you examples, the mean fit factor is 37; Day 2, 30; Day 3, 27. It's fairly consistent.

And then we also looked at Donning 1 vs. Donning 2 vs. Donning 3 and got mean fit factor is 36, 30, and 27.

For the filtering facepiece respirator that was studied with three panels, done one time, one day

our geometric mean fit factor was 37. And looking at them separately, panel 1 had 30; panel 2, 35; and panel 3, 40.

For the elastomeric respirator, we had a single panel for three days. All days combined the geometric mean fit factor 3641. Looking at the days separately, the mean fit factor is 3641, 4023 and 2981.

For Donning 1 looking at them separately, Donning 1, 3294; Donning 2, 3641; and Donning 3, 3641. So fairly consistent numbers.

We looked at between- and within-subject variability. The filtering facepiece single panel done three days. Between-subject variability was .5 which is greater than the within-subject variability of .3.

Looking at the filtering facepiece, 3 panels one day, we got between-subject variability of .8, within-subject .2, and with the elastomeric respirator between-subject variable was .5 and within-subject was higher in this case of 1.2.

And we didn't have a real good explanation

for why the within-subject variability was so much higher for elastomeric facepiece.

Looking at the NIOSH benchmark studies for filtering facepiece respirators and elastomeric respirators, the same way. Between-subject variability range from .3 to 8, all the way up to 8 and within-subject variability range from 1.2 to 2.

And we have to keep in mind here when they did the study, they had the gross mismatches that were allowed in which I think explain some of those high numbers.

Looking at pass rates for filtering facepiece respirators for the first three days, single panel three days combined, we looked at what fit factor could we get to achieve the 75 percent pass rate. That's a criterion in the TIL proposal.

So in this case, if you look on the far right there, you see a 78 percent on the highlighted row. So a fit factor of 25 was the highest fit factor we could get and achieve a pass rate of 75 or greater, 75 percent or greater.

And that the zeros in the -- I got several

tables like this. The zero cells are highlighted in red.

Looking at Day 1, 2 and 3 separately for the filtering facepiece respirator, Day 1 was also a fit factor of 25 was the highest we could get with 75 percent pass criteria. Day 2 was also a fit factor of 25. And Day 3 was a fit factor of 25.

However, because of the requirement that every cell have at least one pass, that fit factor dropped down to 15 because we had some zeroes in cell 1 at the 25 fit factor level.

So this is an example where we feel that requiring at least one cell to pass, one person to pass in each cell is something that's not necessary.

Looking at the filtering facepiece respirator, three panels tested one time the same way. We got a fit factor of 30 was the best we could do to achieve the 75 percent pass rate.

Looking at the panel separately, panel 1 we came up with 25 again. Panel 2 was 25, except we got the same situation recurring where the requirement to have one pass in each cell knocked it down to a fit

factor of 15. And panel 3 was little higher. We were able to get a fit factor of 3 and get close to 75 percent pass rate.

For the elastomeric respirator, one panel tested three days. We got a fit factor of 100 was achieved by 94 percent of the people. So in this case, the elastomeric respirator did quite well using the criteria of 100.

Did the bootstrap analysis. This is of the experimental data that we took for a filtering facepiece respirator and three panels.

What we looked at was what fit factor -- if we required 95 percent pass level for 95 percent of the donnings, what fit factor could we expect?

And in this case, a fit factor of a 10 is the most we could expect to get 95 percent of the donnings to pass with 95 percent confidence.

Using the NIOSH benchmark data on filtering facepieces, none of the respirators achieved the 95/95 criteria.

Using the bootstrap analysis of the NIOSH benchmark data elastomeric respirators, we found

that the -- I don't have it highlighted here. But a fit factor of 10 was necessary to get the 95/95 criteria.

In our overall recommendations, we thought that NIOSH should use something like a 75 percent pass criterion at or near the fit factor of 10, the assigned protection factor, instead of proposal of using a fit factor of 100.

We think they should drop the criteria for having a pass in every cell. We think they should increase the number of subjects in the panel or use multiple panels.

Employ single, consistent method for selecting appropriate size when testing multi-size respirators.

And in this case, we recommend using the OSHA Procedure in 1910.134 Appendix A and letting the person pick the one that's most likely to fit. We found in our study that that worked very, very well.

Consider incorporating multiple tests of the same respirator for each subject to increase the statistical reliability.

Consider the use of multiple panels and/or multiple donnings per subject and a bootstrap analysis approach to assess the probability that a respirator will fit a population of wearers.

And that ends my presentation. Thank you very much for listening.

MR. HEARL: Okay. Thank you.

Any questions from the panel?

Okay. Thanks.

So at this point in the program, we fit the open discussion portion and I'd like to ask if there's anyone who is on the LiveMeeting that would like to make a presentation at this time.

Please identify yourself and now is the time.

MR. PERROTTE: They're able to hear you.

MR. HEARL: Pardon?

MR. PERROTTE: They're able to hear you.

MR. HEARL: Okay.

MR. NEWCOMB: Did you turn them off mute so they can answer?

MR. PERROTTE: Yes.

MR. HEARL: Well, perhaps one of the NIOSH people who is on the LiveMeeting listening in could identify themselves and just guarantee that we're actually getting out.

LIVEMEETING VOICE: Well, I'm on line, Frank. I can hear everything.

MR. HEARL: Okay. Great. Thanks.

LIVEMEETING VOICE: Every is fine in California too.

MR. HEARL: Good to hear.

Is there anyone who's on LiveMeeting that would like to make a presentation?

All right. Okay. That's the case, then hearing nothing right now, we'll see if there's anyone else in the room that would like to make a comment or presentation, if you could please come forward to the microphone.

Going once, going twice. It appears we don't have any further comments. So I think at this point then we'll be moving to close the meeting.

So I'd like to thank everyone for attending today's public meeting. I especially want to thank

our presenters and commenters.

And if we could get back up the slide for the -- some basic information slide from the original one.

MR. PERROTTE: This slide right here, Frank?

MR. HEARL: No --

MR. SZALAJDA: The last slide.

MR. HEARL: -- the last slide, I think.

MR. PERROTTE: The very last slide on this one?

MR. SZALAJDA: Yes.

MR. HEARL: There you go. That's it. The final details.

So as you know, the comment period was extended to September 30, 2010. And there's three means identified for submitting comments to the record which will remain open until September 30, 2010.

You can send it in by the Internet using the www.regulations.gov website. You can send it to the e-mail address: NIOCINDOCKET@cdc.gov and identify the Docket Number of NIOSH 137 or the RIN Number of 0920-AA33, and send it by e-mail to that address. Or

you can mail it to the NIOSH Docket Office at Robert A. Taft Laboratories, L Stop C34, 4676 Columbia Parkway, Cincinnati, Ohio. And it's 45226 is the zip code.

And so that docket will remain open until that time.

So again, I thank the presenters for today, and I thank you all for attending and thank my panel members for being up here with me.

And we will be posting the transcripts of this meeting onto the docket site once they're completed.

And I thank you all very much. Have a good day and have safe travels home.

(Whereupon, the proceedings in the above-captioned matter were concluded at 10:34 a.m.)

CERTIFICATE OF REPORTER

I, Delores M. Green, reporter, do hereby certify that I was authorized to and did report in stenotype notes the foregoing proceedings and that thereafter my stenotype notes were reduced to typewriting under my supervision.

I further certify that the transcript contains a true and correct transcript of my stenotype notes taken therein to the best of my ability and knowledge.

SIGNED this 25th day of August, 2010.

Delores M. Green

Delores M. Green